12/01/97	3056829	Trinordiol
12/01/97	3058001-4	Triphasil-28
6/18/01	3741376-8	Nordette-21
7/17/04	4412805-1	Nordette-21
2/2/06	4902505-3	Nordette-21
2/28/03	4065974-X	
11/30/99	3416111-3	Triphasil-28
6/30/00	3	ı
12/29/00	3640160-3	Triphasil-21
1/25/01	3656040-3	Mirena
3/26/01	3700957-8	Levlite
6/18/01	3741376-8	Nordette-21
8/21/01	3781552-1	Mirena
9/20/01	3796431-3	Alesse-28
8/09/02	3961641-9	Levlite-21
8/15/02	3964208-1	Triquilar
2/20/03	4061279-1	Mirena
3/05/03	4071425-1	Microgynon
11/03/03	4226802-2	Tridiol-28
12/02/03	4245542-7	Mirena
5/21/04	4363772-0	Nordette-21
6/17/04	4382494-3	Mirena
9/27/04	4462728-7	Levlen
2/28/05	4596309-1	
4/04/05	4628502-3	Trinordiol
6/03/05	4686111-4	Alesse-28
7/29/05	4734121-0	Seasonale
8/10/05	4743529-9	Levora-28
3/22/06	4954000-3	Mirena
4/10/06	4975478-5	Mirena
7/20/06	5060812-0	Seasonale
8/17/06	5086087-4	Trinodiol
8/30/06	5095100-X	Plan b
7/21/06	5058172-4	Trinovum
11/21/06	5161338-6	Mirena
4/25/07	5314285-0	Seasonale
5/29/07	5337347-0	Mirena
7/23/07	5399025-1	Seasonale
11/12/99	3396782-0	Nordette

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10/5/2001 3810911-3	Uterine rupture	Mirena	22
1/7/2002 3849708-7	Uterine rupture	Mirena	26
1/7/2002 3849709-9	Uterine rupture	Mirena	
1/7/2002 3849711-7	Uterine rupture	Mirena	
4/2/2002 3896625-2	Uterine rupture	Mirena	22
4/2/2002 3896630-6	Uterine rupture	Mirena	27
4/2/2002 3896633-1	Uterine rupture	Mirena	37
4/2/2002 3896635-5	Uterine rupture	Mirena	34
7/5/2002 3988713-7	Uterine rupture	Mirena	
10/7/2002 4011784-9	Uterine rupture	Mirena	32
10/7/2002 4011785-0	Uterine rupture	Mirena	35
10/7/2002 4011786-2	Uterine rupture	Mirena	40
10/7/2002 4011789-8	Uterine rupture	Mirena	1
10/7/2002 4011790-4	Uterine rupture	Mirena	1
10/7/2002 4011792-8	Uterine rupture	Mirena	
10/7/2002 4011845-4	Uterine rupture	Mirena	
10/7/2002 4011846-6	Uterine rupture	Mirena	24
10/7/2002 4114540-6	Uterine rupture	Mirena	
10/7/2002 4011850-8	Uterine rupture	Mirena	
10/7/2002 4011851-X	Uterine rupture	Mirena	
10/7/2002 4011853-3	Uterine rupture	Mirena	
10/7/2002 4011855-7	Uterine rupture	Mirena	- 1
5/20/2003 4114540-6	Uterine rupture	Mirena	25
5/28/2003 4119350-1	Uterine rupture	Mirena	
0.20.2000			
11/29/1997 3002759-7	Blindness	Trigoa	25
11/26/1997 3002759-7	Renal Artery-Blindness	Trigoa	
2/4/1998 3040177-6	Cerebrovascular-Blind	Nordet te-28	29
2/25/1998 3036909-3	Cerebrovascular-Blind	Nordette-28	28
4/21/1998 3065844-X	Blindness	Norpla nt	18
8/17/2001 378037-2	Blindness	Alesse-28	21
9/9/2002 3974077-1	Blindness	Mirena	40
7/1/2003 4140637-0	Blindness	Microg yno	48
11/3/2003 4226800-9	Blindness	Mirena	22
1/23/2004 4303313-7	Blindness	Mirena	46
3/5/2004 4318867-4	Blindness	Alesse-28	51
4/20/2004 4345337-X	Blindness	Alesse-28	
11/12/2004 4503181-4	Blindness	Nordette-28	17
12/2/2004 4519404-1	Blindness	Levonova	32
12/30/2004 4544258-7	Blindness	Microval	42
2/23/2005 4594822-4	Blindness	Mirena	4 2
3/21/2005 4616743-0	Blindness	Mirena	:
4/7/2005 4631509-3	Blindness		42
6/14/2005 4692274-7	Blindness	Microval	42
5/16/2005 4664826-1	Blindness	Mirena	
6/28/2005 4704285-3	Blindness	Mirena	2 7
7/8/2005 4711193-0	Blindness	Mirena	27
8/24/2005 47534662-4	Blindness	Trinordiol	37
8/29/2005 4757247-4	Blindness	Trinordiol	37
10/20/2005 4807821-1	Blindness	Trinordiol	3 5
10/20/2005 4808026-0	Blindness *		35
2/3/2006 4905825-1	Blindness	Mirena	

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2/28/2006 4930117-4	Blindness	Mirena	40
3/8/2006 4941330-4	Blindness	Mirena	38
3/16/2000 4950874-0	Blindness	Mirena	42
3/29/2006 4961617-9	Renal Artery-Blindness		
4/12/2006 4977413-2	Blindness	Mini-ovral-21	25
4/25/2006 4988256-8	Blindness	Mini-ovral-21	25
6/28/2006 5043057-X	Blindness	Mirena	,
10/30/2006 5143233-1	Disability-Blind	Neogentrol	22
11/21/2006 5162086-9	Blindness	Neogentrol	22
7/27/2007 5399461-3	Blindness	Mirena	23

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10/5/2001 3810911-3	Uterine rupture	Mirena	22
1/7/2002 3849708-7	Uterine rupture	Mirena	26
1/7/2002 3849709-9	Uterine rupture	Mirena	
1/7/2002 3849711-7	Uterine rupture	Mirena	1
4/2/2002 3896625-2	Uterine rupture	Mirena	22
4/2/2002 3896630-6	Uterine rupture	Mirena	27
4/2/2002 3896633-1	Uterine rupture	Mirena	37
4/2/2002 3896635-5	Uterine ruptu re	Mirena	34
7/5/2002 3988713-7	Uterine rupture	Mirena	
10/7/2002 4011784-9	Uterine rupture	Mirena	32
10/7/2002 4011785-0	Uterine rupture	Mirena	35
10/7/2002 4011786-2	Uterine rupture	Mirena	40
10/7/2002 4011789-8	Uterine rupture	Mirena	
10/7/2002 4011790-4	Uterine rupture	Mirena	
10/7/2002 4011792-8	Uterine rupture	Mirena	
10/7/2002 4011845-4	Uterine rupture	Mirena	
10/7/2002 4011846-6	Uterine rupture	Mirena	24
10/7/2002 4114540-6	Uterine rupture	Mirena	
10/7/2002 4011850-8	Uterine rupture	Mirena	
10/7/2002 4011851-X	Uterine rupture	Mirena	
10/7/2002 4011853-3	Uterine rupture	Mirena	
10/7/2002 4011855-7	Uterine rupture	Mirena	1
5/20/2003 4114540-6	Uterine rupture	Mirena	25
5/28/2003 4119350-1	Uterine rupture	Mirena	
3/20/2003 41 19330-1	Sternie raptare		1
11/29/1997 3002759-7	Blindness	Trigoa	25
11/26/1997 3002759-7	Renal Artery-Blindness	Trigoa	
2/4/1998 3040177-6	Cerebrovascular-Blind	Nordette-28	29
2/25/1998 3036909-3	Cerebrovascular-Blind	Nordette-28	28
4/21/1998 3065844-X	Blindness	Norplant	18
8/17/2001 378037-2	Blindness	Alesse-28	21
9/9/2002 3974077-1	Blindness	Mirena	40
7/1/2003 4140637-0	Blindness	Microgyno	48
11/3/2003 4226800-9	Blindness	Mirena	22
1/23/2004 4303313-7	Blindness	Mirena	46
3/5/2004 4318867-4	Blindness	Alesse-28	51
4/20/2004 4345337-X	Blindness	Alesse-28	
	Blindness	Nordette-28	17
11/12/2004 4503181-4 12/2/2004 4519404-1	Blindness	Levonova	32
,	Blindness	Microval	42
12/30/2004 4544258-7		Mirena	42
2/23/2005 4594822-4	Blindness	Mirena	42
3/21/2005 4616743-0	Blindness	Willella	42
4/7/2005 4631509-3	Blindness	Microvol	42
6/14/2005 4692274-7	Blindness	Microval	42
5/16/2005 4664826-1	Blindness	Mirena	07
6/28/2005 4704285-3	Blindness	Mirena	27
7/8/2005 4711193-0	Blindness	Mirena	27
8/24/2005 47534662-4	Blindness	Trinordiol	37
8/29/2005 4757247-4	Blindness	Trinordiol	37 .
10/20/2005 4807821-1	Blindness	Trinordiol	35
10/20/2005 4808026-0	Blindness *		35
2/3/2006 4905825-1	Blindness	Mirena	1

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2/28/2006 4930117-4	Blindness	Mirena	40	
3/8/2006 4941330-4	Blindness	Mirena	38	
3/16/2000 4950874-0	Blindness	Mirena	42	
3/29/2006 4961617-9	Renal Artery-Blindness	3		
4/12/2006 4977413-2	Blindness	Mini-ovral-21	25	
4/25/2006 4988256-8	Blindness	Mini-ovral-21	25	
6/28/2006 5043057-X	Blindness	Mirena		,
10/30/2006 5143233-1	Disability-Blind	Neogentrol	22	
11/21/2006 5162086-9	Blindness	Neogentrol	22	
7/27/2007 5399461-3	Blindness	Mirena	23	

12/1/1997 3058004-X 12/17/1997 3011767-1 1/27/1998 3092371-6	Triphasil-28 Tri Levlen Alesse Norplant	Pulmonary Embolism Pulmonary Embolism Pulmonary Embolism	21 38
1/27/1998 3092371-6	Alesse Norplant	Pulmonary Embolism	
	Norplant	•	38
	•		4.0
2/6/1998 3110645-7	Morplant	Ectopic	18
2/6/1998 3110645-7	Norplant	Ectopic	26
2/6/1998 3119326-7	Norplant	Ectopic	19
2/6/1998 3119794-0	Norplant	Ectopic	30
2/6/1998 3120219-X	Norplant	Ectopic	34
2/6/1998 3120230-9	Norplant	Ectopic	33
2/6/1998 3122909-1	Norplant	Ectopic	26
2/6/1998 3122913-3	Norplant	Ectopic	21
2/6/1998 3122916-9	Norplant	Ectopic	27
2/6/1998 3122921-2	Norplant	Ectopic	37
2/6/1998 3122920-0	Norplant	Ectopic	27
2/6/1998 3122923-6	Norplant	Ectopic	
2/6/1998 3123983-9	Norplant	Ectopic	34
2/24/1998 3120340-6	Norplant	Ectopic	26
3/6/1998 3043939-4	Norplant	Ectopic	35
6/19/1998 3096813-1	Norplant	Ectopic	
7/3/1998 3112441-3	Norplant	Ectopic	
7/8/1998 3103241-9	Norplant	Ectopic	19
8/12/1998 3116969-1	Norplant	Ectopic	37
8/21/1998 3120149-3	Norplant	Ectopic	37
10/15/1998 3143524-X	Norplant	Ectopic	29
4/23/1999 3245978-7	Norplant	Ectopic	26
4/29/1999 3250006-3	Norplant	Ectopic	19
5/13/1999 3261246-1	Norplant	Ectopic	23
	Νοιριατιτ	Ectopic	
6/8/1999 3278037-8	Norplant	Ectopic	19
6/14/1999 3282670-7	Norplant	Letopic	23
6/23/1999 3289826-8	Maralant	Ectopic	39
6/30/1999 3295104-3	Norplant	Letopie	00
3/19/2003 4078643-7	Mirena	Ectopic	
3/19/2003 4079085-0	Levonell-2	Ectopic	22
3/26/2003 4084226-5		Ectopic	35
4/7/2003 4102614-5	Mirena	Ectopic	22
4/7/2003 4102617-0		Ectopic	23
4/7/2003 4102621-2	Mirena	Ectopic	
4/7/2003 4102637-6	Mirena	Ectopic	
4/18/2003 4098438-8	Levonell-2	Ectopic	39
4/21/2003 4099584-5		Ectopic	35
5/23/2003 4116850-5	Postinor-2	Ectopic	34
5/23/2003 4116880-3	Postinor-2	Ectopic	19
5/23/2003 4116881-5	Postinor-2	Ectopic	34
5/23/2003 4116892-X	Postinor-2	Ectopic	20
5/23/2003 4116893-1	Levonell-2	Ectopic	18
5/29/2003 4120381-6	Levonell-2	Ectopic	15
5/29/2003 4120452-4	Levonell-2	Ectopic	15
7/8/2003 4145069-7	Mirena	Ectopic	31
7/16/2003 4143009-7	Levonell-2	Ectopic	35
8/19/2003 4174717-0	Mirena	Ectopic	38
	similar Plan b	Ectopic	
8/28/2003 4181339-4	Sittiliar i Tati D	Lotopio	

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8/13/2007 5412700-5	Mirena	Ectopic	37
8/14/2007 5414340-0	Mirena	Ectopic	
8/14/2007 5414344-8	Mirena	Ectopic	35
2/2/2002 3873965-4	Mirena	Ectopic	
2/28/2002 3877342-1	Levonell-2	Ectopic	20
4/2/2002 3896625-2	Mirena	Ectopic	
4/2/2002 3896628-8	Mirena	Ectopic	30
4/2/2002 3896630-6	Mirena	Ectopic	27
4/2/2002 3896633-1	Mirena	Ectopic	27
4/2/2002 3896635-5	Mirena	Ectopic	34
4/4/2002 3896143-1	Postinor-2	Ectopic	34
5/2/2002 3911763-3	Mirena	Ectopic	34
8/20/2002 3965210-6	Mirena	Ectopic	32
8/21/2002 3966451-4	Mirena	Ectopic	32
10/7/2002 4011787-4	Mirena	Ectopic	
12/24/2002 4035344-9	Mirena	Ectopic	23
12/24/2002 4035347-4	Mirena	Ectopic	33
5/31/2001 3731599-6	Levonell-2	Ectopic	19
11/27/2001 3831699-6	Levonell-2	Ectopic	19
11/27/2001 3831700-X	Levonell-2	Ectopic	19
11/30/2001 3833289-8	Levonell-2	Ectopic	20
2/28/2001 3877342-1	Levonell-2	Ectopic	20
9/11/2001 3974444-6	Levonell-2	Ectopic	29
9/11/2002 3974465-3	Levonell-2	Ectopic	38
3/7/2003 4072621-X	Levonell-2	Ectopic	28
3/7/2003 4072625-7	Levonell-2	Ectopic	26
3/19/2003 4079085-0	Levonell-2	Ectopic	32
4/8/2003 4098438-8	Levonell-2	Ectopic	39
5/23/2003 4116893-1	Levonell-2	Ectopic-cystectomy	18
5/29/2003 4120452-4	Levonell-2	Ectopic	15
7/6/2003 4150460-9	Levonell-2	Ectopic	35
2/12/2004 4295472-X	Levonell-2	Ectopic	22
11/27/2001 3831699-6	Postinor-2	Ectopic	19
11/29/2001 3844159-3	Postinor-2	Ectopic	34
4/4/2002 3896143-1	Postinor-2	Ectopic	26
9/11/2002 3974488-4	Postinor-2	Ectopic	26
10/9/2002 3991046-6	Postinor-2	Ectopic	26
5/23/2003 4116850-5	Postinor-2	Ectopic	34
5/23/2003 4116881-5	Postinor-2	Ectopic	34
5/23/2003 4116892-X	Postinor-2	Ectopic	20
4/20/2004 4345050-9	Plan b	Ectopic	35
3/2/2001 3688557-X	Plan b	Ectopic	35
4/20/2004 4345056-X	Plan b	Ectopic	26
4/13/2005 4635478-1	Nordette-21	Ectopic	34
7/13/2000 3538271-6	Plan b	Ectopic	
8/4/2000 3542945-0	Plan b	Ectopic	27
1/2/2001 3640939-8	Plan b	Ectopic	34
8/28/2003 4182227-X	similar Plan b	Ectopic	
9/29/2003 4201989-6	similar Plan b	Ectopic	26
4/9/2001 3701868-4	Plan b	Ectopic	
5/31/2001 3731596-0	Plan b	Ectopic	
8/8/2003 4181339-4	similar Plan b	Ectopic	
	DI 1-	Ectopic	28
9/2/2005 4764187-3	Plan b	Ectopic Ectopic	27
5/10/2006 4999818-6	Plan b	Letopic	_,

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES N. C. VITAL RECORDS

	Registration 060-	Local i		CERT 00 37/4	IFICATE	OF DEAT	h —				
/	DECEDENT'S NAME FIRST							SEX	4	F DEATH (Mov	
	NIKITA		D S	MOUTHERSON				2 F	Augu	ust 10,	2 006
ļ	SOCIAL SECURITY NUMBE 581-94-5037	R AGE-LI	sst Birthday	UNDER I YEAR Months Days	UND	Moutes	DATE OF E	SIRTH Month. Ly 24,1	Day BI	PITHPLACE (C	ounty and State
	4,	5.	56.	·	Sc.		6.		9,07	Washin	ton DC
1	WAS DECEDENT EVER IN L ARMED FORCES? (Yest or N				DE PLAC	E OF DEATH (C)	eck only one	9)			
1	NO			inpatient 🛱 ER/Outp	useni 🕽 🖂	O OTHER: C		ome 🔲 Resi		Other (Specia	
DEGEDENT-	FACILITY NAME OF not instit		set and number)		m or loca arlott	TION OF DEATH		SIDE CITY LIN		COUNTY OF	
	CMC -UNIV			95.			94	<u> </u>		90,	nburg Co.
1	MARITAL STATUS Married, Married, Widowed, Divorced		SURVIVING SPC	OUSE (If wife, give make	ten name) C	ECEDENTS USU				_	USINESSANDUSTRY
	10. Divorced		11.			one during most o	Enter	ainer		12h Amu	sement Park
ŀ	RESIDENCE-STATE	COUNTY	_	CITY, TOWN, DA			s	TREET AND			
į	13a NC	Meck16	enburg	13c Charlo	tte		1	6630 F			
	Man or Mal	COOE	Was Decedent	of Hispanic Origin? (Si city Cuban, Maxican,	vecify Yes or Verto Piloan,	RACE-Americ Black, White, I		DECEDEN			y only highest grade 0-12 College (13-17+)
Į	Yes 28.	227	etc.) 🗆 Yes	No (Specify)	/	Blk	,.,]	(7+	out out of the tray
	FATHER'S NAME (FIRST, MICH	die, Layl	114		グニ	MOTHER'S N	IAME (First,	Middle, Maide	n Sumame	,	
PARENTS	Klevin S	touffer	ſ		V	Sh.	eila N	4oody			
	INFORMANT'S NAME (Type	/Print)		MAILING ADDRESS	i (Sire.	W or Rund R	oute Numbe	r, City or Town	, State, Za	o Code)	DATE AMENDED
INFORMANT	Sheila Moody	Υ		753 Chri	s Dr,	A'00li	s,NC	28082			190.
>	Part L Enter the decases, injuri	es, or complica		ne death. Do not enter th		. /_ 'wc o		erreel, shock or	heart fallure	.	Approximate interval
[***	acco, alcohol, o	or drug use. List onl	y one cause on each the	PRINT or TY	, C		71.4		`	Between Onset and Death
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DEATH	that industed events	¢									
1	resulting in death) LAST.	DU	E TO JOH AS A COR	SEQUENCE OF):							
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	BE REPORTED TO, AND C	EATIFIED BY	A MEDICAL EXA	MINER ON A MEDICA	L EXAMINER	'S CERTIFICATE	OF DEATH.	ANY DEATH F	ALLING IN	TO THESE C	ATEGORIES IS WITHIN
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Contentions Rise over the "Morning after Pill"

KEENE – The Keene Planned Parenthood office was one of seven Northern New England Planned Parenthood facilities in New Hampshire that gave away free Plan B emergency contraception on Wednesday December 6. Three Free EC signs were displayed at the Planned Parenthood office at 8 Middle St. in Keene. Protesters against Planned Parenthood gathered outside the office to demonstrate their concerns regarding the safety the Plan B pill.

Wednesday evening, the Respect Life Committee sponsored a discussion about the dangers of birth control pills and emergency contraception at the Clairvaux Center in downtown Keene. The event was well attended and the audience included students from Keene State College. The discussion featured two guest speakers, Ebony Moody from Washington D.C., and Dr. Jonathan Abel, a board certified family medicine doctor from Massachusetts.

Ms. Moody spoke concerning the August 2006 death of her sister, Niki Moody, from a pulmonary embolism, which was directly attributed to the oral contraceptive Lo Ovral. Niki Moody was a college graduate and a young mother, who had only begun using the oral contraceptive three weeks prior to her death. A FDA Freedom of Information Report Selected for Ethinyl and Lo Ovral details 34,980 adverse cases reported to the FDA since 1997. This FDA report covers only oral contraceptives, such as Lo Ovral, which contain the hormone Ethinyl estradiol.

Following Ms. Moody's heartbreaking story, Dr. Abel gave a talk called, "What Happened to Plan A?" He gave an introduction to oral contraceptives and spoke about the health risks associated with oral contraceptives and the emergency contraception Plan B. Dr. Abel stressed that oral contraceptives are not necessary in family planning, since safe alternatives exist. In addition, Dr. Abel pointed out that emergency contraception can cause a chemical abortion, which many women taking Plan B may not know. Dr. Abel's informative presentation led into an animated question and answer period.

Jack Laurent, a former New Hampshire state representative, presented additional information regarding a parental abortion notification bill, which passed the N.H. state legislature and was signed into law by former Governor Craig Benson. The bill has been challenged by Planned Parenthood as unconstitutional and Mr. Laurent states that the bill will most likely be repealed. Mr. Laurent also discussed an emergency contraception bill, Senate Bill 30, which was passed into state law in June 2005. This law makes New Hampshire a "pharmaceutical collaborative" state (with eight other states) and allows a nurse or pharmacist to dispense emergency contraception with no age restrictions for minors. According to www.GO2EC.org, approximately 200 pharmacists in N.H. have received training to initiate prescriptions for emergency contraception. Emergency contraception is covered by Medicaid, HMOs, and Title X. Title X provides federal money to the state for funding school programs. This state law effectively means that even young children may get emergency contraception over the counter.

RECEIVED AT DRUG SAFETY SURVEILLANCE 01-DEC-1997-2084

Unknown

B. Adverse event or product problem

ME

ICAL PRO

3. Sex

X female

male

Product problem (e.g., defects/malfunctions)

JI. DAVIUS, PA. 19087

1. Patient dentifier 2. Age at time

1. IX Adverse event and/or

in confidence

A. Patient information

of event:

Date

of buth:

Page

4. Weight

or

Ibs

kgs

Individual Safety Report

3/93 03N

FDA Use Only C. Suspect medication(s) 1. Name (give labeled strength & mfr/labeler, if known) *1 TRINORDIOL (0.05MG LNG/0.03MG E.E., 0.075 LNG/0.04MG E.E., 0.125MG LNG/0.03MG E.E.) 3. Therapy dates (if unknown, give duration) 2. Dose, frequency & route used 1 1 TABLET ONCE DAILY ORAL 1 YEAR #2 4. Diagnosis for use (indication) 5. Event abated after use stopped or dose reduced Unknown #1 yes no X doesn't #2 yes no doesn't 8. Lot # (if known) #1 7. Exp. date (if known) 8. Event reappeared after reintroduction #2 #2 #1 yes no X doesn't 9. NOC # - for product problems only (if known) #2 __yes __no __dcesn't 10. Concomitant medical products and therapy dates (exclude treatment of event) See following page G. All manufacturers 1. Contact office - name/address (& MFG site for devices) (610) 902-3760 **WYETH-AYERST LABORATORIES** Report source (check all that apply) 170 RADNOR CHESTER ROAD ST. DAVIDS, PA. 19087 X foreign study KAREL F. BERNADY, PH.D. literature consumer X health professional 4. Date received by manufacturer (mo/day/yr) 06 / 24 / 97 user facility 19-192 (A)NDA# COMPANY INO # representative distributor 6. If INO, protocol# PLA# other: pre-1938 yes yes 7. Type of report (check all that apply) OTC T yes 5-day 8. Adverse event term(s) 15-day 10-day X periodic CEREBRAL THROMBOSIS X initial follow-up # VONITING DIARRHEA 9. Mfr. report number HEADACKE 8-97176-003N

2. Outcomes attributed to adverse event (check all that apply)
X death disability
ife-threatening (mo/day/yr) congenital anomaly
hospitalization – initial or prolonged permanent impairment/damage
recovered X other: serious
3. Date of event 04 / 10 / 97 4. Date of this report 06 / 25 / 97
(mo/day/yr) (mo/day/yr)
5. Cescribe event or problem
The patient, who took Trinordiol (equivalent to Triphasil),
experienced diarrhea, vomiting and headache for two days
prior to lapsing into a coma. An MRI revealed CEREBRAL
THROMBOPHLEBITIS; the patient subsequently died. No
autopsy.
'
8. Relevant tests/laboratory data, including dates
DATE TEST RESULT
Unknown MRI Cerebral thrombophlebitis
•
7. Other re evant history, including preexisting medical conditions (e.g., allergies,
race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
None provided
The second secon
•
DATE SENT TO FDA
NOV 2.5 1997 19970380
Submission of a report does not constitute an admission th

2. Health professional? V....

1. Name, address & phone #

3. Occupation I N/A

E. Initial reporter

4. Initial reporter also sent report to FDA

yes X no unk

FRANCE

RECEIVED AT DRUG SAFETY SURVEILLANCE
01-DEC-1997-2085

ICAL I

Individual Safety Report

11/10/93

76-003N

31. UAVIUS, PA. 1906/

Page

FDA Use Only

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

SPASMINE 3 tablets daily ORAL (02 / 18 / 97 to 04 / 12 / 97)

ZOVIRAX 800 mg QID ORAL (04 / 00 / 96 to 04 / 00 / 97)

MEDWATC

PRODUCTS REPC



RECEIVED AT DRUG SAFETY SURVEILLANCE
01-DEC-1997-5265 170 ST.

01-DEC-1997-5265	1 of <u>2</u>	ra.u.a.
A. Patient information	C. Suspect medication(s)	FDA Use Only
1. Patient dentifier 2. Age at time of event; 23 YR 3. Sex 4. Weight	1. Name (give labeled strength & mfr/labeler if known)	•
or X female 129 lbs	*1 TRIPHASIL-28 TABLETS	
In confidence of birth:		÷
B. Adverse event or product problem	*2	
X Adverse event and/or Product problem (e.g., defects/maifunctions) 2. Outcomes attributed to adverse event (check all that apply)		
X death Unknown disability	2. Dose, frequency & route used 3. Therapy date #1 1 TABLET ONCE DAILY ORAL #1 08 / 08	s (if unknown, give duration) / 96 to 04 / 14 / 97
ife-threatening (mo/day/yr) congenital anomaly	¥2 #2	7 70 10 04 7 14 7 97
X hospitalization – in-tial or prolonged recovered recovered recovered		
other:	4. Diagnosis for use (indication) ** REGULATE MENSES/DYSMENORRHEA	5. Event abated after use stopped or dose reduced
3. Date of event 04 / 14 / 97 4. Date of this report 04 / 28 / 97	*2	#1 yes no X doesn't
this report 04 / 28 / 97 (mo/day/yr) 5. Describe event or problem		
· .	8. Lot # (if known) 7. Exp. date (if known)	Li, Li Li apply
The patient, with Down's Syndrome, presented to the ER unresponsive with CPR in progress. Her color was	*1 #1 #1	8. Event reappeared after reintroduction
dusty-blue, petechia were present on face, skin cool and she		#1 yes no X doesn't
had orange-red emesis coming from her mouth. Suctioning and	9. NDC # - for product problems only (if known)	#2 yes no doesn't apply
intubation were attempted; intubation was unsuccessful and	10. Concomitant medical products and therapy dates (exclude	
the patient subsequently died. The provisional autopsy report revealed an ACUTE PULMONARY EMBOLUS.	See following page	
report revented all ACOTE POLMONARY EMBOLUS.	G. All manufacturers	
	1. Contact office - name/address (& MFG site for devices)	2. Phone number
	WYETH-AYERST LABORATORIES	(610). 902-3760
	170 RADNOR CHESTER ROAD	3. Report source (check all that apply)
	ST. DAVIDS, PA. 19087	foreign
	KAREL F. BERNADY, PH.D.	study
	Joseph V. Selling, This	literature
		X health professional
	4. Oats received by manufacturer S. (A)NDA = 19-190	user facility
	04 / 24 / 97 IND #	company representative
6. Relevant tests/laboratory data, including dates	6. If INO, protocol# PLA#	distributor
	pre-1938	ather:
	(Check all that apply)	1
	product	es
	5-day 15-day 8. Adverse event term(s) 10-day X periodic PULMONARY EMBOLU	ıs
	X initial follow-up #	Tigh,
		* ·
(Cont.)	9. Mfr. report number	0 1 1997
 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 	8-97118-249N	0 1 1337
Down's Syndrome; hypothyroidism; used Depo-Provera in the		
past (q 3 months from to to with weight gain	E. Initial reporter	
101 lb. (105	1. Name, address & phone #	
T. Upjohn has been notified of this adverse event.		
DATE SENT TO FOA		00006
(2) 20	2. Health professional? 3. Occupation 4, li	nitial reporter also
Submission of a report does not constitute an admission that		ent report to FDA



MEDWATCH

WYETU-

THE ENA MEDICAL PRODUCTS REPORTING PROGRAM

Approved by the FCA on 11/10/93

f feport #	
	8-97118-249N

UF/Dist report #

FOA Use Only

170

RECEIVED AT DRUG SAFETY SURVEILLANCE

_2 of _2_

Box B.6 - Relevant Tests/Laboratory Data, including dates

(Continuation)

DATE TEST

RESULT

Provisional autopsy report

Coiled thrombus in main pulmonary artery occluding both right and left pulmonary arteries with partial organization of thrombus in secondary branch of left pulmonary artery; peripheral wedge infarct of lower left lung lobe

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event)

(Continuation)

Individual Safety Report

LEVOTHYROXINE 0.075 mg IRON SUPPLEMENT

DEC 0 1 1997

History of the second										Page		1 of 1	1
,			· ·				·		-				
ADVEDCE EXPE					ТТ			П	- T-	Т			
ADVERSE EXPER											\bot		
1. PATIENT 1a, COUNTRY	2. DATE C		2a. AGE	FORMATI		PERIENCE		8-12.	CUE	27. 41.			
INITIALS Denmar	Oay	Month	UNITS 33Yr	F	Day 20	Month APR	Year 2001	0-12.	APPA	X ALL IOPRIATE IRSE RÉA	E TO NOTIO	N	٠
7. DESCRIBE EXPERIENCE(S) PULMONARY EMBOLISM									PATIE	NT DIE	D		
Information was received on 14-JUN-2001 from the Health Authority, via Schering AG Germany concerning a 33-year-old female patient who had taken therapy with Microgynon (0.15mg levonorgestrel/0.03mg ethinyl estradiol) (equivalent to Nordette) for an unspecified indication. Therapy began in 1997 and ended on 20-APR-2001.								PROL	VED O ONGED IENT ITALIZA)	N		
Medical history was not provided. The dose regimen was I tablet daily. It is unknown if the patient was taking concomitant therapy. The patient experienced pulmonary embolism (pulmonary embolism) on and was hospitalized. Her treatment was unspecified. The patient died on						INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY							
									LIFE T	HREAT	ENII	NG	
									NONE	OF TH	E AB	OVE	
13 RELEVANT TESTS/LABORATORY DATA None Provided.							RECOVERED						
II.		SUSPECT	DRUG(S)	INFORMA	TION			<u> </u>					
14. SUSPECT DRUG(S) (INCLUDE ACTIVE SUBSTANCE(S)) #1 MICROGYNON (0.15MG LEVONORGESTREL/0.03MG ETHINYL ESTRADIOL, TABLET)						20. DID REACTION ABATE AFTER STOPPING DRUG?			· - · · ·				
15. DAILY DOSE(S) 16. ROUTE(S) OF ADMINSTRATION					YES	X N	0		N/A				
#1 1 Tablet 1x per 1 Day													
17. INDICATION(S) FOR USE				,				21. DID REACTION REAPPEAR AFTER REINTRODUCTION?					
18. THERAPY DATES (FROM/TO) #1 00-UNK-1997 / 20-Apr-2	001	19. THERAPY (DURATION				~ 		YES	Пи	0	X 1	WA.
III.		ONCOMITA			HSTORY	,		1					
22 CONCOMITANT DRUGS AND DATES O	F ADMINISTRATION (Exc	lude those used to t	reat event) (DA	VMO/YR)	· · · · · · · · · · · · · · · · · · ·						-		
										1			
23. OTHER RELEVANT HISTORY (e.g. diago	rection allegan access	1		·	B	ECEN	VED:				· · · · · ·		
UNK	. comos, and god, pragramo	y with less thorist of	period, aic./		JU	N 1 8	2001						
					CI	DR/CI)EH						
IV. ONLY FOR REPORTS SU		NUFACTUR	ER										
24a. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code) WYETH LABS (RA) 201 King of Prussia Sixth Floor Radnor, PA 19087-5114 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) (via				a Sche	ering :	rG)){	SS)				
Local Marketing No NDA 19-668	24b. MFR CONTRI									JUN	1 !	9 20	01
24c. DATE RECEIVED 24d. REPORT		6414JUN2001.											
	ATURE X AUT	NSUMER BULATORY THORITY				J1 14		2007					
	ESSIONAL LICE	ENSE							ال	JN 1	5 <i>7</i>	001	
Cale of this report 15-Jun-2001	25a REPORT TYP	FOLLOV	NUP							TE SEN	-		



or use by user-facilities, utors and manufacturers for IANDATORY reporting King Pharmacouticals, Inc.

	Relay	s Inter	metenet	, inc
FDA FIOI	imile Apo	ovet:	SO-JUN-	1906

Mir report #	
	K20040069
UF/Dist report #	
	FDA Use On

	SAD I MODEC 13 REFO	KILIO I NOCION		Pag	c
A. Patient Informa	ation				ı
1. Patient identifier	2. Age at time	40.7/	3. Sex	4. Weight	l
	of event:	16 Years	⊠ female	154.3 Iba	l
	Date		☐ male	or	l
in confidence	of birth:			70.0 kgs	l
B. Adverse event	or product proble	em			l
1. Adverse ever	nt and/or	Product problem	(e.g., defects/	malfunction)	
2. Outcomes attribut (check all that ap					
(Greek an mat ap	, Fird,	disability			
death .		congenitz	Il anomaly		
tife-threatening	(MARCON)	mequired i	ntervention to	prevent	ĺ
hospitalization	- initial or prolonged		t impairment/o	amage :	
3. Date		4. Date of			
of event (03/31/2004	this report	07/26/2	2004	
5. Describe event or	problem				
		(Related symptoms if	any seperated	by commas)	
Pulmonary infa Pulmonary emi					
		oedema NOS			
Small pericardi	al effusion[Per	icardial effusion			
Case Description		d		l	
10MAY2004 vi	i received by K	ling Pharmaceut ex Laboratories.	Cais, inc.	on	
reported that a	16 year-old fe	male patient rec	n regular eived oral	ory additiontly	
levonorgestrel/e	ethinyl estradio	ol 1 tablet daily s	tarted 13J	AN2004 for	
oral contracepti	ion. There we	re no concomita	nt medicati	ons. Past	
medical history	was significan	it for smoking the	ee cigaret	tes/day,	
being overweig	ht with a body	mass index of 2	7.7, a rupti	ure of the	
lateral collatera	I ligament of th	ne left ankle on 0	6NOV200	1, closed	
1 BUT 10 BUTCH 1	ignt tittn metat	arsal, tonsillitis o	liagnosed (on	
symptoms on	d treated with	penicillin, and a	recurrence	or tonsilitis	
continued in ad	ditional info se	ction		,	
6. Relevant tests/labo	ratory data, includir	g dates			
#1		re 120/70 mmH	9	ſ	
#2	Blood tests N				
#4	Respiratory r				
#5	Pulse rate 76		_	1	
	l Oxygen satu	re 119/57 mmHe ration measurem	} lent on air	100 %	
continued in a	dditional info	ection	ioni on an	100 /	
7. Other relevant histo	xy, including preexi	sting medical condition	s (a.g. silernie:		
race, pregnancy, s	inoking and alcohol	use, hepatic/renal dys	function, etc.)		
#2	to UNK Histori	rical Condition, (cal Condition, (c	ontinued)		
		istorical Condition, (c		led)	
#4 UNK, Curre	ent Condition.	Smoker (3 per d	, (Somme av)	,	
#5 UNK, Curre	ent Condition.	Overweight (con	tinued)	ł	

FDA
3600A E

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

of3				FDA Use Only
C. Suspect medication	(s)			8
1. Name (give labeled str	ength & mfr/labeler,	¥ known)		
#1. NORDETTE -21	LEVONORGES	T (contin	ued)	
			/	
#2. 2. Dose, frequency & rout	la se ad	2 75		114
		3. 1161a	hai square ((if unknown, give duration)
#1. 1 tablet, qd, Oral		#1. 01/	13/2004	to 03/31/2004
#2 .		#2.		<i>;</i>
4. Diagnosis for use (indi	eation)			t abated after use
#1. Oral contraception	ก			ed or dose reduced
#2.	7.5		*".	yes 🔀 no 🗌 apply
6. Lot# (if known)	7. Exp. date (if know	m)	#2. 🔲	yes no doesn't
#1. UNK	#1. UNK		R Event	reappeared after
	#2.		reintro	oduction
9. NDC# - for product pro	biems only (if known)	#1. 📙	yes no apply
			#2. 🗌	yes no apply
10. Concomitant medical	products and therep	y dates (ex	clude trea	atment of event)
NI				
G. All Manufacturers	***			
1. Contact office - name/ac	idress (& mfring site	for device	3)	2. Phone number
King Pharmaceutics			-,	9196537005
	•			İ
501 Fifth Street				
Bristol, TN 37620	UNITED STATES	8	•	3. Report source (check all that apply)
	J	•		⊠ foreign GBR
				study CSIN
				literature
				15
Date received by manufacturer	5.			—
(moneyly)	(A)NDA #	18-668		businessional .
07/14/2004 6. If IND, protocol #	INO #			user tacity
o. II IND, protocol #	PLA#			company
	pre-1938	☐ yes		distributor
7. Type of report (check all that apply)	1,000			15
☐ 5-day 🔯 16-day	OTC product	□ усз		other: Manufacturer:
	8. Adverse	event term	1(2)	
10-day periodic	Pulmona	ry infarct	ion, Pul	monary embolism,
☐ Initial ☐ follow-up i	Chest pai	in, Dyspi	noea, Co	ough, Granuloma
9. Mfr. report number	NOS, Pul	monary	oedema	NOS, o section
K200400695	CONTRIBUTE OF C	i iii audii	OHA HI	o secuon
				·
E. Initial reporter 1. Name & address				
1. Name a souress	pho	ne #		
,	56,7.00			
	UNITED ST	ATES		
2. Health professional ?	3. Occupation	· · · · · · · · · · · · · · · · · · ·		1-11-1
	i ·	Mura:	1	Initial reporter also sent report to FDA
⊠ yes ☐ no	Other Manufac	nurer	- 1,	
				L)yes Lino ⊠iunk
			7	
			با جمعه	op Stanff

Experience Report (continued)

of a report does not constitute in that medical personnel, user caused or contributed to the event.

King Pharmaceuticals, Inc. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration K200400695

UF/Dist report #

Additi	ional late	ormation		Page 2 of 3	· ·	50
						FDA Use Only
55.	EVEN	I DESCRIP	TION (cont.)			
1	****					
133/	AN2004	4. The patie	int's mother reported that he	r daughter experienced right sided pa	nin on 27144 Doon :	
knoc	cked it.	The patien	t took two unspecified pain k	dillers and went to bed. The next day	in on 27 MAR 2004. She den	ied having fallen or
sligh	าปัง. Or		she returned from school	I due to main The	sne reported feeling better be	ut that it still hurt
make	e an ap	pointment y	with her general practitiones	and test the	nt reported feeling better. The	e mother was unable to
eme	raencv	denartmen	the mother repeted the title	and took the patient to the emergency be patient experienced difficulty broath	y department on	On the way to the
to the	a emer	Cency dena	the mother reported that the	e patient experienced difficulty breath of right-sided chest pain, which was	ning and that it hurt to cough	The nations property
non-	produc	gency depa	rtment with a six day history	of right-sided chest pain, which was	dull with sham exacerbations	and energiated
3017	produc	uve cougn.	one denied any history of the	auma, expectorating blood, fever, or stender along the fourth lifth and sixth	shortness of breath An aver	, and associated
note:	antiotti	ianues. Ine	nght chest wall was mildly t	iender along the fourth, fifth, and sixth MHq. respiratory rate 20, and her over	The with no associated and	mination did not reveal
noted	a. Her	pulse was 7	6, blood pressure 119/57 mi	mHg, respiratory rate 20, and her oxy try bilaterally. An electrocardiogram	(OAD poturation was 4000)	lling or skin changes
equa	n expar	nsion of both	i lung fields and good air ent	try bilaterally. An electrocardiogram to the rib. She was discharged on die	yen saturation was 100% on	room air. There was
Ine	patient	t was diagno	sed with a soft tissue injury	to the chi Chi	was performed and nothing a	abnormal was detected.
with i	her ger	neral practiti	Oner if the nain nersisted it.	Over are actually the	ciolenac and paracetamol an	d advised to follow-up
patie	nt conti	inued to exc	erience nain and difficulty by	roothing On The Control Was Up	scondinued. During the subse	equent week, the
later	that ev	enina she v	omited On	e was observed sleeping at 9 am and	t complained to her mother o	f feeling unwell and
wası	unable	to awaken h	er daughter and absenced the	e was observed sleeping at 9 am and	11:30 pm by her parents. At	5:30 pm the mother
A pos	st morte	em examina	tion remaind a laws the	e was observed sleeping at 9 am and hat she was pale and did not appear to this nulmonary embolic mainly affects.	to be breathing. The patient	died on
pulmo	onary h	ree Thoro	tota elec analliarge infomb	not she was pale and did not appear to the least throughout embolic mainly affect of thrombotic embolic prospert in the least thrombotic embolic	ting the right pulmonary arter	v and the right
infarc	orially a	right loves	were also smaller amounts o	of thrombotic embolis mainly affect of thrombotic emboli present in the left emorthage on the right parietal places	lung. There was a wedge s	haned pulmona-
email	norico.	right lower	lobe overlying the area of he	or promodic emboli present in the left emorrhage on the right parietal pleura f pneumonia or lung tumors. Paragot	. There was also bilateral out	Imped pullionary
3111411	perical	ruiai enusioi	n. There was no evidence of	f pneumonia or lung tumors. Paracet is a cause of death. There was so sh	lamol was within the thermal	imonary edema and a
and o	ices no	t support ac	ute paracetamol overdose a	is a cause of death. There was no ob- detected in the blood. The pathologic	Nions evidence of live therapel	duc range at 4 mg/l
TOHOW	/ed a pr	revious over	dose. No other drugs were	detected in the blood. The pathologish weeks previously secondary to a secondary	of commented of liver toxicit	ty that might have
lung v	was not	t acute and p	probably occurred one to two	o weeks previously, secondary to a sr	st commented that the pulmo	nary infarct in the right
cause	of the	chest pain.	The large pulmonary embol	lus was versus and a si	mail embolus, and was likely	to have been the
cm dia	ameter	than the lef	calf at 38 cm diameter and	mountail beautiful Title patriologist	stated that the right calf was	slightly larger at 40
thromi	botic po	ulmonary er	obolus and 2) pulmonany infe	nus was very recent. The pathologist may well have been the source of the arct. The coroner concluded that the	e pulmonary embolus. The c	ause of death was 1)
		•	and any pointed any line	arci. The coroner concluded that the	death was due to natural cau	ises.
Follow	v-up inf	omation wa	s received by Vine Dhama			
details	s. nastu	medical hist	on modical social standard	ceuticals, Inc. on 14JUL2004 via fax fi	rom Berlex Laboratories. Ad-	ditional events avent
The da	ate and	cause of d	eath were updated.	tory and diagnostic test results, and p	ost mortem examination resu	ilts were provided
			salii word updated.			nors provided.
						1
B6.	. LABOR	RATORY DA	ΓΑ			1
<u>'</u>	# (Date	Test / Assessment / No	otes Boouts		
	7				Normal High / Low	· 1
	•		Electrocardiogram	Nothing abnor	mal	
				detected		
	8		Post mortem			
•					•-	
•		•	Summary of patholog	gical findings was:		· 1
			1. Large thrombetic a	Birder initialities were:		
: '	•		Large thrombotic p Perinheral rules	ournonary embolus		!
			2. Peripheral pulmon:	ary infarction right lung		1
			3. Right pleural granu	ulation tissue reaction with inflammatic	on	ŀ
			The contonary edema			l
			The contonary edema		5 1.	
·			 Pulmonary edema Small pericardial e 			
	9		5. Small pericardial e	ffusion		
	9		The contonary edema	ffusion		
· · · · ·	9		5. Small pericardial e	ffusion 4 mg/l	6	
	9		5. Small pericardial e	ffusion		
	9	-	5. Small pericardial e	ffusion 4 mg/l	6	
		DELEVIS	5. Small pericardial e Paracetamol level No other drugs were of	ffusion 4 mg/l	6	
		RELEVANT	5. Small pericardial e Paracetamol level No other drugs were of	ffusion 4 mg/l	6	
	OTHER		5. Small pericardial e Paracetamol level No other drugs were of	ffusion 4 mg/l	6	
	OTHER	RELEVANT	5. Small pericardial e Paracetamol level No other drugs were of	ffusion 4 mg/l	6	
	OTHER		5. Small pericardial e Paracetamol level No other drugs were of the condition Type / Condition	ffusion 4 mg/l detected in the blood. Notes	6 2	
B7. 0	OTHER	Stop Date	5. Small pericardial e Paracetamol level No other drugs were of	ffusion 4 mg/l detected in the blood:	6 2	



(continued)

ton of a report does not constitute ssion that medical personnel, user _____istributor, manufacturer or product caused or contributed to the event. King Pharmaceuticals, Inc.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

	FOOD PROMIT SERVICE - FOOD &	nd Orus Administras
Mit report #		
		K20040069
UF/Dist suport #	,	THEFT
		

	 · 		Page 3 of 3	FDA Use Or
2	UNK	Historical Condition Foot fracture	Right closed fracture metatarsal 5th	
3	•	Historical Condition	Sore throat with swollen red tonsils. Occasi tired. No nodes. Treated with penicillin, so	e throat symptom ongoing 3/52
	Ongoing	Tonsillitis	Recurrence of symptoms noted on 13JAN2	004
5	UNK:	Current Condition Overweight	Body mass Index = 27.7 (70 kg, 159 cm)	

C1. Name (cont.)

Suspect Medication #1: NORDETTE -21(LEVONORGESTREL, ETHINYLESTRADIOL) Tablet

G8. ADVERSE EVENT TERMS (cont.)
Pericardial effusion

. 1872 -		• • • • • • • • • • • • • • • • • • • •		٠.	user-tacitities, manufacturers for			-	FCIA H	ecsimile Approver attache
	ELYYA	ICn-			RY reporting		Mir mport	,	-	
	MEDICAL PRODUCTS REP		King !	Lustur	aceuticals, Inc.		1.9F/Oist rep	on #		K20 <u>04006</u>
A. Patient Inf	ormation.			Pa.	ge 1 of 2					
1. Patient ident					C. Suspect medica	tion(s)		تحظ		FDA Use C
UNK	of event:	16 Years	3. Sex 4. Weight		1. Name (give labels	d strength & mi	fr/isbeler, if	known)		L
	Or Date		female UNK	lbs	#1. NORDETTE	-21(LEVONO	DRGEST	(continu	ad\	
in confidence	of birth:	UNK	male UNK	kgs	#2.			Contande	,uj	······································
B. Adverse cv	ent or product probl	em		9s	2. Dose, frequency &	route used		3 Therany	distant (18	
_	event and/or				lí .		1		*****	own, give duration)
	tributed to adverse even		(e.g., defects/malfunction)		#1. 1 tablet, qd, C)rai	[¥1. 01/13	V2004 to 03	/31/2004
(check all th	at apply)	_			#2.			#2		. ,
⊠		disability			4. Diagnosis for use (#1. Oral contrace			5	Event abated	after use
⊠ death	- Characteria	Congenita	anomaly		#2.	puon		I.	stopped or do	Traesob ICA
life-threate	_		tervention to prevent impairment/damage		6. Lat# (if known)	7. Exp. date	(K known)	—		J vo ⊠ apply
hospitaliza	ition - initial or prolonged	other:	paintenovaniage		#1. UNK	#1. UNK	•		2. 🔲 yes 🗀	no doesn't
3. Date		4. Date of		_	#2,	#2.		8.	Event reappe	ared after
of event	03/31/2004	this report	05/18/2004	ı	9. NDC# - for product		if known)		reintroduction	n The Kon doesn't
5. Describe even	t or problem	(months)				• •	,	- 1	===	- ca apply
Event Verbatin	(PREFERRED TERM)	(Related symptoms if a	ny seperated by commas	, 1	10 Concentrate variation				2. 🔲 yes 🔲	no doesn't
Pulmonary e	embolism[Pulmon	ary embolism]			10. Concomitant medic	en blognets and	d therapy da	ites (exclu	de treatment o	f event)
Case Descri	ntion:			- 1						
This report w	vas received by K	ing Pharmacautic	olo les si	- 1	<u> </u>					
1 VIVIA 1 ZUU4	via tax from Berle	x Laboratories	A regulation, suth a	rity	G. All Manufacturers					
sported dial	a to year-old ten	nale natient recei	vad oral	- 1	1. Contact office - name	/address (& mfr	ring site for	devices)	2. PI	hone number
e a numer de ante	eretninyi estradio	l 1 tablet daily sta	rted 13 IANISONA 4	or	King Pharmaceut	icals, Inc.			919	96537005
ignificant pa	ption. There wer	e no concomitant	medications or							
ii ievonorges	stret/ethinyl estrac	iol therapy the n	ationt augustics	n	501 Fifth Street				3 R4	port source
The second second	noonsiii aliu died.	I DAIA Was no a	ant maria	1.	Bristol, TN 37620	UNITED ST	TATES		Chec	ck all that apply)
variation !	penomea. The p	robable cause of	death was listed a	9						foreign GBR /
ulmonary en	nbolism.			"						atudy /
					}				十日	literation .
			•		4. Date received by	5.				consumer /
			,	İ	wavniscinter		IDA# 18-6	368		health professional
				- 1	05/10/2004		. #		اَحا	/ /
Relevant tests/iai	boratory data, including	datus		_ .	6. If IND, protocol#	PLA	\ #		1 -	ompany
None .									"	aprasariasiya
					7. Type of report (check all that apply)	pre-	1938	yes		hetributor /
				-	5-day 🛛 15-day	OTO		yes	⊠ g	Anulacturer
				-		<u> </u>	Verse even			
					10-day periodic	Pulo	nonary en	nbolism		. /
					☑ initial ☐ follow-up	*				/
ther relevant his	tory, including preexistin	o medical conditions (s	e ellerel		9. Mfr. report number					
ace, pregnancy,	smoking and alcohol us	e, hepatic/renal dystund	g. allergies. tion, etc.)	11	K200400695					/ [
•				1 6	E. Initial reporter				/	
				- 1 г	1. Name & address					
			4			_	phone #]
								<i>,</i>	The	20
							_/		111) C
_	Submission of a repor	t does not	,			UNITE	XTATE:	3	MAY	
1977 V	magical hat zoutuel! fill	Of Iacility, distributor	nn admission that manufacturer or product	2	. Health professional ?	3. Occupation			MAY 2	I 2004
·	caused or contributed	to the event.	or product	١.		Other Man			4. Initial report	rteralso tto FDA
acsimile				10	yes no				! — _] no ⊠ unk
				L				ı		A MEN OUR



King Pharmaceuticals, Inc.

FDA Use Only

U.S. DEPARTMENT OF HEALTH AND HU	WAN SLHVICE
Public Health Service - Food and Dru	g Administratio

Mir report # K200400695 UF/Dist report #

(continued)

E.,

manufacturer or product caused or contributed to the event.

Page 2 of 2

aport does not constitute , medical personnel, user

Additional Information

C1. Name (cont.)

Suspect Medication #1: NORDETTE -21(LEVONORGESTREL, ETHINYLESTRADIOL) Tablet

DSS MAY 2 1 2004

MAY 1 9 2004



or use by user-facilities, , distributors and manufacturers for MANDATORY reporting

Relays International	, Inc., FDA Faceimile	Approvet: 11-JUN-1996
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FDA Use Only

The FDA Safety Information and Adverse Event Penarting Progr

Adverse Event Reporting Program	J	Page 1 of 2	· İ			FDA Use O
A. PATIENT INFORMATION		C SUS	PECT MEDICATION	I(S)		raxogra
1. Patient identifier 2. Age at Time	3. Sex 4. Weight		(Give labeled strength &		known)	
UNK of Event: UNK or Date	Female UNK to		dette 21 Day(LEVO		·	
of Birth: UNK	Male LINIX	kgs #2. AM	DXICILLIN(AMOXIC	CILLIN) (cont	tinued)	
B. ADVERSE EVENT OR PRODUCT PROBLEM			Frequency & Route Us			unknown, give duration) timate)
1. Adverse Event and/or Product Problem	r (e.g., defects/malfunctions)	#1. UN	K, UNK, Oral		1. duration 183	days
2. Outcomes Attributed to Adverse Event		#2. 1.5	g, qd, Oral		12. UNK	
(Check all that apply) Disability		4. Diagn	osis for Use (Indication)			Abated After Use d or Dose Reduced?
Deeth UNK Congenital	Anomaly	11—	er respiratory (cont	inuad)	I	es No Apply
Life-threatening (mo/day/yr) Required In	ntervention to Prevent	6. Lot #		Date (if known)	, 	
Hospitalization - initial or prolonged Other:	Impairment/Damage	#1. UNI			/ #2. Y	es No Doesn't
		#2. UNI	(#2. UN	IK		teappeared After duction?
	Report (mo/day/year) /01/2006	9. NDC#	(For product problems or	nly)	#1. 🗆 Ϋ	es No Apply
5. Describe Event or Problem		L			#2. 🔲 Yo	es No X Doesn't
Event Verbetim [PREFERRED TERM] (Related symptoms if a	ny separated by commas)	10. Cond	omitant Medical Produc	cts and Thera	py Dates (Exclude t	reatment of event)
Severe neutropenia[Neutropenia] Anemia[Anaemia]		NI '				
Leukopenia[Leukopenia]						
		COL	MANUSACTURERO			
Case Description:			VIANUFACTURERS t Office - Name/Address		ctuded Site	2. Phone Number
Information regarding an adverse event associa	ated with Nordette	for Dev	Ce6)	- leuro menore	caring one	2019303302
was derived from scientific literature. The artic		Barru	aboratories			
Contraceptive Methods in Women with System	ic Lupus					
Erythematosus, was obtained from The New E	ngland Journal of	400 ch	nestnut Ridge Road			3. Report Source
Medicine. It discussed findings from a single bi involving 162 women with systemic lupus eryth	ino cinical trial	امیمر ا	diff Lake, NJ 07677-	7668 UNIT	ED STATES	(Check all that apply)
randomly assigned to combined oral contracep	tives a propestin-onl	7 1 1			, XI	Foreign
pill, or a copper intrauterine device (IUD). The	combined oral	"			/4	Study
contraceptive regimen consisted of 30 µg of etr	ninyl estradiol plus 15	50			[]	Literature
μg of levonorgestrel (Nordette). The progestin-	only pill contained 30		ceived by	5.		Consumer
ру of levonorgestrel (Microlut, Schering Mexica	na). The	Manufa	celved by cturer(mo/day/yr)	(A)NDA # 18	-668	Health Professional
continued in additional info section		4	1/26/2006	IND#		User Facility
		6. If IND,	live Protocol #	PLA#	ļ	Company
6. Relevant Tests/Laboratory Data, Including Dates		7 L. ;				l '
#1 Anemia, Leukopenia 500 (neutrophils 55%	6)	7. Type of		Pre-1938 {	Yes	Distributor
		112	all that apply)	отс	□ Yes	Other:
		LJ 5-da∤	⊠ 15-day	Product l		
		10-d	Periodic		vent Term(s) a, Anaemia, Leui	kaania
		Initial	Follow-up #1	reconoperin	a, Alabilia, Leu	корепіа
		9. Menute	turer Report Number			
7. Other Relevant History, Including Preexisting Medical Cond	ditions (e.g. allergies,	006392				
race, pregnancy, smoking and alcohol use, hepatic/renal dysfu #1 UNK, Historical Memo, History of drug rela	unction, etc.)					_
(Azathioprine)	teu teukopenia		L REPORTER			
• • • • • • • • • • • • • • • • • • • •		1. Name as	nd Address	Phone	# UNK	
				-		
		1 9				

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

DSS

4. Initial Reporter Also

Sent Report to FDA

Yes No V Unk

3. Occupation

Physician

2. Health Professional?

Yes : No



(continued)

ion of a report does not constitute sion that medical personnel, user HAUSHILLY, Importer, distributor, manufacturer or product caused or contributed to the event.

	Publi	c Health Service -	Food and Drug Administration
Report #			
/Importer Reg	ort #		006392

FDA Use Only

Page 2 of 2

Additional Information

B5. EVENT DESCRIPTION (cont.)

IUD was TCu 380A copper device (Ortho Pharmaceuticals).

The objective of the study was to investigate whether there were clinically significant differences in systemic lupus erythematosus activity, as measured by the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), in women taking combined oral contraceptives in comparison with those using a progestin-only pill or IUD.

Findings of the study revealed that there were no significant differences among the groups during the trial in global or maximum disease activity, incidence or probability of flares, or medication use.

One patient, receiving combined oral contraceptives (Nordette), died during the trial; her death was ascribed to amoxicillin-related severe

Additional information was received on 01/26/2006.

The author reported that the duration of Nordette therapy was six months. Amoxicillin 1.5 grams/day was prescribed for an upper respiratory tract infection. On an unknown date, lab work indicated anemia, leukopenia 500 (neutrophils 55%). In addition, it was reported that the patient had a history of drug related leukopenia (azathioprine).

MedWatch Case Comment:

Submission of this 15-day report does not constitute an admission that the reported event is an unlabeled event.

C1. Name (cont.)

Suspect Medication #1: Nordette 21 Day(LEVONORGESTREL, ETHINYLESTRADIOL) Tablet

Suspect Medication #2: AMOXICILLIN(AMOXICILLIN)

C4. Diagnosis for use (cont.)

#2: Upper respiratory tract infection

G3. Report source literature description

Journal: The New England Journal of Medicine

Author: Sanchez-Guerrero, J, Uribe AG, Jimenez-Santana L, Mestanza-Perbita M, Lara-Reyes P, Seuc AH, Cravioto MD

Title: A trial of contraceptive methods in women with systemic lupus ergthernatosus

Volume: 353 Year: 2005 Pages: 2539-2549

Individual Safety Re	port
Individual Safety Re	IN SAN INTO REAL COLUM
ADRECTALY DO DI	

VOLUNTARY reporting alth professionals of adverse

Form App	roved: OME	No. 0910-0291 Expires:12/31/1 See OMB statement on revers
DA Use Only	H Pad	THE STATE OF THE S

user facility distributor

CDER "

4065974-X-00-01 THE FDA MEDICAL PRODUCTS REPORTING PROGRAM	product problems	87724
A. Patient information	T of T	
1. Patient identifier 2. Age at time 3 Sex 4 Weight	C. Suspect medication(s)	
of event: 40	1. Name (give labeled strength & mfr/labeler, if known)	
In confidence of birth:	#2 Oxtoo No was 150 OF	1
B. Adverse event or product problem		unk own, give duration
1. Adverse event and/or Product problem (e.g. defects/malfunctions)	110m/16 (or best estimate	um aweeks
Outcomes attributed to adverse event (check all that apply) disability	"2 I po QD "2 unknow	
death congenital anomaly	4. Diagnosis for use (indication) 5. E	vent abated after use
life-threatening permanent impairment/damage	"menorrheagia"	topped or dose reduce
hospitalization – initial or prolonged other:	menorr neadia	des no doesi
3. Date of event are all of this report 2-21-03	#1 A A A A	yesnodoesr apply
5. Describe event or problem		ivent reappeared after eintroduction
Diament Inlus	#E ==	yes no Doesr
Pulmonary Embolus —	#2	yes no doesn
	10. Concomitant medical products and therapy dates (exclude	e treatment of event)
patient had been on		
Ortho Novum 150 for an		
Office Howard 100 for all		
unspecified time period,	D. Suspect medical device	
	2. Type of device	
s was recently Did to	3 Manufactures	
Nordette 21 day - presented		Operator of device health professional
• • •		ay user/patient other:
With PE on 2-20-03		
1114 12 311 1 40 00	6. RECEIVED 5	Expiration date
. Relevant tests/laboratory data, including dates	model #	(mo/dey/yr)
	catalog # FEB 2 8 2003 7.	If implanted, give date (nix/dey/yr)
	serial #MEDWATCH CTI !	
nss	lot # 8.	If explanted, give date (mo/day/yr)
000	other#	
FEB 2:8 2003	Device available for evaluation? (Do not send to FD/ yes no returned to manufacturer on the send to FD/ yes no returned to the send to FD/ yes no returned to the send to FD/ yes no returned to the send to FD/ yes no returned to the send to FD/ yes no returned to	
	10. Concomitant medical products and therapy dates (exclude to	
Other relevant history, including preexisting medical conditions (e.g., allergies.	Process and merapy dates (exclude to	reatment of event)
race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)		
demaking	E. Reporter (see confidentiality section on ba	ack)
Øsmoking Øalcohol	1. Name, address & phone #	
@alcohoT	Marmo	
7 300		
	2. Health professional? 3. Occupation 4. Also	
Mail to: MEDWATCH OF FAX to:		reported to



5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178



ORTING PROGRAM

Approved by the	FDA on 09/24/1999
Mfr report #	8-99180-072A
UF/Dist report #	

A. atient informatio	TO EARLY VIEW CONTRACTOR OF THE	Service Contract Contract				FDA Use O
1, Patient identifier 1. 2. Age at time	3. Sex	4. Weight	# ECASuspe	ct medicatio	D(S)	
UNK of event:	NK X temale	UNK Ibs	1. Name (give label	ed strength & mfr/labeler, if	known)	
Date of		or	12			
in confidence Birth:	male	kgs	11 "			
EZAdverse eventor	productions		2. Dose, frequency	& route used	3 Therany date	s (if unknown, give duration)
1. X Adverse event	Product problem (e.g., o	AT ANY AT MEN AND PARTY AND PROPERTY.	#11 Tablet	1x per 1 Day,	#1 12 Day	s (ir oliunown, give ouration)
2. Outcomes attributed to adverse event	1 rococc problem (e.g., (erects/mailunctions)	_ Orai		1	
(check all that apply)	disability		* 2		*2	
X death	congenital anomaly	,	4. Diagnosis for use	(lastantan)		· · · · · · · · · · · · · · · · · · ·
(mo/day/yr)	required intervention permanent impairm	n to prevent	#1 UNK	(mocator)	5. sto	Event abated after use apped or dose reduced
hospitalization-initial or prolonged	other:	en v dan istratio				1 yes no X app
recovered	L. J onlar.		1 2			
3. Date of event UNK	4. Date of this report	11/23/1999	4			yes no does
(mo/day/yr) 5. Describe event or problem	(mo/dey/yr)	11/23/1999	6. Lot # (if known)	7. Exp date (if known		
STROKE. Information has	been received from	an		1 - '	8. E nein	Event reappeared after stroduction
(age unspecified) who had	identified female particle properties that the prescribed Tri	tient phasil-28	# 2	# 2		1 yes no X doesn
long-term heavy bleeding	d), Medical history with her menses resu	included				
attorney, regarding an un (age unspecified) who had therapy (dates unspecifie long-term heavy bleeding persistent iron deficienc therapy was not provided. of pills in the physician 12 days the patient took which the patient took the which the patient took the patient was the patient took the patient took the patient	y anemia. Concomita The patient was give	int drug en a pack	9. NDC # - for produ	ct problems only (if known)	.2	her uo abbi
12 days the patient took	s office, and over 4 tablets. The inte	the next	10. Concomitant med	ical products and therapy of	tates (exclude tenes	ment of every
which the patient took the lays after receiving Trip suffered a stroke and die was provided.	e tablets is unknown asil-28 therapy the	. Twelve patient		, , , , , , , , , , , , , , , , , , ,	arios (éverene nestr	nancol event)
was provided.	d. No further infor	mation	G2 All ma	nufacturers	CAMBEL SEC	ALTERNATION DE L'ANNE DE L
			1. Contact office - nar			2. Phone number
į			WYETH LABS (170 Radnor C	RA)		6109023760
			St. Davids,	PA 19087		3. Report source.
			Karel F. Ber			(check all that apply)
			11	NOV 3 (1999	foreign
			11	•	1000	study
						literature
						X consumer
			4. Date received by m	anufacturer 5.		health professional
. Relevant tests/laboratory data, including da	les		(mo/day/yr)		NDA L9-190	user facility
None Provided.			06/22/	"	0 #	company
			6. If IND, protocol #	PL.	A #	distributor
					1938 yes	other:
		j	7. Type of report	OTC Prod		—
		Ì		8. Ad	verse event term(s)	1
Other relevant history, including preexisting	medical conditions		5-day15			accident NOS
.g., affergies, race, pregnancy, smoking and THER MEDICAL HISTORY:		ion, etc.)	10-day X per	iodic		
ong-term heavy bleeding warraistent iron deficiency	ith her menses and		X initial follo	ow-up #		
and addicted CA	andita.		9. Mfr. report number			
			8-99180-	0724		
		1				
		ł	Sealnitial re	porteis	ASPAY DESCRIPTION	SERVICES :
		İ	1. Name & address		phone #	
			9			
		1	1			• •
		-				•
		-	}			
			2 1/2 - 1/2	.		
orm 3500A (facsimile) (Impulum person	a report does not constitute an adm nel, user facility, distributor, manufa	ission that	2. Health professional?	3. Occupation		al reporter also nt report to FDA
caused or contr	fouled to the event.	د ا	yes X no		ا ا	yes no X unk

	Individual Saf	ety Report	· .						!		Pa	ge	1 of 2	<u>. </u>
	3646166-3-66-6 RSE EXPERI	ENCE REPOR	RT					П	<u> </u>	- 		T		_ _
1. PATIENT	1a. COUNTRY		REACT	ION INFO	RMATIO	N.		11		<u> </u>	L_			\perp
INITIALS	France	2. DATE OF BIRTH Day Month		2a AGE UNITS 38Yr	3. SEX	4-6. EX	PERIENCE Month	Year	8-12	ĀP	IECK ALL PROPRI VERSE F	ATF TO) ION	
7. DESCRIBE E THROMBOTIC	XPERIENCE(S) THROMBOCYTOPENIC	PURPURA	_1			l		J	X	PAT	IENT D	IED		
Abstract; TRINORDIOL LEVONORGES ESTRADIOL) indication contracept included on have sever the patient purpura, 12	42b) concerning a (0.05MG LEVONORG TREL/0.04MG ETHIN (equivalent to T were unspecified ive Adepal (levonocasional use of a thrombocytopenia was hospitalized arge ecchymoses, costandoratory DATA Jing page.	. 08-DEC-2000, from ura: Role of oral 38 Yr old female 1 ESTREL/0.03MG ETHI YL ESTRADIOL/0.1251 riphasil) for an 18 0. Her medication Drgestrel and ethir TYLENOL (PARACETAN a (10 giga/L). Some 1. On admission, a cephalalgia and eye (cont'd)	contracep patient want ESTRA MG LEVONC 8 month danistory myl estra MOL). The estime for a clinical eground m	who had to the total transfer of the total transfer of the total transfer of the total transfer of the total transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of transfer of the transfer of t	Therapie taken the 175MG 1/0.03MG (therapy I prior to Concomit was casthe init ation reeding.	2000; ETHIND dates use of ant the cually ial di vealed A cran	55: with L and the or erapy noted agnosi	al		PROINPA HOS INVO PER: SIGN DISA INCA LIFE	DLVED LONGIATION OF THE PACITY	ZATH VCE (NT OR Y VTEN) DF ING	
14. SUSPECT DRU	G(S) (INCLUDE ACTIVE SUB	STANCE(S))	PECT DRU	JG(S).JNF	ORMATI	ON.:	apityri sai	e Jacobie	_ 		14.50		7.3.3	—
TABLET)	OL (0.05MG LNG/0.	03MG EE/0.075MG LN	G/0.04MG	EE/0.125	MG LNG/	0.03MG	EE,				CTION A		G?	
15. DAILY DOSE(S)				16. ROUTI	E(S) OF ADMI	NSTRATIO)N		-	YES		NO	X N/	4
17. INDICATION(S) # 1	FOR USE								21.	DID REA	CTION RI	EAPPE DUC,TK	AR ON?	
18. THERAPY DATI #1 Unknown	ES (FROM/TO)	19. THE #1 Un	RAPY DURAT known	ION					.	YES	□ '	10	X N/A	
	DRUGS AND DATES OF ADA VACETAMOL), Unknow	CONCOI IINISTRATION (Exclude those u	MITANT D	PRUG(S)	AND HIS	TORY			Art (1 - 35) The system of	X . (1)	. : . ⁽ 4) :		- 21 2	_
3. OTHER RELEVA JNK	NT HISTORY (e.g. diagnostics	, allergics, pregnancy with last m	onth of period,	etc.)				· · · · · · · · · · · · · · · · · · ·				77 <u></u>		-
V. ONLY FOR	REPORTS SUBMI	TITED BY MANUFAC	TÜRER						projection and the		. F.			-
WYETH LABS 201 King of Sixth Floor Radnor, PA 1	(RA) Prussia						//	CHIM	REC'	RORES)SS	-
Markening No. NDA 1 DATE RECEIVED BY MANUFACTURES	24d REPORT SOUR STUDY X LITERATUR	CONSUMER						DE	C 2 9	200 0		IN () 2 20	10:
20-Dec-2000	PHOFESSIC													
DEC 2	8 ZUUU C	25a REPORT TYPE NITIAL X FO	LLOWUP					DE	C 2	9 201	00			

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ADVERSE EXPERIENCE REPORT

Manufacturer Control Number:

HQ4722412DEC2000

Box # 7 - DESCRIBE EXPERIENCE(S)

(Continuation)

densitometry was performed and was normal. Laboratory testing revealed hemolytic anemia, the presence of schizocytes, persistent thrombopenia (without coagulation disorders) and acute renal failure. In addition, infectious etiologies and collagen disease were ruled out. The patient was diagnosed with thrombotic thrombocytopenic purpura (Thrombotic thrombocytopenic purpura). Despite intensive treatment which included fresh frozen plasma, plasma exchange and platelet infusions, the patient died on day twelve of the hospitalization. An autopsy revealed diffuse capillary thrombi involving most organs and confirmed diagnosis of thrombotic microangiopathy. A copy of the literature abstract is attached. CANCELED: This case is canceled as it is a duplicate of 8-99182-003A.

Box # 13 - RELEVANT TESTS/LABORATORY DATA

(Continuation)

Test Name

Date

Result

Normal Range

Laboratory test abnormal NOS

Autopsy showed diffuse capillary thrombi involving most organs and confirmed diagnosis of thrombotic microangiopathy.

Platelet count decreased

10 giga L

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DEC 0 7 2000

<13> Unique Identifier 203439

GSSE/RESS

Title

Fatal thrombotic thrombocytopenic purpura: Role of oral contraceptives? Author

Zenut M. Lamaison D. Merle P. Souweine B. Caillaud D Institution

Centre Regional de Pharmacovigilance, BP: 38 - 68001 Source

Therapie 55(3):413, Abstr: 42b, 2000 May-Jun Meeting Data

4th Annual Congress of French Society of Pharmacology, Rouen, 10-12 Apr 2000

Abstract

A severe thrombopenia (10 giga/1) was casually discovered in a 38 year-

old woman. She has been for few years on oral contraceptives ADEPAL (R)

(levonorgestrel and ethinylestradiol) then TRINORDIOL(R) (levonorgestrel

and ethinylestradiol) for 18 months and occasionally acetaminophen.

admission, she presented with purpura and large ecchymoses, cephalalgia

and eyeground minor bleeding otherwise clinical examination and

tomodensitometry were normal. Additional investigation showed hemolytic

anemia and the presence of schizocytes, persistent thrombopenia (without

coagulation disorders) and acute renal failure, leading to the diagnosis

of thrombotic thrombocytopenic purpura (TTP). Diagnostic of infectious

etiologies and collagen disease was ruled out. Despite intense treatment

combining fresh frozen plasma, plasma exchange, and platelet infusion

patient died on hospital day 12. Autopsy showed diffuse capillaries thrombi involving the most organs and confirmed the diagnosis of thrombotic microangiopathy. Due to the lack of other etiologies, the responsibility of TRINORDIOL(R) (C1S2) was raised. Nine cases of thrombocytopenia were reported in women treated by levonorgestrel implant,

three of whom were hospitalized and treated for TTP, one another died (WYSOWSKI DK and GREEN L., 1995). Another case of TTP has been mentioned

in a 16 öld girl on low dose oral progestatives (CAILLARD S., 1998).

JAN 02 2001

individual Safety Report

VIELLIVVA

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	Approved by FDA, Oct. 15th, 1993
Mir report #	
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UF/Dist report #	
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THE EDA MEDICAL PRODUCTO PERSONNIA	Wayne, NJ		
	_ of <u>2</u>		FDA Use Only
A. Patient information	C. Suspect medica	ition(s)	
1. Patient initials 2. Age at time of event: 34 years 4. Weight	1. Name (give labeled strength i	& mfr/labeler, if know	n)^
Of Date X female Of	MIRENA (levonorg	estrel)	
in confidence of birth: male 70 kg	s #2		
B. Adverse event or product problem	2. Dose, frequency & route use	ed 3. Therapy d	ates (if unknown, give duration)
1. X Adverse event and/or Product problem e.g., (defects/malfunction	s) #1 <continued></continued>	#1 238 da	(USUMME)
Outcomes attributed to adverse event (check all that apply)	#2	#2	-
death congenital anomaly	4. Diagnosis for use (indication		E E
(ed Mon yyy) required Intervention to prevent	#1 Contraception	•	5. Event abated after use stopped or dose reduced
permanent impairment/damage	#2		#1 yes no x doesn't
x hospitalization - initial or prolonged other:		rp. date (if known)	#2 yes no doesn't
event 10 Apr 2000 this report 24 Tan 2001	#1 Unknown #1	the actor (it sales with	8. Event reappeared after
(6d Mon yyyy) 5. Describe event or problem	#2 #2		reintroduction
The initial and four (4) follow-up reports for	9. NDC # - for product problems of	only (if known)	#1 yes no x doesn't
to IND 22,697. The initial case was submitted		- January	#2 ves no doesn't
on 24 Jul 00 (serial no. 056): follow-up #1 on	10. Concomitant medical produ	icts and therapy date	
23 Aug 00 (serial no. 061); follow-up #2 on 15 Sep 00 (serial no. 068); follow-up #3 on 24 Oct	Unknown		
00 (serial no. 081); and follow-up #4 on 03 Jan 01 (serial no. 092).			
Based on additional information received post-approval, this case was determined to be			
reportable to the Mirena NDA (21-225).	G. All manufacturer		
Physician's report via sales rep on 20 Jul 00	1. Contact office - name/address	s & mfring site for de-	
and phone call on 21 Jul 00:	Berlex Laboratories, I	nc.	(888) 237-5394
34 year-old patient who was on Mirena since Aug	300 Fairfield Road		3. Report source (check all that apply)
99 collapsed in bathroom. Resusitation without success. Pt died. Autopsy was not performed. No	Wayne, NJ 07470		
risk factors. Physician is not informed about further details. However, although he does not	05A		study
l see any causal relationship to Mirana haller			literature
send a written report.	4. Date received by manufacture	e E al-II-a	m health professional
Suppl. (16 Aug 00):	(ad Mon yyyy)	f 5. similar to: (A)NDA # 21-22	25 1 — 1
6. Relevant tests/laboratory data, including dates	20 Jul 2000	IND#	user facility
None reported	6. If IND, protocol #	PLA#	x company representative
	7. Type of report	_ pre-1938	
	(check all that apply)	Product yes	s ather:
	5-day x 15-day	8. Adverse event	term(s)
	10-day periodic	EMB PULM	
	X Initial	THROMBOPHLI CONVULS	EB DEEP
7. Other relevant history, including preexisting medical conditions (e.g., aller-	9. Mfr. report number	HEART ARRE	ST
grees, race, pragriancy, smoking and alcohol use, hepatic/renal dysfunctions, etc.)	00/01147-GBD		
Patient has asthma in history, no risk factors, multipara (2 children), allergy to penicillin.	E. Reporter		
No clotting disorder in known.	1. Name, address & phone #		
	h the state of brother		DSS
			000
			JAN 2 5 2001
	Country of origin: G	ermany	2001
Submission of a report does not constitute an	2. Health professional? 3. Occup		4. Initial reporter also
admission that medical personnel, user facility, distributor manufacturer or product caused or	xyes no Physi		sent report to FDA
FDA Form 1500A (693) contributed to the event.		JAN 2 5	7 00 Yes X no Lunk





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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 2

Continuing	Page
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B.5. Describe event or	problem
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Suppl. (11 Sep 00):

Phone call with the reporting physician: There is no evidence for extrauterine pregnancy and abdominal bleeding in this patient. The patient probably died due to a cardiac event. Unfortunately no autopsy was done.

Suppl. (18 Oct 00):

Phone call with reporting physician. Physician spoke to patient's sister who told him that patient's mother was with the patient when the event occurred. It was said that pt developed "convulsions". There were no signs of an ectopic pregnancy.

Suppl. (20 Dec 00):

Report from the emergency physician and written report from the hospital (department of internal medicine). Emergency physician was called on the when emergency physician arrived husband had already performed CPR for 15 minutes because of apnea/ difficult breathing. An intubation and a defibrillation (due to ventricular fibrillation) were performed. Patient received 1 ampoule of adrenalin via tube and 6 ampoules adrenalin i.v.. Red scum was discharged out of the tubus. No spontaneous breathing could be observed. For a short time pain reaction was still present. A buffering was performed with sodium bicarbonate and 50 mg Dopamine were applied i.v. Only little cardiac reaction to continued CPR with deformed ventricular complex. Due to dilated pupils, no RR and no cardiac rhythm CPR was stopped.

Husband said that an attack of asthma is unlikely. As the patient was already dead when she was admitted to the hospital no lab data or other investigations were done.

Diagnosis: suspected fulminant pulmonary embolism due to thrombosis of pelvic vein.

Suppl. (16 Jan 01):

Phone call with gynecologist to get further information. No clotting disorder is known in this patient and in patient's sister.

Suppl. (17 Jan 01):

Phone call with internist to get further information. Deep vein thrombosis as well as pulmonary embolism are only tentative diagnoses, unconfirmed by any investigations, based solely on the clinical symptoms.

Further information will be requested.

C. Suspect medication #1

C.2. Dose, frequency & route used

0.02 mg intra-uterine IUS

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THE FDA MEDIC	CAL PRODUCTS F					Way	ne, NJ					
A Patient	in formation	REPORTING P	ROGRAM	Page 1	•	1 2						
1. Patient Initials	information					C. Suspect n	nedic	ation	(e)			FDA Use (
Tadon initials	of event: 45	years	3. Sex	4. Weight	7	1. Name (pive labeled	strength	2 mich	sheles Wi			· · · · · · · · · · · · · · · · · · ·
la andida	Date		x female	or lbs		#1 MIRANOVA	(levon	orge	strel, et	hinvid	estradic	ο 1)
In confidence		nown	male	kgs	.	8 2						
b. Adverse	event or pro	duct prot	olem			2. Dose, frequency &	route us	ed	3 Thereny	datas		
1. X Adverse eve		duct problem	.g., (defects/	malfunctions)	#1 1 coated ta			from/to (or b	est estima:	m) (II INKNOWN	, give duratio
2. Outcomes attrib (check all that ap	outed to adverse eve	nt disability			7	#2			1 1990	- app	rox. 5	years
X death 20	01		al anomaly			4. Diagnosis for use (lia alla sals		#2	 -		
Iffe-threatenin	Idd Man wood	C required	Intervention to) pravent		#1 Unknown	(ILIGICETION)		5. E	vent abate	d after use dose reduce
1	• n • initial or prolonged	beumane	nt impalment	/damage		1 2					yes []	
3. Date of	The state of projection				╽	6. Lot # (if known)	17.5			_		apply
event 2001	l	4. Date of this report	6 Apr	2001	П	#1 Unknown	#1	φ. date	(if known)	<u> </u>	yes n	appry
5. Describe event o	r problem	(did Mon yyyy)			$\ \cdot \ $	#2				- 8. Ev	vent reapp introduction	eared either
Gynecologis	t's report:				1 -	9. NDC # - for product p	#2	-1 (11)		1 _]yes []n	o C∃dbesn't
Pt has been	taking Mirar	nova for a	- מיצטיממו	atelar	$\ \ $	tor product p	·· JUHHITIS (any (II I	known)			
prior to int	take of Wine	scory or h	ypertens	ion	\prod	10. Concomitant medic Unknown	cal produ	cts and	themov day	142	yesn	
for three we	eks in Jan (11 due to	cardiova	work Scular		Unknown			- a windy bat	es (exc	nnee treatu	ent of (ivent)
the last tim	ne and evamin	aw the pt	in e	for								
(the same va	lue se it	mre was I	50/ 90 m	m Hg [
did not have	lue as it wa a varicosis	 Some da 	rs befor Vs ago n	e). Pt								
did not arra	nge for an -	TH SCHOOL	. Physic	ian		G. All manufac	cturer	s				
relatives di under Mirano		f event p	t was st	ill	11	. Contact office - name	address	& mfri	ng site for de	vices	2. Phone r	number
	· · · ·				- [Berlex Laborato				1		237-5394
Pathologist's results are a of the right	s report to a	ynecologi	ist: Auto	opsy	1	300 Fairfield Ro	ad	ic.			3. Report a	source of that apply)
of the right	heart. No er	mbolism ar	a nyperi id no	trophy		Wayne, NJ 0747 USA	0				× foreig	
told the repo	orting omes	be found	l. Pathol	logist	'	55 A					study	
gynecologist	nor patholog	sible. Ne	ither		1					j	literat	
relationship	between exit	us and Mi	. Causal ranova i	.n	4.	Date received by man		1			const	ſ
ccontinued			_		1		u:acturer	5. SI	Tiller to: DA # <u>20</u> – 8 6	50	x health profes	
Relevant tests/labo	retory data, including	dates			_	6 Mar 2001		1	D#	-	user f	
					"	ii kiio, protocol #		PL	A#		x compa	any sentative
Diagnostic In Derformed: No	vestigation:	Autopsy	was		7.	Type of report		pre-1	938 yes	s	distrib	
t had hypert	ropby of the	o cerebra		tion,		(check all that apply)		OTC	at Dyes]other:	۱ حد
Suppl. (actigne be pos	sible.		- 11	[8. Adv	rerse event t	lerm(s)		
ailure rt bechich was not	cause of hear	sy result: rt valve }	acute	heart	[10-day periodic		HEA	RT FAIL	RIGI	IT	0
hich was not	known.		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,	Γ	Initial X follow-up	ſ					9 2
Other relevant histor ples, race, pregnancy,	ry, including preexis	ting medical cr	onditions (e.c.		9. A	Afr. report number						2001
ples, race, pregnancy, t had a histo ntake of Mir-				ns, etc.)	01	L/00393-GBD	- 1					
ntake of Mira	mova.	ension pr	ior to		E	. Reporter				بخصا		
						isme, address & phone						
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					Co	untry of origi	n: Ge	man	v			
	Submission of a rep admission that medi				2. H	saith professional? 3.	Occupa	tion		i. inkla	reporter s	also
	distributor manufact contributed to the ex		user tacility, t caused or		×	yes no I	Physic	ian		sent	report to F	DA I
•		TOTIL		L						ye	es no	[X] unk





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Continuing Page

B.5. Describe event or problem

Suppl. (26 Mar 01): Phone call with gynecologist who reports autopsy result which was given orally (written report not available). Autopsy result: acute heart failure rt because of heart valve hypertrophy which was not known. No relationship with Miranova.

Page 2 of 2

Case closed.

4.															
Г	I MARIO MARIO ANTE ANTE ANTE	Blad om meen inn meen sinn se	D Maria man	1								Р	age	1	1 of 1
'	*374 1376					·									·
ADVE	RSE EXPER	RIENCE RE		<u></u> .		T		Τ		Т	<u> </u>	- -	\neg	Т	
I.				CTION INFO	RMATIC	N.							\perp	上	
1. PATIENT INITIALS	1a. COUNTRY	2. OATE	OF BIRTH	2a. AGE UNITS	3. SEX	4-6.	EXPERI			8-12	C	HECK AL	LL		
1.05500,05.5	Denmark			33Yr	F	Day 20	Mo A	nth .PR	Year 2001		Ã	OVEASE	REAC	TION	i
PULMONARY	XPERIENCE(S) EMBOLISM									X	PAT	FIENT	DIEC)	
Microgynor	on was received oncerning a 33-y : (0.15mg levono specified indica	ear-old female rgestrel/0.03m	patient who g ethinyl es	had taken	therapy	with	Mara		2)		PR(INP	OLVEI OLONO ATIEN SPITAI	GED IT		4
if the pat	story was not p ient was taking pulmonary embol ified. The pati	rovided. The d concomitant t ism) on	ose regimen herapy. The	was 1 table	es daily	. It	is un		m.		PEF SIG DIS	OLVEI RSISTE NIFICA ABILIT APACI	ENCE ANT 'Y OF		:
						N.					LIFE	THRE	EATE	NIN	Ğ
											NONE OF THE ABOVE				
13 RELEVANT TO None Prov	ESTS/LABORATORY DAT/ ided.	A			······································			·			REC	OVER	ŧΕD		
II.	UG(S) (INCLUDE ACTIVE		SUSPECT	DRUG(S) IN	ORMAT	ION				1					
#1 MICROGY:	NON (0.15MG LEVO	NORGESTREL/0.()3MG ETHINYL							20.	AFTER	ACTION STOPP	ING DI		
*1 1 Table	1x per 1 Day			16. ROUT #1 Ora	E(S) OF ADM	MINSTRA	TION				YES	X	Jио	L	_] N/A
17. INDICATION(S	i) FOR USE											ACTION REINTR			
18. THERAPY DA	PS (FROM/TO) 997 / 20-Apr-20	01	19. THERAPY OF	URATION							YES		ОИ		N/A
III.	TORUCS AND DATES OF	(ONCOMITAN	NT DRUG(S)	AND HI	STOR	Y								
Unknown	T DRUGS AND DATES OF	ADMINISTRATION (Exc	lude lhose used to tre	eat event) (DA/MO/	YR)										
23. OTHER RELEV UNK	ANT HISTORY (e.g. diagno	stics, allergies, pregnanc	y with last month of p	period, etc.)			ECI								
	JUN 1 8 2001														
IV ON V.FO	D DEPOSTO OUE					C	DR/	CE							
24a, NAME AND AD	R REPORTS SUE	BMITTED BY MARKET (Include Zip Code)	NUFACTURE		ED OPPO										
WYETH LABS 201 King of Sixth Floor Radnor, PA	(RA) Prussia 19087-5114	Reg	OTHER REFERENCE NUMBERS: Regulatory Authority (HP) (via Schering AG) 01/01322-CDS							S					
ocal Marketing No. NDA	18-668									JUI	N 1	9	2001		
24c. DATE RECEIVE BY MANUFACTUR	STUDY LITERAT	CON REG	ISUMER ULATORY HORITY				ji	! · N	:	(00)					
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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page <u>1</u> of <u>2</u>

A. Patient i	nformation				C. Suspect medication(s)						
1. Patient Initials	ı or ———	years	3. Sex	4. Weight	1. Name (give labeled #1 MIRENA (lev			•			
in confidence	Date of birth: Unknown	own	male	or kgs	#2						
B. Adverse	event or proc	luct pro	blem		2. Dose, frequency &	route used	3. Therapy date fromto (or best es	es (i: unknown, give duration)			
1. X Adverse eve	ent and/or Prod	uct problem	e.g., (defects	/maifunctions)	#1 0.02 mg in	trauterine		200% - 27 Jul 2001			
	buted to adverse even				#2		#2				
(check all that ap	opiy)	disabil	•		4. Diagnosis for use	(indication)		5. Event abated after use			
x death	(dd Mon yyyy)		nital anomaly and intervention	to prevent	#1 reduction	of menstru		stopped or dose reduced			
life-threatenin	-	L perma	nent impairme		#2			#1 yes no apply			
	n - initial or prolonged	other:			6. Lot # (if known)	7. Exp. da	ite (if known)	#2 yes no apply			
3. Date of event Unk (ad Mon yyyy)	nown	4. Date of this repo		g 2001	#1 Unknown	#1		Event reappeared after reintroduction			
5. Describe event	-				9. NDC # - for product	#2	if known)	#1 yes no x doesn't apply			
-	fessional repo		v curaia	allu	s. NDC # - for product	problems only (#2 yes no doesn't			
sterilized Mirena inse menstrual i Mirena was menstrual c experienced	atient who was and presenting erted on 20 Juflow as advise inserted on toycle. Since 2 dabdominal patter doctor rec	ng chron ul 01, t ed by he the seco 21 Jul 0 ain, vom	ic anemic oreduce r hemato nd day o 1 the pariting and the control of the control	a had logist. f her tient d	10. Concomitant me none indicat	•	and therapy dates	s (exclude treatment of event)			
	ine). On 1988 r physician. S				G. All manuf	acturers					
ultrasonogi	ram was perfor	rmed. No	abnorma	lities	1. Contact office - na	ame/address & r	mfring site for dev	rices 2. Phone number			
in the genital area were seen and Mirena was well positioned. Due to the dehydration the patient was hospitalized on gastroenterologist diagnosed pancreatitis. The patient experienced some symptoms of pancreatitis already whilst she was travelling, before returning for Mirena insertion according to patients husband.				the The is. The velling,	Berlex Laboratories, Inc. 300 Fairfield Road Wayne, NJ 07470 USA (888) 237-55 3. Report source (check all that an included incl						
In the morn	ning of	the	patient	died.	4. Data received by manufacturer 5. similar to:						
Outcome: <	died				(dd Mon yyyy) 7 Aug 2001	25 user facility					
6. Relevant tests/l	laboratory data, includ	ling dates			6. If IND, protocol #		IND # PLA #	company representative			
None report	ted						рге-1938 🔲 уе				
					7. Type of report (check all that appl	y)	OTC productye	other:			
						riodic	3. Adverse event PANCREATIT	• •			
	history, including pre- nancy, smoking and alo				9. Mfr. report number 01/02166-CDS						
Before Mire surgically	t suffered from the sterilized, he sterilized, he ted some symptons.	the pat nad been	travell pancreat	ing and	E. Reporter 1. Name, address &	phone #					
			AUG 2.2		Country of o			4. Initial reporter also			
TOTAL A	Submission of a	a report doe	s not constitu	te an				sent report to FDA			

x yes no

<continued>

yes x no unk



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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 2

Continuing Page

B.5. Describe event or problem

Reporters comment: It was a coincidence that the patient presented with pancreatitis during the use of Mirena.

Suppl. (07 Aug 01): According to initial information cause of death pancreatitis. During the first day of hospitalization amylase and lipase values were measured which were normal. No further information available.

Case closed.

E.3. Occupation

Health Professional

DSS

AUG 2 2 2001



TA LINE	Ardnal 29.	TOTY KO	port						, S. N.				Page	1 of 2	
N. 33786								:	SEP 1	701)ĵ				
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	COUNTRY				EACTIO	NINFO	RMATIO	N .			لِـــــــــــــــــــــــــــــــــــــ				
1. PATIENT 1a. INITIALS	COUNTRY		2. DATE O		124	AGE UNITS	3. SEX	4-6. EX	PERIENCE	*******	8-12		ECK ALL PROPRIATE		
	Canada		Lary	Month	l l	20Yr	F	Day 11	Month SEP	Year 2001		APF AD\	PROPRIATE PERSEREAC	TO CTION	
7. DESCRIBE EXPER PULMONARY EMB		ıls:ons N	JOS; Blo	od press	ure dec	hassar		I	L	L	X	PATI	ENT DIED)	
Information was 20-year-old for and mental disethinyl estractions	as received emale patier sorder NEC	on 13-SE nt. The Therapy	P-2001, patient with A	from a l's concu.	healthcarrent hi	are pro	included	m:ld	obesit	У	X	PRO	LVED OR LONGED TIENT PITALIZAT		
hydrochloride) (clozapine), C (convulsions N	Topamax (Clonazepam a NOS) on	topirama und *Sere	ncomita te), Fl quil'. and was	nt theraponase (f) The pati	py inclu luticaso ient exp	nded Ef	fexor XR pionate) ed a sei	(venl , Cloz zure	afaxin aril	e		PERS SIGN DISA	LVED SISTENCE IFICANT BILITY OR PACITY		
her blood pres died on embolism (pulm	. Acc	ording to	Dressur	re decres	ecod)	Cubaaa						LIFE :	THREATE	NING	
												NONE	OF THE	ABOVE	
3. RELEVANT TESTSA None Provided		Ā										RECO	VERED		
	والعاد الإربار العرجان			SHEDEO	T DDU	/C\ 141=	OD445=:								
4. SUSPECT DRUG(S):	(INCLUDE ACTIVE	SUBSTANCE	SII				ORMATIC	JN .		<u>.</u>)			
1 ALESSE-28 (LEVONORGEST	REL/ETHIN	MYL ESTR	ADIOL/IN	ERT, TAI	BLET)							CTION ABAT		
5. DAILY DOSE(S)													_		
1 l Tablet lx	per 1 Day					16. ROUTS	(S) OF ADMI	NSTRATIC	N			YES	NO	X N/A	
. INDICATION(S) FOR	USE						-				21 DID DE 1000				
Contraception	on NOS										21. DID REACTION REAPPEAR AFTER REINTRODUCTION?				
THERAPY DATES (FI			T	19. THERAP	Y DURATION	v					TYES THO THE				
00-Mar-2001	/ 00-UNK-20	01		#1 Unkno	wn					}				<u> </u>	
lest ja			C	NCOMIT	ANT DR	UG(S)	AND HIS	TORY	10.70a						
CONCOMITANT DRUG FEXOR XR (VEN	33 WAD DATES OF	AUMINISTRA'	TION (Exclud	le those used to	o treal event)	(DA/MO/Y	R)							(conl'd)	
OPAMAX (TOPIRA LONASE (FLUTIC LCZARIL (CLOZA	MATE), Unkn ASONE PROPI	own ONATE), (ikilowii											
OTHER RELEVANT HI	STORY (e.g. diagno	stics, allergics,	pregnancy v	vith last month	of period, etc	:.)									
pesity; Mental		EC													
ONLY FOR RE	PORTS SUE	MITTED	BY MAN	UFACTU	RER	gida si 🏄 🛦	9.4	110.	(4) (A)	- 1					
WYETH LABS (RA) OTHER REFERENCE NUMBE															
201 King of Prussia Sixth Floor Radnor, PA 19087-5114 Healthcare Professional (Wyeth-Canada) - 2001-486										6					
Markenio No. #1 NDA 20-	-683 >		CONTROL			1									
DATE RECEIVED	24d REPORT S	<u> </u>	ng59924	4SEP2001	<u> </u>	4								2 0 201	
BY MANUFACTURER	STUDY		CONS						~C	5	SEP 2 0 200				
	LITERAT		REGUL AUTHO	ATORY DRITY				1	No.						
13-Sep-2001	X PROFES		LICEN	SE					0S	2001					
of this report	1		_			1		SEI	٠ ۵ ٢	-			1 9 200		
19-Sep-2001												DATES	SENT TO F	DAI	

THE WALL STREET WALL AVERST AROUNTED	Page 2 of 2
TIGNICIAT: Sarety KOETHEAVERST LABORATORISC	

Manufacturer Control Number: HQ5992414SEP2001

Box # 22 - CONCOMITANT DRUGS AND DATES OF ADMINISTRATION CLONAZEPAM (CLONAZEPAM), Unknown

(Continuation)

DSS SEP 21 2001

SEP 2 0 2001



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting Berlex Laboratories

Mit report II	USA-2002-001670
UF/Old. report 6	
···	FDA Use Only

yes no xunk

Relays international, Inc.

				-	rage roto	2	• •	L			FDA Use On
A. Patient infor		er en en en			C. Sus	pect medica	ition(s)		19 1		13.00
1. Patient Identifier 2. Age at time 3. Sex 4. Weight			Name (give labeled strength & mfr/labeler, if known)								
UNK	or	41 Years	X female	UNK bs	#1. Levlite 21 or 28(LEVONORG (continued)						
in confidence	Date of birth:	UNK	male	UNK Jos	#2.						
B. Adverse eve	nt or product prob	lem			2. Dose,	trequency & ro	oute used	3. Therag	py dates (if u	ınknown, give o	iuration)
1. X Adverse ever	nt and/or	Product problem	(e.g., defects/	malfunctions)	#1. UI	NK, UNK, U	NK	#1. UN	•		
2. Outcomes attribu	ited to adverse event		· · · · · · · · · · · · · · · · · · ·		# 2.			# 2.			
(check all that a	pply)	disability			1 !	osis for use (in	dication)		5. Event about	eted after use or dose reduce	
x death	UNK	congenita	anomaly		#1. UN #2.	NK			#1. ye		doesn't X apply
life-threatenin	ig (many)	required in	ntervention to p t impairment/d	prevent		(If known)	7. Exp. date (if kno	Wn)	#2 7º		doesn1
X hospitalization	n - Initial or prolonged	other:	campan menoo	аладе	#1. UN	vik	#1. UNK				apply .
3. Date		4. Date of			#2.		#2.		8. Event rea	sppeared after action	4
of event	UNK	this report	08/07	//2002	9. NDC 1	- for product p	problems only (if know	Mn)	#1. 🔲 ye	. 🗆 [2	k apply
5. Describe event o	r problem	1			{	. •		ļ	#2. 🗍 ye	• [] ~ [apply
embolus in the	right main pulm	onary artery (fa	ıtal)[Pulmo	nary			products and therap		clude treatm	ent of event)	
embolism]	ara theamharffus	•		_	TYLENO	L EXTRA-STI	RENGTH UNK to U FERROUS SULFAT	NK W Index	IDO		
focal nodular h	ava thrombus[Inf typerplasia in the	erior vena cava	l obstructio	on] mlosisl	continued	in additional ir	No section	A) UNK	JUNK		
uterine leiomy	oma-associated th	nver[rocal non	ine fibroid	piasiaj d	G. All M	anufacturer	g	anger sææ.			
antiphospholip	id antibody syndi	rome[Antiphos	pholipid sy	ndrome]							
abdominal pair	n[Abdominal pair	NOS]		•	Berlex	omos - name/a Laboratories	iddress (& mfring siti	for devices	6)	2. Phone num	
nausca[Nausea										+1 8882	375394
diarrhea[Diarrh	noea NOS] nal tenderness or	. + b			6 West	Belt				3. Report sou	ros
dysfibrinogene	mia[Acquired dy:	i ilie rigni(Abd sfibrinogensem	ominai tend	iernessj			806 UNITED ST	TATES	,	(check all that	apply)
,		onormogenaen:	uaj							[] foreign	
Case Description	on:									moy	
Literature:									1	▼ Iterature	
sontinued in a	14141 1 1	.•			4. Date rec	peived by	5.			Consumer	
continued in ac	lditional info sect	ion			manufa	cturer		NDA 20-	-860	Y health profession	
						26/2002	IND#			User fectit	
			_		6. If IND, p	rotocol#			İ	Company	y
6. Relevant tests/fab	oratory data, including	dates					PLA#			representa	12×e
#2 Activated	bin time 15.53 (1 partial thrombor	1.58 to 15.0s)	- (00- 4- 06		7. Type of		pre-193	3 🔲 yes		distributor	
#3 Internation	nal normalized r	ntio 1 21	s (235 to 30	^(\$)	I	If that apply)	OTC product	704		Other:	
#4 Hepatitis	panel pending					₩ 15-day	<u> </u>				
#5 Urinalysi:	s, Moderate Stre	eptococcus virio	dans		10-day	periodic periodic	8. Adverse	-	-	ena caval ob	
#6 Stool (co	ontinued)				T tritted	ollow-up #	Focal nodu	lar hyperp	Jasia, Uter	ine fibroids,	aruction,
	additional info se				9. Mfr. repo		continued i	n addition	al info sect	ion	
 Other relevant hist race preparer 	tory, including preedsti moking and alcohol us	ng medical condition	ıs (e.g. ellergie	6,	USA-20	02-001670					
#1 Historical	Condition, Anae	e, nepanc/renal dyst zmia NOS (cont	unction, etc.)								
#2 UNK Histo	orical Condition,	(continued)			E; Initial	reporter 📑		g argan			
#3 UNK Histo	orical Condition,	(continued)			1. Name &	address	ph	one #		UNK	
#4 UNK Othe	r, (continued)			l			}	_			
continued in a	idditional info se	ction				UN	IITED STATES		Δ	UG 0 9	2002
-											اعتمد
A 6	Submission of a re	port does not con:	stitute an adn	nission that	2 Haabt -	mfassional C	3 0				
	medical personnel, product caused or	, user lacility, distr contributed to the	ibutor, menu: event, ==	acturer, or	4. 11600101 0	rofessional 7	3. Occupation Professor / Fa	culty mer		itial reporter als ant report to FD	
		-		100	1		,				



X yes no

(continued)

lubmission of a report does not constitute n admission that medical personnel, user cility, distributor, manufacturar or product caused or contributed to the event.

U.S. DEPARTMENT	OF HEALTH AND HUMAN SERVICES Service - Food and Drug Administration
Mir report #	USA-2002-001670
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Page 2 of 5

Additional Information

B5. EVENT DESCRIPTION (cont.)

'Vena Cava Thrombus and Fatal Pulmonary Embolus'

A 41 y.o. African-American female with a history of dysfunctional bleeding attributed to a history of uterine leiomyomas and heterozygous for Arg506Gln mutation of the Factor V gene (Factor V Leiden mutation), on Levlite for an unspecified amount of time and indication experienced abdominal pain, fullness in her lower extremities, nausea, and diarrhea for about 7 days duration.

She was admitted to the hospital (date unspecified) and physical examination was remarkable for tachycardia (heart rate =120), diffuse abdominal tenderness on the right, a palpable liver mass 1 cm below the costal margin, and +1 lower extremity swelling bilaterally. On the second day of hospitalization she experienced a sudden onset of dyspnea with a respiratory rate greater than 40, which rapidly progressed to appnea. She was intubated and progressed to asystole. Attempts to resuscitate failed, and she died.

An autopsy revealed a thrombus in the inferior vena cava and an embolus in the right main pulmonary artery, which caused the patient's sudden apnea and death. Postmortem examination of routine sections from the lung revealed both recent and remote, organized thromboembolia. The presence of older organizing thrombi may indicate an ongoing, chronic process and suggest a hereditary or acquired biochemical mechanism of long-standing duration. Further analysis of the postmortem gross examination and laboratory results yielded 6 possible explanations as a cause for the patient's thrombosis that led to her sudden death: (1) focal nodular hyperplasia in the liver, (2) uterine leiomyoma-associated thrombosis; (3) the antiphospholipid antibody syndrome; (4) dysfibrinogenemia; (5) oral contraceptive use; and (6) the Factor V Leiden mutation.

Reporter's comment: Inferior vena cava stenosis and thrombosis have been implicated with oral contraceptive usage, which provides plausible explanation of the patient's thrombotic event. We believe that more than one of the identified risk factors contributed to the patient's hypercoaguable state. The possibility exists that the thrombus in the inferior vena cava may have been directly caused by the oral contraceptives with the remaining identified risk factors enhancing the hypercoaguable effect of the oral contraceptive.

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Page 3 of 5

# Date	Test / Assessment / Notes	Results	NT 1 494 2 12	
6	Stool	ACSUIS	Normal High / Low	
	No ova or parasites; Clostridium diffic	ila saastina		
7	AST (SGOT)	65 U/L	40.717	<u> </u>
	• •	03 0/1	42 U/L	
8			10 U/L	
0	ALT (SGPT)	138 U/L	33 U/L	
			7 U/L	<i>y</i>
9	Hemoglobin	8.0 g/dL	16.1 g/dL .	
		-	12.0 g/dL	
10	**		12.0 g (L)	
••	Hematocrit	28.5%	48.0%	
		·*	36.0%	
11	Thrombin time	100.0s	10.7s	
		100.00	8.9s	
12			0.75	
12	Antithrombin III	0.92 U/ml	1.29 U/ml	
			0.95 U/ml	
13	Anti-phospholipid: IgG	2 GPL		
	t washaren Pa	2 GPL	11 GPL	
			0 GPL	
14	Anti-phospholipid: IgM	5 MPL	13 MPL	
			0 MPL	
15	Anti-cardiolipid: IgG		V 1.42 D	
	And-cardioripid; 180	10 GPA		
			<25 GPA	
16	Anti-cardiolipid: IgM	4 MPA		
			<10 MPA	
17	Anti-cardiolipid: IgA			
	Autu-cardionpid: IgA	3 APA		
			<12 APA	
18	Anti-phosphatidyserine: IgG	20 GPS		
		-v -ci D	<10 Ope	
19			<10 GPS	
.,	Anti-phosphatidyserine: IgM	17 MPS		
			<26 MPS	
20	Anti-Beta2GPI: IgG	2 004		
		3 SGA	9 SGA	
0.1			0 SGA	
21	Anti-Beta2GPI: IgM	9 SMA	26 SMA	
			0 SMA	8 110 6
22	Anti Data 2001. 1		- world k	AUG 0 9
	Anti-Beta2GPI: IgA	. 7 SA	19 SA	
			0 SA	
23	LAC screening (DW ratio)	C No Clot		 .

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07-Aus-2002 14:00:07

bmission of a report does not constitute admission that medical personnel, user lity, distributor, manufacturer or product caused or contributed to the event. Berlex Laboratories

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USA-2002-001670

(continued)

Page 4 of 5

FDA Use Only 24 Hexagonal phospholipid No Clot 8s 25 Lp(a) 4.0 mg/dL 36.3 mg/dL 8.9 mg/dL 26 Reptilase time 12.2s 21.88 13.6s 27 Fibrinogen 439 mg/dL 450 mg/dL 180 mg/dL 28 HPIA 0.1 0.5 0.0 29 TAT 74.9 2.5 1.3 30 D-DIMQ 7.0 0.3 0.0 31 Factor V Leiden Arg506Gln - Heterozy Arg506 - Hamazygous 32 Factor II Leiden G20210 - Homozygous G20210 - Hamazygous 33 Methylenetetrahydrofolate reductase C677 - Homozygous C677 - Homozygous **B7. OTHER RELEVANT HISTORY**

#	Start/Stop Date	Condition Type / Condition	Notes
I 	UNK Ongoing	Historical Condition Anaemia NOS	chronic anemia
2	UNK	Historical Condition Uterine fibroids	history of uterine leiomyomas
3	UNK	Historical Condition Dysfunctional uterine bleeding	attributed to a history of uterine leiomyomas
4	UNK	Other one full term pregnancy at 31 years of age	
5	UNK	Family History Diabetes mellitus NOS	
6	UNK	Family History Hypertension NOS	
7	UNK	Family History Coronary artery disease NOS	
8	UNK Ongoing	Factor V deficiency	patient is heterozygous for Arg506Gln mutation of the Factor V gene (Factor V Leiden mutation)

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Mir report #	h Service - Food and Drug Administration
UF/Dint. Happet #	USA-2002-001670
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Page 5 of 5

C1. Name (cont.)

Suspect Medication #1: Levlite 21 or 28(LEVONORGESTREL, ETHINYLESTRADIOL) Coated tablet

C10. CONCOMITANT MEDICAL PRODUCTS

COMPAZINE (PROCHLORPERAZINE EDISYLATE) UNK to UNK TETRACYCLINE (TETRACYCLINE) UNK to UNK

G3. Report source literature description

Journal: Laboratory Medicine

Title: Vena cava thrombus and fatal pulmonary embolus

Volume: 33 Year: 2002 Pages: 553-555

G8. ADVERSE EVENT TERMS (cont.)

Antiphospholipid syndrome, Abdominal pain NOS, Peripheral swelling, Nausea, Diarrhoea NOS, Tachycardia NOS, Abdominal tenderness, Acquired dysfibrinogenaemia

AUG 0 9 2002

	ii ii ii nu mur						Page 1 of 2
*3964208-1-00-01		·		<u></u>			
INI EKIMITOWAL			г		 		
ADVERSE EXPERIENCE RE	PORT						RECEIVED
	OF BIRTH	ON INFORMATIO	ĎÑZ.	Milion.	1.04		Allo Carlo
Denmark		UNITS	4-6. E Day	XPERIE!		Year	8-12/1U THECK OLIZUUZ APPROPRIATE TO
7. DESCRIBE EXPERIENCE(S).		30Yr F	14	J	AN	2002	CDR/CDER
CEREBRAL INFARCTION; Carotid artery the	combosis; Convul	sions NOS					X PATIENT DIED
							☐ INVOLVED OR
Information was received from a regular concerning a 30-year-old female patient degression, and she was a base of the concerning and she was a base of the concerning and she was a base of the concerning and she was a base of the concerning and she was a base of the concerning and she was a base of the concerning and she was a base of the concerning and she was a base of the concerning and she was a she	· The mandames -				uded		PROLONGED
depression, and she was a heavy cigaret disposition for cardiovascular diseases (desographical deports)	te amoker Pemi	lu himeann is		_			INPATIENT HOSPITALIZATION
1 (2000 general/echinyl estragion) for 4 m	Conthe in 2000 "	Therapy with m			ilon 0.05	nca	INVOLVED
levonorgestrel/0.03mg ethinyl estradiol estradiol/0.125mg levonorgestrel/0.03mg	/0.075mm levono:	raactual/a aam		7		-	PERSISTENCE OF SIGNIFICANT
Dieces equivalent, for bleeding dist	urbances began c	N 28-CPR-2001			on on		DISABILITY OR INCAPACITY
Cipramil (citalogram hydrobromide). On	let daily. Conco	omitant therap	y incl	uded			LIFE THREATENING
1 revealed nothing abnormal. On 14-JAN-20	02, the parient	avmarianced a	7		ided		
	NOS) which progr ontd)	essed to comp	lete r	ight	medi	a	NONE OF THE ABOVE
13. RELEVANT TESTS/LABORATORY DATA See following page.							RECOVERED
	* SUSPECT DRUG	C/S) INFORMAT	iovis:	W. Com	laye ()	# A A 4 2	
14. SUSPECT DRUG(S) (INCLUDE ACTIVE SUBSTANCE(S)) #1 TRIQUILAR (LEVONORGESTREL/ETHINYL ES		O O CHILLIAN	IOINEG	08-d(2) 2 1. 3	13.05.19	N-SERV	20. DID REACTION ABATE
CONTROL (ADVONONCEDIRABLY BIRINIL ES	radiol, Tablet)						AFTER STOPPING DRUG?
15. DAILY DOSE(S)		16. ROUTE(S) OF ADI	MINSTRA	ПОМ			YES NO IN N/A
#1 1 Tablet 1x per 1 Day		#1 Oral					
17. INDICATION(S) FOR USE #1 Menometrorrhagia				-			21, DID REACTION REAPPEAR
18. THERAPY DATES (FROMTO)							AFTER REINTRODUCTION?
#1 28-Sep-2001 / 27-Dec-2001	19. THERAPY DURATION #1 91 Day	ON					YES NO X N/A
22 CONCONTANT DELICO AND AND AND AND AND AND AND AND AND AND	-						
22. CONCOMINATION CEXTES OF ADMINISTRATION (Exch	ide those used to treat eveni	t) (DA/MO/YR)	STORY	6 P 4 -		MS.	型解於物質等以為學
CIPRAMIL (CITALOPRAM HYDROBROMIDE), unkn	own, 01-May-2003	L / UNK					
22 OTHER DELIGIOUS							
23. OTHER RELEVANT HISTORY (a.g. diagnostics, altergics, pregnancy CONCURRENT CONDITIONS:	with last month of period, el	ic.)					
Depression NEC; Cigarette smoker							
IV. ONLY FOR REPORTS SUBMITTED BY MA	VIII OTUDYDET		ela Carano	Sin a was	ny vara	, www.compto	
24a. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code)	YUPAG TURER		Days		**************************************	**************************************	
WYETH LABS (RA) 201 King of Prussia		OTHER REFE Regulatory				- SA	G-2002-001624
Sixth Floor Radnor, PA 19087-5114							i
Port Marketine No.							76 S
24b. MFR CONTROL NO. #1 NUA 19-192 PQ3635207AUG2002							AUG 1 6 2002
4c. DATE RECEIVED 24d. REPORT SOURCE BY STUDY CON	SUMER						- 2002
MANUFACTURER LITERATURE X REG	ULATORY						
HEALTH AUT	HORITY						
PROFESSIONAL LICE	N 2E	1					

Date of this report

14-Aug-2002

25a. REPORT TYPE

FOLLOWUP

X INITIAL

AUG 1 4 2002 AUG 1 50456ENT TO FDA

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	*3964208-1-00-02+	 		
L	ADVERSE EXPERIENCE REPORT			

Manufacturer Control Number:

HQ3635207AUG2002

Box # 7 - DESCRIBE EXPERIENCE(S)

(Continuation)

infarction (cerebral infarction) with oedema and "incarceration" and a thrombotic mass in the right carotis interna (carotid artery thrombosis). The patient died on as a result of the adverse event. Autopsy results showed a fixed big thrombotic mass in the right carotis interna, mild arteriosclerotic wall changes, a clot mass in the left carotis, and other vessels of the brain were

Box # 13 - RELEVANT TESTS/LABORATORY DATA

(Continuation)

Test Name

<u>Date</u> Blood cholesterol Result

Normal Range

normal

DSS AUG 1 6 2002



THE PDA MEDICAL PRODUCTS REPORTING PROGRAM

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Page 1 of 2

Mr report a	FOA Facsimile Approval: 30-JUN-199
UP/Olet report #	SAG-2002-007615
	FDA Use One

A. Patient inform						Cucanal					FDAU
1. Patient Identifier	2. Age at time		3. Sex	4. Weight		Suspect medi					
	of event	42 Years	X female	UNK Da		· Mirena// E3/	ed strength & min ONORGESTRI	lebeler, if known)		
in confidence	Date of birth:	UNK	male .	UNK kg			ONORGESTRI	CL) (continued	.)		
B. Adverse even	t or product prot	olem			I	Dose, frequency &	route used	2 75			
1. X Adverse event								,	y dates (If un		•
2. Outcomes attribut		Product problem	(e.g., defects/	malfunctions)	#2	20 μg. (contin	lued)		4/2000 to 0	7/18/200	12
(check all that ap	or in egyelse eveut	disability				Diagnosis for use	(la afficient)	#2			
X death		٠ اسا				Menorrhagia /			5. Event abate stopped or	dose reck	se uced
☐ life-threatening	- Sandrie	congenital			# 2.	TVZCHOVY122P12 /	contraception	,	11. 🔲 yee	☐ no	X apply
		permanen	ntervention to p t impairment/d	xovent amage	6. L	ot # (if known)	7. Exp. date (W known)	2 7 ves		doesn't
	initial or prolonged	other:		-	1 1.	UNK	#1. UNK	L		<u></u>	L apply
3. Date of event		4. Date of			- 12		# 2,		3. Event reappresent reintroduction	peared afte	er
	07/18/2002	this report	02/19/	2003	9. N	DC # - for product	t problems only (if	known)	1. yes		X apply
5. Describe event or p					-				2 7	T] on [Commit
fatal pulmonary	embolism[Pulm	onary embolism	1]		10. C	oncomitant medic	al products and th	nerapy dates (ex	Chirle treatme		apply
Case Description	:				NI			•••		IN OI MARI	U
A health profession	onal reported: A	female patient	had Miren	a incerted in							
THE STREET, OF COL	auaccouon in i	YYY. Nhe died 👊	rddanly E.			l Manufacture	76				
unknown. Pulmo	nary embolism	or cardiovascula	ir accident?	?							
Suppl. (13 Feb 20	03): A 42-year-	-old female paris	ent not ove	erusiahe	Ber	ex Laboratorie	/address (& miring s	g site for devices) 2.	Phone nu	mber
out a ticary SHIOK	ÇI. Nad levonori	Pésirel (Mirana)		the 24 Jul					f	+1 8882	2375394
2000, in the indic	ation perimenor	pausal menorrha	gia.			est Belt			3.	Report so	urce
She died on the	Ans	autopsy was per		1	Way	me, NJ 07470-6	5806 UNITED	STATES	tan	eck all tha	at apply)
ecorded cause of	death was pulm	onary embolism	n.	the					\1=	loreign	ZAF
•			-		11				N=] study	
					1 2 500				1=	Rereture	T
					man	received by ufacturer	5. (A)NDA	* NDA 21-2			1
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. Relevant tests/labora	toga detail to the				e. If IN	, protocol #	IND #			veer facilit	4
NI	iory data, including	Clates					PLA			represents	100
						of report call that apply)	pre-1s	□ /		distributor	
					5-0		OTC.			other;	
						ay periodic	8. Advers	e event term(s)		\longrightarrow	
						Y follow-up #		ry embolism			1
						port number					1
Other relevant history,	including preexistin	g medical conditions	(e.g. allergier			2002-007615					
#1 UNK, Concur	ent Condition	. hepatic/renal dysiu Smoker (heavy	nction, etc.)		l			•			,
#2 UNK, Concur	ent Condition	(no overweight)	Silloker)		E. Initi:	al reporter					
			-	ĺ		& address	P	hone # Withhe	ld		
					Nam	e and address w	vithheld.			1	
									•	۲.	
Sut	omission of a reco	rt does not constitu		_ 							
Mark History	arcar personner, us	er tactiffy dietribut	or manuface	ion that urer, or	2. Health	professional?	3. Occupation		4.7		
proc	uuca caused of cor	ntributed to the eve	int	• •				Professional	1.		

X yes no

FEB 2 0 2003



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U.S. DEPARTMEN	IT OF HEALTH AND HUMAN SERVICE Service - Food and Drug Administrator
Mi report 8	
UF/OleL report #	SAG-2002-007615

Page 2 of 2

Additional Information

C1. Name (cont.)

Suspect Medication #1: Mirena(LEVONORGESTREL) IUS

C2. Dose, frequency & route used (cont.)

Suspect Medication #1: 20 μg, cont, Intra-uterine

FEB 2 0 2003

1100	Individual Sa	afety Report	 11 881 1781 1881	-	*		· · · ·					Page	1 of 2	
						-			RECF	IVED		·		
	71425-1-00-0	_					<u> </u>			_				
ADVE	RSE EXPE							1 1	MAR 0	20 p3				
1. PATIENT	1a. COUNTRY	I 2 DATI	E OF BIRTH	REAC	MONINFO				DBIC	משתי	3 () or	- 15 S		
INITIALS	United Kir	Day		Year	UNITS	3. SEX	4-6. EX	PERIENCE	ONSEY	8-12		K ALL OPRIATE TO	0	
7 DESCRIBE E	EXPERIENCE(S)	igdom /		l	31Yr	F	00	JAN	2003			RSE REACT		
MYOCARDIA	L INFARCTION (LL	T:MYOCARDIAL	NFARCTI	ON): Th	rombosi e /	IIT. The		_,		XF	ATIE	NT DIED		
	erosis(LLT:Athe west Level Term	+ COCTETORIE)	_	.,,	. 01100818	TILL : TILL	ompos1	9);		1 —		VED OR		
Informatio	on has been rec	eived from a r	eaul ata	was made be							ROLC VPATII	ONGED ENT		
1 22 1007-01	ro remere bacle	nt who was a c	igarett.	a amokas	e Mha m					I		TALIZATI	ON	
levonorges	strel/0.03mg et	oscierosis and hinvl astradic	l obesit;	y Thei	capy with	Microgy	mon (C).15mg				STENCE	OF	
- Journa acche	TOU DEGAU OU 6.	-JAN-2003 and	ended or	n 13TAN	1-2002	The day			1			ICANT LITY OR		
Protest CX	ly. It is unknown to the control of	ocardial intar	ction (r	mvocardi	7 1 1 1 1 1 1 1 1				he	IV.	ICAPA	ACITY		
I CITT OUR COLD	(thrombosis), s hospitalized.	and atherosch	erneie	/arhawa-		· · · -					FE TH	HREATEN	NING	
	21000 pressure	(C	Hg, body cont'd)	y were p	ndex of	with th 28. The	e foll patie	owing nt die	i	N	ONE (OF THE A	ABOVE	
13. RELEVANT TE	STS/LABORATORY DATA	A		,						☐ RI	ECOV	'ERED		
11.		ay a same	2112	ECT DE	UG(S) INF	ODMAT								
14. SUSPECT DRU	UG(S) (INCLUDE ACTIVE	SUBSTANCE(S))				ORMAII	UN			20 DID	REACT	TION ABATE		
1	NON (LEVONORGES	TREL/ETHINYL F	ESTRADIO	L, TABL	ET)					AFT	ER STC	PPING DR	UG?	
15. DAILY DOSE(S	5)				Les pour	5(0) 05 15:				□ YE	:0	□ №	₩	
#1 l tablet	daily				#1 Ora:	E(S) OF ADM	INSTRATIO	М		LJ ''	.0		X) N/A	
17. INDICATION(S										21. DID	REACT	ION REAPP	EAR	
18. THERAPY DAT	traception(LLT	:Oral contrace								AFTI	ER REIN	VTRODUCT	ION?	
	003 / 13-Jan-2	003	19. THE	RAPY DURA	TION					YE	s	NO	X N/A	
111.			<u> </u>	•										
	DRUGS AND DATES OF	ADMINISTRATION (Exc	LUNCO!	WITANT I	DRUG(S)	AND HIS	TORY				is,			
Unknown					and (Elemen	,								
23 OTHER RELEVA	ANT HIETOPH (-									
CONCORRENT														
Obesity (LLT	:Obesity); Smok	er (LLT: Cigare	te smok	er); At	heroscler	osis(LL	T:Athe	roscler	cosis)		25	SS		
										MAR	0 6	2003		
244. NAME AND ADD	R REPORTS SUE	MITTED BY MA	NUFAC	TURER		ulanji sas	Market P	ar Tuas			2.5			
WYETH LABS	(RA)	REM (Iniciade Zip Code)				ER REFER								
201 King of Sixth Floor					Aff:	ulatory iliate F	Author ef Num	rity (H 1 -	P)					
Radnor, PA	19087-5114													
	18-668	24b. MFR CONTR HQWYE	OL NO. 651625FE	B03	\exists									
24c. DATE RECEIVED BY	24d. REPORT S		NSUMER							MARN	4 7	YNN:3		
MANUFACTURE		TURE IX REC	SULATOR	Y						MAR 0 4 2003 DATESENT TO FDA				
24 - Feb - 200	HEALTH	AUT	HORITY ENSE							J.,		·		
Date of this report	PROFES	SSIONAL LICE								las -			-	
04-Mar-200	3	X INITIAL		LLOWUP						MAR O	5 2	003		
		·									_			

Individual Safety Report				-	 	-	,	Page		? of 2	_
AUVERSE EXPERIENCE REP	ORT										
Manufacturer Control Number: HQWYE651625FEB0	3								 		_
Box # 7 - DESCRIBE EXPERIENCE(S) on The cause of death was	(Continuation identified as the m		infa	rction.							_
Box # 13 - RELEVANT TESTS/LABORATORY DAT	TA (Continua	ition)					·				_
Test Name Date Result		<u>N</u>	ormal	Range	•						
Blood pressure(LLT:Blood pressure) 130/71 mm Hg	·	_							;		
Body mass index(LLT:Body mass index)											

DSS MAR 0 6 2003

WYETH-AYERST LABORATORIES		
Individual Sasatu Parant	DECEIVED	
10 -	RECEIVED	
	NOV 0 3 2003	
REACTION	NEORMATION	
1. PATIENT 1a. COUNTRY 2. DATE OF BIRTH 2a. AGE	3 SEX LA LAG EXPERIENCE ONSET	8-12. CHECK ALL APPROPRIATE
Japan Day Month Year UNIT		TO ADVERSE REACTION
7. DESCRIBE EXPERIENCE(S)	30 765 2003	X PATIENT DIED
MYOCARDIAL INFARCTION(LLT:MYOCARDIAL INFARCTION); Sinus a		X PATIENT DIED
arrhythmia); Electrocardiogram T wave abnormal(LLT:Electrabnormal)	ocardiogram T wave	X INVOLVED OR PROLONGED
[LLT = Lowest Level Term]		INPATIENT
Follow-up information was received from a gynecolgist reg	arding patient details	HOSPITALIZATION
product details, medical history, hospital course, lab re	sults, treatment, cause of	INVOLVED PERSISTENCE OF
death and the addition of 2 serious adverse events. Infor		SIGNIFICANT DISABILITY OR
healthcare professional regarding a 43-year-old Asian fem Tridiol (0.05mg levonorgestrel/0.03mg ethinyl estradiol/0		INCAPACITY
levonorgestrel/0.04mg ethinyl estradiol/0.125mg levonorge	strel/0.03mg ethinyl	LIFE THREATENING
estradiol tablet) therapy and experienced a myocardial in MEDICAL HISTORY:	rarction.	_
The patient's concurrent illness includes cystitis.		NONE OF THE ABOVE
(cont'd) 13. RELEVANT TESTS/LABORATORY DATA		RECOVERED
See following page.		
II. SUSPECT DRUG	S) INFORMATION	
14. SUSPECT DRUG(S) (INCLUDE ACTIVE SUBSTANCE(S)) #1 TRIDIOL-28 (LEVONORGESTREL/ETHINYL ESTRADIOL/INERT, TA	BLET)	20. DID REACTION ABATE AFTER STOPPING DRUG?
(cont'd)		TYES TNO IN N/A
(1)	6. ROUTE(S) OF ADMINSTRATION 1 Oral	
#1 1 tablet daily 17. INDICATION(S) FOR USE		21. DID REACTION REAPPEAR
#1 Contraception NOS(LLT:Contraception)		AFTER REINTRODUCTION?
18. THERAPY DATES (FROMTO) 19. THERAPY DURATION		YES NO X NA
#1 22-Sep-1999 / 00-Mar-2002	•	
III. CONCOMITANT DRI	G(S) AND HISTORY	
22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)	DAMOYR)	
Unknown		,
20 OTHER DELIVERY HETODY I disposition allowing propagative has mostly of paried at		
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc. CONCURRENT CONDITIONS:)	
Occupational environmental problem NOS(LLT:Occupational e	nvironmental problem NOS)	
PAST CONDITIONS:		
Cystitis NOS(LLT:Cystitis)	and the second s	
IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER 24a. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code)		
WYETH LABS (RA)	OTHER REFERENCE NUMBERS: Affiliate Ref Num - TRs-	
P.O. Box 7667 Philadelphia, PA 19101-7667		Doo
		DSS
Local Marketing No. 24b. MFR CONTROL NO. HQWYE582109SEP03	NOV 0.4 2003	
#1 NDX 19-190 HQWYE582109SEP03 24c. DATE RECEIVED 24d. REPORT SOURCE	OCT 3 1 2000	•
BY STUDY CONSUMER	DATE SENT TO FO	, , , , , , , , , , , , , , , , , , ,
MANUFACTURE REGULATORY AUTHORITY		
24-Oct-2003 HEALTH LICENSE		101 0 0 2002
Date of this report 25a. REPORT TYPE	†	NOV 0 3 2003
31-Oct-2003 X INITIAL FOLLOWUP		

						√							
Individual Safety Report									·	Pag	е	2 of	2
	-												
AL 4226802-22-00-02 AL 4226802-2-00-02 AL 4226802-2-00-02			T			T	T	T				T	\exists
Manufacturer Control Number: HQWYE582109SEP03					<u></u>								
PRODUCT DETAILS: Indication for Tridiol-28 was contraception. The to Mar-2002 and then was 1 tablet daily (oral) fidiscontinued. CONCOMITANT THERAPY: Concomitant medications were not reported. EVENT DETAILS: On the patient had an electrocardiog and T wave abnormal (electrocardiogram T wave abrincluded a cardiotonic drug. The patient was enco however, she refused. On 02-Sep-2003, the patient ambulance brought the patient back to snother hos (myocardial infarction), and subsequently died on consists of high temperatures and she sweats a loput a high stress load on her heart. The physicia and Tridiol was possibly related. TEST RESULTS: Electrocardiogram (results: normal) was done in and T wave abnormal) was done on The cause of death was reported as myocardial infarctuals.	gram which showed cormal). The pate ouraged to transfer condition we apital. The pate of the pate of the condition of the pate of the condition of the conditio	ed sien sfer orse ient of s	inus t wa to ned expo	ari s ho anot with erie the alai	rhythrospita ther hincrenced paties pati	mia (alize nospi a my lent's	sinud artal ng cocares wo	wa us on che cdi ork cen	arrhyttreatm st pai al inf envir	hmia nent n. A arct comen	tly) ion toos	, ,	
Box # 13 - RELEVANT TESTS/LABORATORY DATA Test Name	(Continuation)									· · · · · · · · · · · · · · · · · · ·			
Date Result		Nor	mal	Rang	ge								
Electrocardiogram(LLT:Electrocardiogram) normal sinus arrhythmia and T wave ab	normal												
SUSPECT DRUG(S) INFORMATION (Continuat 14. SUSPECT DRUG(S)	ion)		<u> </u>										
# 1.2 TRIDIOL-28 (LEVONORGESTREL/ETHINYL ESTRADIOL	/INERT, TABLET)	ı											
15. DAILY DOSE(S)													

1.2 1 tablet daily

16. ROUTE OF ADMINISTRATION

1.2 Oral

18. THERAPY DATES

1.2 24-Apr-2002 / 30-Aug-2003

19. THERAPY DURATION

1.2 494 Day

DSS

NOV 0 4 2003



A. Patient information

1. X Adverse event and/or

(check all that apply)

life-threatening

2. Outcomes attributed to adverse event

X hospitalization - initial or prolonged

11/17/2003

1. Patient identifier

in confidence

X death

3. Date

of event



40 Years

2. Age at time

of event

of birth: B. Adverse event or product problem For use by user-facilities, ibutors and manufacturers for MANDATORY reporting Berlex La

Pag

4. Weight

X female male

Product problem (e.g., defects/malfunctions)

required intervention to prevent

permanent impairment/damage Medically Significant

12/01/2003

disability

4. Date of

this report

congenital anomaly

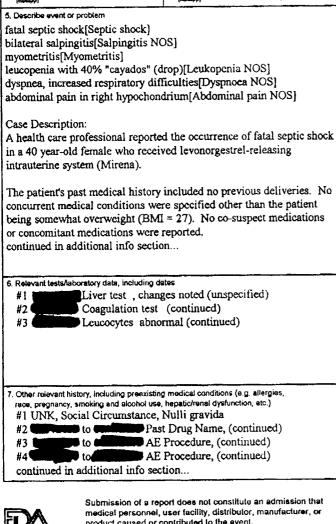
143.3 lbs

65.0 kgs

FDA Facsimile	Approv	rat: 30-	JUN-1	999
				_

CO-SHR-03-017632

boratories		LIF/Dist. nep	oort #	
e 1 of 2				FDA Use Only
C. Suspect medication(s)			
Name (give labeled streng)		if known)		
#1. Mirena(LEVONORO	ESTREL) (0	ontinued))	
# 2.				
2. Dose, frequency & route us	bed			f unknown, give duration)
#1. 20 (continued)			13/2003	to 11/18/2003
#2.		# 2.		
4. Diagnosis for use (indication	on)			abated after use
#1. Menorrhagia			жорр. # 1. П	yes no X apply
#2.	exp. date (if known	4m\		E Contain
6. Lot # (if known) 7. 5 # 1. UNK #1		wiii)	#2. 📙	Aee
				reappeared after
#2. #2 9. NDC # - for product proble		vn)		yes no X apply
, ,			#2.	yes no apply
10. Concomitant medical prod	lunte and there	v dates /		
10. Concomitant medical prod NONE UNK to UNK	иось анд шагар	y udles (6)	~ 	actions of again
•				
G. All Manufacturers				
Contact office - name/addre Berlex Laboratories Harri Helajarvi, M.D. Director, Medical Asses	, -	a for device	as)	2. Phone number +1 8882375394
harri.helajarvi@berlex.c Fax: +1 973 305 5315	om			(check all that apply)
Global Med. Safety Sur				✓ toreign COL
Wayne, NJ 07470-6806	UNITED S	TATES		study
				[Sterature
4. Date received by	5.			consumer
manufacturer	(A)NDA#	NDA 2	1-225	professional
11/19/2003	IND#			user facility
6. If IND, protocol#	PLA#			company representative
7. Type of report	pre-190	38 🔲 уе	2	distributor
(check all that apply)	отс	. ″∏ye	ıs.	other:
[5-dey [15-dey	product			
10-day periodic	8. Adverse Sentic sho			OS, Myometritis,
Y initial 1 tollow-up#	Leukoper		_	ea NOS, Abdominal/pain
9. Mfr. report number	NOS			/
CO-SHR-03-017632	}			1
E. Initial reporter	i			
1, Name & address		phone #		UNK /
		UNK		
				<u> </u>
2. Health professional?	3. Occupation	D C		Initial reporter also sent report to FDA
x yes no	Health Car	e Profess	ional	yes no x unk





product caused or contributed to the event.

Individual Safety Report

Submission of a report does not constitute an admission that medical personnel, user ibutor, manufacturer or product or contributed to the event.

Mr report #	GO OUD 02 015/20
	CO-SHR-03-017632
UF/Diet, report #	
	FDA Use Onto

Page 2 of 2

Additional Information

B5. EVENT DESCRIPTION (cont.)

On 13 Nov 2003, Mirena was inserted for menorrhagia.

Approximately 4 days following insertion, the patient was hospitalized for abdominal pain in the right hypochrondrium, with dyspnea. Abdominal CT and ultrasound ruled out biliary disease and any abdominal abscess. Twelve hours following admission, the patient experienced changes in her liver and coagulation tests (results not specified) and leucopenia with 40% "cayados" (drop) with increased respiratory difficulty. Repeat CT and abdominal ultrasound were unremarkable. A laparotomy was performed with the following finding: myometritis and bilateral salpingitis; no uterine or intestinal perforation was noted. Treatment included a hysterectomy, left salpingo-oophorectomy and right salpingectomy. Approximately six hours following procedure, the patient presented with hemodynamic impairment, septic shock and died on 18 Nov 2003.

An autopsy was performed with the recorded cause of death noted as septic shock.

Reporter's Comment:

The reporting health care professional considered that the event was possibily related to treatment with Mirena.

B6. LABORATORY DATA

130. 13	ABORATORI DATA	`			
#	Date	Test / Assessment / Notes	Results	Normal High / Low	
2		Coagulation test			
		changes noted (unspecified)			
3		Leucocytes			
		abnormal leucopenia with 40% of "cayados"			

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
2	77	Past Drug Name T CU 380A	No similar reaction observed.
3		AE Procedure Computerised tomogram	Ruled out biliary disease or abdominal abscess; upon repeat no abnormal findings noted.
4	_	AE Procedure Ultrasound abdomen	Ruled out biliary disease or abdominal abscess; upon repeat no abnormal findings noted.
5		AE Procedure Laparotomy	Myometritis and bilateral salpingitis were noted. No uterine or intestinal perforation was seen.
6		AE Procedure Hysterectomy NOS	
7		AE Procedure Salpingo-oophorectomy unilateral	left
8	7	AE Procedure Salpingectomy	right
9	UNK	Concurrent Condition Overweight	Body Mass Index = 27 (65 kg, 157 cm)

C1. Name (cont.)

Suspect Medication #1: Mirena(LEVONORGESTREL) IUS

C2. Dose, frequency & route used (cont.)

Suspect Medication #1: 20 µg/day, cont, Intra-uterine



MED**W**ATCH

THE FDA MEDICAL PRODUCTS REPORTING PROCRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting Berlex Laboratories

ifr report #	
	CH-2004-02521
F/Dist report #	

Relays international, Inc. FDA Fechinile Approvet 30-JUN-1999

Page 1 of 2

				1.486	1 01 2				· · · · · · · · · · · · · · · · · · ·	FDA Use Only
A. Patient Informa	ition				C. Suspe	ct medicatio	on(s)			
1. Patient identifier	2. Age at time	0.4	3. Sex	4. Weight	1. Name	(give labeled r	strength & mft/lebeler,	if known)		
	or —	34 years		220.5 tos	#1. Mire	ana(LEVON	ORGESTREL) (a	ontinued)		
t	Date of birth:		☐ male	100.0 kgs	#2.					
In confidence					2. Dose,	frequency & ro	oute used	.3. Therapy da	stes (If unkn	nown, give duration)
B. Adverse event		Product problem	(a.n. defects)	mathunction)	#1. 20 ((continued)		#1. 11/-/20	 003. durat	tion UNK
2. Oulcomes attribut			(8.0., 08.802	mainiciony	#2.			#2.	,	
(check all that ap		_			4. Dlagno	osis for use (In	dication)	·	Event abate	ed after use
·		disability				traception				dose reduced
death		congenita	l anomaly	·	#2.			#1.	· 🔲 yes [☐ no 図 doesn't apply
☐ life-threatening	3	mequired in permaner	ntervention to	prevent damage	6. Lot# (#	•	7. Exp. data (if know	wn) #2	yes [no doesn't
hospitalization	- initial or prolonged	d Other:			#1. UNI	`	#1. UNK #2.		Event reapp	
3. Oute		4. Date of			#2.	- for product o	problems only (if knows		reintroduction	That to the second seco
of event (04/02/2004	this report	06/16/	2004	8.100#	· IO poole p	noodenis only (it knows			on doesn't
5. Describe event or					 			#2		L no L apply
		[] (Related symptoms if				omitant medica	al products and therap	by dates (exclud	ie treatment	of event)
glioblastoma (s	severe headac	he, brain edema	, death)[G	lioblastoma]	NI					
Casa Dasarinti	ioni									
Case Descripti		on 11 May 2004	the coor	rongo of						
	•	ale who was pre		1		nufacturers				
IUD (Mirena).	Occurring 1611	iaic wilo was pie	SC IDEC IC	vonoi gasti ai	ı		/address (& mfring site	o for devices)		. Phone number 1 8882375394
ioo (miiona).				1	Berlex Harri k	cınc. Helajarvi, M.	n		- 1	1 000237 3334
Concurrent me	edical condition	ns and concomite	int medica	tions were			Assessment			
not reported.						elajarvi@be			3.	Report source
·					Fax: +	1 973 305 5	5315		No.	heck all that apply)
The patient ha	d Mirena Inser	ted for contracep	tion in				ity Surveillance, 6 0-8806 UNITED 5		/ 2	X toreign CHE
D-4 5	-1				'''	3,110 07 47 0		31A1CQ	([[study
ľ	•	d about headach		I] IKerature
	•	atient has been l diagnosed to be "	•							Consumer
continued in a		•	payoriolog	, icai .	4. Data re- manufa	celved by cturer	5. (A)NDA#	NDA 21-22	s 5	heelth protessional
				1	,,,,,,,	6/14/2004				_ /
				į	6. If IND,		IND#		L	user facility /
6. Relevant tests/leb	nonical state inches	Inc. detee			''		PLA#		[company representative
NI	AND AND AND AND AND AND AND AND AND AND	ing cases			7. Type of		pre-1938	y==		distributor /
					-	all that apply) y [⊠] 15-day	OTC	yes		oher: /
						r <u>policodi</u> ny ∏ periodi	8 Adver	e event term(s)		
				ŀ		, ,	Glioblas	toma		
						⊠ follow-	Up# I			/
		·			1	ort number				
race, pregnancy,	smoking and alcoho	disting medical condition of use, hepatic/renal dy	sfunction, etc.)	CH-2002	4-025211				
		Computerised to			E. Initial	reporter				
(C1; suspect	ed thalamus in	farction and thro	mbosis ba	isiliaris.)	1, Name &	address	to	none# Withh	eld /	J
					Name	and addres	<u>Ľ.</u>		/	
		D23		ļ	1				/	
				ŀ				1	//	
		JUN 2 1 20	04					1	<i>V</i>	
		report does not const	itute an admi		2 Health (professional?	3. Occupation		4. Inti-	al reporter also
		el, user facility, distrib outed to the event.	utor, manufa	cturer, or product			physician			t report to FDA
1500A - Fecularita					⊠ yes	no no	1		,	yes 🔲 no 🔯 unk



Medication and Device Experience Report (continued) submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEDARTMENT O	# 105 A1 T1	
U.S. DEPARTMENT O	T REALIN AND	HUMAN SERVICES
Public Health So	ervice - Food en	d Drug Administration

Beriex Laboratories

FDA Use Only

Mt report # CH-2004-025211

UR/Dist report #

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Additional Information

B5. EVENT DESCRIPTION (cont.)

After Easter, the treating physician has seen an obiturary notice in the newspaper and is now contacting the physicians in the hospital to find out more about the cause of death of this patient.

Further information has been requested.

Suppl. (14 Jun 2004): Patient's demographics added. Patient was 34 years old, patient's weight was 100 kg. Reaction onset was 2 Apr 2004. Patient has had severe headache for one week. She vomited once during the night. Afterwards pronounced brain oedema. CT findings: suspected the lambs infarction and thrombosis basiliaris. Patient died on

Report from the pathology: brain tumor / glioblastoma.

Reporter's Comment:

Suppl. (14 Jun 2004): Reporter's opinion: No causal relationship with Mirena

C1. Name (cont.)

Suspect Medication #1: Mirena(LEVONORGESTREL) IUS

C2. Dose, frequency & route used (cont.)

Suspect Medication #1: 20 µg/day, cont, intra-uterine

DSS JUN 2 1 2004



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Air report #	
#/Diet report #	 US-2004-02820

Relays International, Inc. FDA Fecelmile Approvat: 30-JUN-1999

THE PUA MEDIC	AL PRODUCTS REP	OKIDIO PROGRAM		Pag	e 1 of 2			FDA Use Only
A Patient Informa	tion				C. Suspect medication	on(s)		
1. Patient identifier	2. Age at time of event:	24 years	3. Şex	4. Weight 240.0 tos	1. Name (give labeled #1. Levien 28(ETH	-	•	,
	Date of birth:		male	108.8 kgs	#2.			
in confidence				TXXIX No.	2. Dose, frequency & r	oute used	3. Therapy date	es (if unknown, give duration)
B Adverse event					#1. 1 tab(s), (conti	nued\	#1 03//200	14 to 06/09/2004
1. Adverse ever	nt and/or	Product problem	(e.g., defects/	malfunction)		ildou)		10 00/03/2004
2. Outcomes attribut (check all that ap		nt			#2. 4. Diagnosis for use (ir	rdication)	#2.	ent abated after use
(Crock an tract ap	49)	disability			#1. Oral contracep	*		opped or dose reduced
death _		congenitu	d anomaly		#2.		#1. [yes no S apply
life-threatening)		ntervention to at impairment/		5. Lot# (if known)	7. Exp. date (If kno	WT\) #2. [yes no doesn't
hospitalization	- initial or prolong	ed other:			#1. UNK	#1. UNK ,		rent reappeared after
3. Date of event	06/09/2004	4. Date of this report	09/24/	2004	9. NDC# - for product	#2. problems only (if know		introduction yes no apply
		(#2. [yes no doesn't
blood clots in t lethargy)[Cere	REFERRED TER he brain (sev bral thrombos troke[Haemo	rrhagic stroke]		d by commas)	10. Concomitant medical No Concomitant M	edication UNK to t	•	treatment of event)
Case Descripti A nurse report with a severe i year-old Cauce estradiol/levon past medical i concomitant m allergies. In M contraception, patient experie	ion: ed the occurr neadache, vo asian female orgestre! (Le istory, report edications. S IAR 2004, the Approximate enced severe ed to the eme nospitalized. dditional Info	rence of a fatal blo miting, and lethar who received ethin vien 28). The pat- edly had no health She was a non-sme e patient initiated to ely 3 months later headache, vomitingency room by the The section	gy in an or nyl ient had no n problems loker and levien 28 i on (1)	o significant and took no had no for the chargy. She	1. Contact office - name Berlex Laborator Harri Helajarvi, M Director, Medical harri.helajarvi@t Fax: +1 973 305 Global Med. Safe	a/eddross (& mitting sitings of the company of the	West Belt STATES NDA 18-782	2. Phone number +1 8882375394 3. Report source (check all that apply) foreign study Herature consumer health professional user facility company representative distributor other:
race, pregnancy #1 UNK, alle #2 UNK, hist #3 UNK, soc #4 UNK, con	smoking and alor rgy (None) orical conditional ial circumstal	pexisting medical conditions to use, hepatic/renal dy on (continued) noe, Non-smoker tion, Qbesity (con o section	/sfunction, etc		□ 5-day ☑ 15-da □ 10-day □ perioc □ initial ☑ follow 9. Mfr. report number US-2004-028202 E. Initial reporter 1. Name & address	y product B. Adven Cerebri Cup # 1 Cardiac	fallure	Haemorrhagic stroke, DSS
FDA	Submission of medical person	a report does not cons			2. Health professional			FP 2 9 2004 4. Initial reporter also sent report to FDA

yes no

☐ yes ☐ no 🛭 unk



(continued)

eport does not constitute I medical personnel, user rackity, distributor, manufacturer or product caused or contributed to the event.

U.S. (DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC Health Service - Food and Drug Administration
With resport #	US-2004-028202
JF/Dist report #	
	FDA Use Only

			Page 2 of 2	FDA Use Only
-	Information ENT DESCRIPTIO	N (cont.)		
		m blood clots in the brain on @	Treatment was not specified.	
obese (determi	correction from pro ned the patient ex	evious report) patient also experienced a hemorragic stroke	tiated Levien 28 for contraception (correction orienced a massive stroke identified on a CT after the rapid development of the blood cloent, or coronary aftery disease. The patient	scan on the lit was ts. There was no known previous
			to insert a shunt to drain fluid. A nurse cont	
She als	o stated the physic	ne nurse stated the morbidly ob clan did not identify any coagul stroke due to a blood clot that r	pese patient (BMI = 43.9) did not have any in opathy or coagulation problems. The death resulted in heart failure.	nfection and was a "healthy" female. certificate reportedly stated the patient
•	itional information		•	
Case cl	osed.			
The nur	er's Comment: se stated the phys developed blood c	ician suspected a probable rel lots rapidly which caused a he	ationship between the patient's death and tr morrhagic stroke thát ultimately lead to her d	eatment with Levien 28 because the leath and heart failure.
87. ·	OTHER RELEVANT	HISTORY		
#	Start/Stop Date	Condition Type / Condition	Notes	
2	UNK	historical condition	Patient had no reported health problems	
4	UNK ,	concurrent condition Obesity	Suppl. (15 SEP 2004): BMI = 43.9 (108.8)	sg, 157.5 cm), morbid obesity
5	UNK	AE Dx procedure Computerised tomogram abnormal	Suppl. (15 SEP 2004): Showed a massive	e stroke
6	UNK	AE Tx procedure Shunts	Suppl. (15 SEP 2004):	
7	//1999 //2004	past drug name DEPO PROVERA	Suppl. (15 SEP 2004):	
	Name (cont.) pect Medication #	1: Levien 28(ETHINYLESTRAD	DIOL, LEVONORGESTREL) coated tablet	
		k route used (cont.) 1: 1 tab(s), 1x/day, Oral		DSS

SEP 2 9 2004

•				ı					Pa	age	1 of 2	\neg
Wyeth	ı	Individual S	afety Repor	- t								_
NTERNATIO	NAL	4596309-1-00-						П				П
ADVERSE E	XPERIEN	CE REPUR	1						_ <u></u>			닉
	_ numbers and	A grant of the property of the	REACTION IN		4-6. EXPER	RIENCE C		8-12.	CHECKA	LL APPRO	PRIATE	_
PATIENT 18. COUNT		2. DATE OF BIRTH	2a. AGE UNITS	3. SEX		Month	Year		TO ADVE	RSE REAC	HOIT	
INITIALS	France	Day Month	Year 32Yr	c F	00	oct	2004	X	PATIENT	DIED		
DESCRIBE EXPERIENCE(ULMONARY EMBOLIS	S)	ARCTUR PULMONAR	Y EMBOLISM);	Cardio-res	spiratory	•				-n 00		
rrest(LLT:Cardio	-respiratory el Term}	arresc							PROLON INPATIE HOSPIT	NGED NT	ON	
Information was r	eceived from	a healthcare pr	ofessional vi	la French	regulator	cy and			INVOLV		:	
Information was r authority (AFSSAP	s) regarding	a 32-year-old f	emale patient	who rece	ived Ader 1/0.04mg	ethin	yl		PERSIS	TENT O	Ŕ	
uthority (AFSSAF 0.15mg levonorge estradiol tablet)	strel/0.03mg	ethinyl estradi	sive pulmona	ry embolis	m and				SIGNIFI			
estradiol tablet) cardio-respirator	therapy and	Experience	-						INCAPA			
APRICAL HISTORY:			dese vein f	or which s	he under	went		X	LIFE TH	IREATE	NING	
MEDICAL HISTORY: The patient's convaricose vein ope	ncurrent illr	ess includes var	stient had a	body mass	index of	27, 8	he -					
varicose vein ope did not suffer f	eration (in C	emia or arterial	hypertension	, she had	no perso	nal or	=		NONE	OF THE	ABOVE	
family history of	f thrombosis	•										
		(cont'd)							RECO\	/ERED		
13. RELEVANT TESTS/LABO										1947-11		
See following p		SH2	SPECT DRUG	S) INFORM	ATION				DID REAC			
11.	NUMBER ACTIVE SURS	TANCE (S))						20	AFTER ST	OPPING D	RUG?	
14. SUSPECT DRUG(S) (INC # 1 ADEPAL (LEVON	ORGESTREL/ET	HINYL ESTRADIOL,	TABLET, 0)									
* 1		(cont'd)	}					\dashv Γ	YES		X C	N/A
15. DAILY DOSE(S)				16. ROUTE(S) OF	- ADMINSTRAT	ION						
#1 1 Tablet 1x P	er 1 Day			#1 Oral				+	1. DID REA	CTION REA	VPPEAR	
17. INDICATION(S) FOR U								'	AFTER R	EINTRODU	JCTION?	
#1 Contraception	(LLT:Contrac	eption)							□ YES	ΠN	o 🛭	N/A
18. THERAPY DATES (FRO		19.	THERAPY DURATION					_		ш.		
#1 Unknown	2	i	several year								11 784	16.
	50 E 177	CON	COMITANT DR	UG(S) AN	D HISTOR	Υ		100		The leaf is	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	is.
111.	· · · · · · · · · · · · · · · · · · ·											
22. CONCOMITANT DRUG	N-FRACTION,	MINISTRATION (Exclude the SODIUM SALT), One	e injection o	of 0.20 ml	, 00-Oct-	2004	/ 00-00	t - 2004				
TOARMOX (UTINITIES											()	
			fact month of period. 5	rtc.)				1.	1.5 2	3 200	Ü	
		ics, allergics, pregnancy with		•				ye.		إيعم		
CONCURRENT CONL	LT:Varicose	veins of lower e	xtremities)					3,5	0.00	Earle.	1 ∮\$	
PAST CONDITIONS	sporation (LLI	:Varicose vein	peration)			sa tide sadki.	11 1 72 File 14.0	2011年	That I was a	रिक्र के किसे से देवें स्ट्रांक की से देवें	or Tables	- 3
Varicose vein	COOPTS SIIR	MITTED BY MANU	FACTURER						is.	<u> </u>		
24a. NAME AND ADDRES	S OF MANUFACTUR	ER (Include Zip Code)		OTHER	REFEREN	CE NUM	BERS:	205000	28			
WYETH LABS (RI				Reg A	uchority	Ret N	ium - 13	,03000				
D 0 B0x 7667		:7										
Philadelphia,	LW TATATA 100											
		24b. MFR CONTROL	NO.	7			FE	B 2	5 2005			
Local Marketing No. #1 NDA 1	9-192	FRWYE444	4721FEB05						TOFDA			
24c. DATE RECEIVED	24d. REPORT		IMER				الجه	-	4 m 1 m 1			
BY	STUDY	REGU	LATORY								D MAR -	2
MANUFACTURER	LITERA	TURE AUTHO	ORITY	1								
21 505-2005	→ HEALT	H ESSIONAL LICEN	ISE							Å	MAR -	. 1
21-Feb-2005	PROFE	258. REPORT TYPE	<u> </u>			FE	B 28	2005	!	•	11TH	1
Date of this report		X INITIAL	FOLLOWUP	,								
25-Feb-2005		1 🖺 """"										

V	V	V	e	t	1	1
•	•	7	_		_	_

Wyeth Pharmaceuticals Inc. 80x 8299 PHILADELPHIA, PA 19101

Individual	Safety Report
	Safety Report
4528502-3-00)—01 -01

Page	1 of	2

INTERNATIONAL

ADVER	SE EXPERIENC	CERE	1.01	DEAG	TION INFO	RMATIO	N	II	4		
l.		2. DATE C	E BIRTH	KEAC	28. AGE	3. SEX	4-6. EX	PERIENCE	ONSET	8-12.	CHECK ALL APPROPRIATE
1. PATIENT INITIALS	1a. COUNTRY	Day	Month	Year	UNITS		Day	Month	Year		TO ADVERSE REACTION
INTIAGS	Sweden	Jay			33Yr	F	J		<u> </u>	4	·
2 DESCRIBE EV	PERIENCE(S)									X	PATIENT DIED
7. DESCRIBE EX	embolism (LLT : Pulmona	RY EMBOLI	SM)								INVOLVED OR
(LLT = Low	est Level Terml										PROLONGED
				data	entry erro	rs.			-		INPATIENT
	was reversioned in o						tory a	uthorit	У		HOSPITALIZATION
											INVOLVED A PERSISTENT OR
levonordes	a 33-year-old female trel/0.03mg ethinyl	estradio:	1/0.07	5mg lev	onorgestre	1/0.04m	g ethi	nyi nyi			SIGNIFICANT
estradiol/	0,125mg levonorgestr	.e1\0.01mg	g ethi	nyl est	radiol tab	oreci cu	crapy	and			DISABILITY OR
experience	d pulmonary embolism	1.									INCAPACITY
MEDICAL HI	STORY: edical history was n	ot provi	ded.								LIFE THREATENING
Indication	TAILS: , dose and dates of	Trinordi	ol the	rapy w	ere not pro	ovided.					NONE OF THE ABOVE
CONCOMITAN	T THERAPY:		cont'd)								
		((JOINU)							7 ~	RECOVERED
	ESTS/LABORATORY DATA										
None Pro	/ided.			20527	DDUC(S) 14	IEOPM A	TION				
11.			SU	SPECI	DRUG(S) IN	TONINA	11.014			20	DID REACTION ABATE
14. SUSPECT DE	RUG(S) (INCLUDE ACTIVE SUBSTA DIOL (LEVONORGESTREL)	ANCE(S)) /ETHINYL	ESTRAD	IOL, T	ABLET)]	AFTER STOPPING DRUG?
#1 TRINORI	TOP (DEADHOVOES IVER)									_	3 F3 F3
					Tre 60	UTE(S) OF A	DMINSTR	ATION		\dashv \square	YES NO X NA
15. DAILY DOSE	(S)					nknown	COMING IT	,,,,,,,,,			
#1										-	I. DID REACTION REAPPEAR
17. INDICATION	(S) FOR USE										AFTER REINTRODUCTION?
#1 `										_	TYES TINO X NA
18 THERAPY	ATES (FROMTO)		19.	THERAPY	DURATION					L	YES NO X NA
#1 Unknow			# 1	Unknow	'n						
			1	001/IT/	NT DRUG/	S) AND	HISTO	RY		200	CEIVED
111.					NT DRUG		111010				UCIYED
22. CONCOMITA	NT DRUGS AND DATES OF ADMI	NISTRATION (exclude (na	se used to	(real event) (OA)	10/110/				م م	0 4 2005
Unknown										et b	CAN'T
										וחי	2 / CDED
										ועט	R/CDER
23 OTHER REI	EVANT HISTORY (e.g. diagnostics,	allergics, pregr	nancy with	last month	of period, etc.)						
UNK	•- •- •- •- •- •- •- •- •- •- •- •-										
											
IV. ONLY	FOR REPORTS SUBMI	TTED BY	MANU	FACTU	RER						
248. NAME AND	ADDRESS OF MANUFACTURER	(Include Zip Co	de)		İ	OTHER R	EFEREN	ICE NUM	BERS:	. กรรา	27
	ARMACEUTICALS INC.					Regulat	ory Au	itnoric	y (HP)	. 0321	21
P.O. Box	7667 phia, PA 19101-7667										
FILLTAGE	burnt in account	AP	R 0 4	1 20 05							
1111111111	No.	24b. MFR CO							556	2005	
Local Marketing #1	NDA 19-192			423MAR	05			A	PR (L.)	7005	D00
24c. DATE REC	EIVED " 24d. REPORT SOU	IRCE	05:::					24	TESET	វត្តខ្មែ	DSS
BY	STUDY		CONSU		1						
MANUFAC	LITERATU	RE X	REGUL AUTHO	RITY							APR 0 5 2005
	- HEALTH	[-7	LICENS								2003
21-Mar	-2005 X PROFESS								•		
Date of this rep	ort	25a. REPOR			OWILE						
01-Apr	-2005	X INITIA	L	FOLI	LOWUP						

													Page	1 of	2
•	ATTOM MANA MANA	VIOLAL SETET	Y RESS	ا ۱۳۹۱ میلی اور ا	14) (SAP										
IN Alives	* 4686	111-4-00-01+ NF ENICH	# F2 1 :	"	1961 1961										
ADVE	To come I is at the					TION INFO	RMACIO	NAT OF							FEE
1. PATIENT	1a. COUNTR	Υ	2. DATE O			2a. AGE UNITS	3. SEX	4-8. EXI	PERIENCE	ONSET	8-12.		K ALL APP		
INITIALS		Canada	Day	Month	Year	26Yr	P	Day	Month	Year		102	wense n		·
7. DESCRIBE EX			1								X	PATIE	NT DIE)	
MESENTERIC [LLT = Low		ON(LLT:MESENTE	RIC ART	ERY TH	ROMBOSI	S); Asp1:	ration (L	LT: Aspi	ration	1)		INVOL	VED OF	₹	
Additional	linforma	tion was recei	ved fro	m a he	althcar	e profes	sional r	egardir	ng pat:	ient		PROL INPAT	ONGED IENT		
demographi	ics and a	utopsy results										-	ITALIZA	TION	
female pat	ient who	ceived from a received Ales	se-28 (0.1mg	levonor	gestrel/	0.02 mg e	thinyl					VED A ISTENT	or ²	
estradiol/	inert ta	ablet) therapy and died after	and exp	erienc Alesse	ed fres	h thrombo	osis of a	the sup nths.	perior				FICANT BILITY O		
MEDICAL HI	STORY:												PACITY		
PRODUCT DE	ETAILS:	current illness										LIFET	HREAT	ENING	j
		esse-28 was men let 1 time per			ation c	of therapy	y was 3	months	. Dose			NONE	OF THE	E ABO\	Æ
				ont'd)								DECC	VEDED		
13. RELEVANT TO None Prov													VERED		
112.32				SUS	PECTD	RUG(S) IN	FORMAT	TION:			_				
14. SUSPECT DR	RUG(\$) (INCLU - 28 (LEVO	DDE ACTIVE SUBSTANCE ONORGESTREL/ETH	E(S))	TRADIO	L/INERT	TABLET)				20		CTION ABA		
												1 400	L., *	۰ E	
15. DAILY DOSE(16. RO	UTE(S) OF AD	MINSTRAT	TION		1 L	J YES	ЦΝ	о <u>(х</u>	J N/A
#1 1 Table		- Day									21	. DID REA	CTION RE	APPEAR	
l	• •	(:Menorrhagia)										AFTER F	REINTROD	UCTION	'
18. THERAPY DA	•	TO)			HERAPY DL	JRATION				•	1 [] YES	□ N	O X] N/A
#1 Unknown	1				3 Mth				-kontroller						Consideration Fig.
III.	A DOUGE A	ND DATES OF ADMINIST				TDRUG(S		ISTOR	YA Ş			e en u		21.	2742
NONE (NONE			1411011 (620				-					RFC	EIV	'ED	
									••			JUN	0 6 2	005	
CONCURRENT	r CONDITI									•	C	DR	/ CE)FF	≀
Obesity(Li	LT:Obesit	y); Smoker(LL1	::Smoker); Alc	ohol u	se (LLT : Al	cohol us	e)							•
IV. ONLY F	OR REPO	ORTS SUBMITTE	D BY M	ANUFA	CTURE	R	/ `` }#	5(1) (3)		77.72	47. Y \$	190	MAR	7.7-3	1757
24a, NAME AND	ADDRESS OF	MANUFACTURER (Inclu					OTHER RE		* *	ERS:					
P.O. Box	7667	19101-7667				'	arriilge.	e Kel I	-un						
Philadelp	pnia, PA	19101-7007				} !									
Local Marketing N	6. NDA (20-6)		MFR CONT	ROL NO. E73111	3MAY05					•••				DS	SS
24c. DATE RECE		24d. REPORT SOURCE						1)ل ه ۱	N 0 3	200	5	••	16.0	0 000
BY MANUFACT	TURER .	STUDY	_	ONSUMI EGULAT				1	JAIE	IN 0 3 SENT	OT'	FDA	JU	N _	8 2005
	11	☐ LITERATURE ☐ HEALTH	A(JTHORI									•		
24-May-2	2005	PROFESSION		CENSE		1									

JUN 0 6 2005

03-Jun-2005

Date of this report

25a. REPORT TYPE
INITIAL

X FOLLOWUP

AUVERSE EXPERIENCE REPORT

Manufacturer Control Number:

HQWYE731113MAY05

Box # 7 - DESCRIBE EXPERIENCE(S)

(Continuation)

CONCOMITANT THERAPY:

Patient was not taking concomitant therapy.

EVENT DETAILS:

The autopsy cause of death was reported as "ischemic bowel disease with extensive ischemia of the small bowel due to fresh thrombosis of the superior mesenteric artery (mesenteric occlusion) associated with terminal aspiration (aspiration) of foreign material". No further details were provided.

DSS

JUN - 8 2005



TATED & AUJTOTT

use by user-facilities,	
ors and manufacturers for	r
NDATORY reporting	

Mir report #	-		005287
UF/Dist report #		 	ANDEO!

Relays International, Inc. FDA Facsimile Approval: 11-JUN-1999

1411717			\i :11	UFA	Dist report #	
THE FDA MEDICAL PRODUC	TS REPORTING PROGRAM	- - Pag	e 1 of f			FOA Use On
A. Patient Information			C. Suspect medicatio	on(s)		
1. Patient identifier 2. Age at	time	3. Sex 4. Weight	1. Name (give labeled a		eler, if known)	
of even		fermale UNK lbs	## Spannedoll 53	ONODOESTE)C (sootinused)	, N
or Date		or or	#1. Seasonale(LEV	ONORGESTA	E (CONTINUED)	<i></i>
of birth:	UNK	male UNK kgs	#2.			
	et eroblem		2. Dose, frequency & ro	oute used	3. Therapy	y dates (if unknown, give duration)
B. Adverse event or produc			#1. UNK, UNK, Ore	al	#1 -/-//	2004, duration UNK
1 Adverse event and/or	Product proble	m(e.g., defects/malfunction)			_	Level, date of the
2. Outcomes attributed to adve	rse event		#2.		#2.	5 F
(check all that apply)	disablit	у	4. Diagnosis for use (in #1. UNK	dication)	1	5. Event abated after use stopped or dose reduced
ズ death	congen	ital anomaly	#1. UNK			#1. yes no apply
(00)	<u> </u>	•	6. Lot# (if known)	7. Exp. date (If	known)	UN STATE
life-threatening	D lednied	d Intervention to prevent ent impairment/damage	#1. UNK	#1. UNK	,	#2. yes no doesn't apply
hospitalization - initial or	prolonged 🔀 other:	Medically Significant	*1. Olak	#1. OIVIC	-	8. Event reappeared after
3. Date	4. Date of		#2.	#2.		reintroduction
of event//200	1 11	07/28/2005	9. NDC# - for product p	problems only (If kr	nown)	#1 yes no apply UN
(mediasys)	(moresyle)		1		İ	#2. yes no doesn't
5. Describe event or problem	ED TERM (Related symptoms	If any seperated by commas)	10 Concomitant medic	al products and th	erany dates (exc	clude treatment of event)
Blood clot in the legiDe		a will seberated by common	NI	an processor une un	orapy calco (cac	Made a describing of district
Blood clot in heart(Intra	·					
Blood dot in lung(Puin						
Cardiac arrest[Cardiac	•		C. All Manufacturers			
Brain damage[Brain da	_		G. All Manufacturers 1, Contact office - name		site for devices	s) 2. Phone number
Diam damago(Diam o	ago]		Barr Laboratories	•		2019303302
Case Description:			Salvatore Peritor			
	ed regarding a 31 Ve	ar old female patient that		0, ,		
		ethinylestradiol) Tablets	400 Chestnut Rid	ige Road		3. Report source
0.15/0.03 mg for an ur			Woodcliff Lake, N	ij 0767 7-7668	UNITED ST	TATES (check all that apply)
was initiated in the Fal			! !			foreign
		ed to her heart causing				I study
cardiac arrest. She wa						⊠ klerature
damage. The dot trav						15
she expire	ed. No additional info	mation was available.	4. Date received by	5.		consumer
one expire	Ju. 114 danie 116 116 116 116 116 116 116 116 116 11		manufacturer	(A)NO	DA # 21-544	health professional
continued in additional	l info section		07/26/2005	5 IND		User fecility
			6. If INO, protocol #		•	-
0. Dulawad ta at- 4-bt	to lookydoo det		-	PLA	#	company representative
 Relevant tests/laboratory da NI 	ra, including cates		7. Type of report	pre-	1938 🔲 yes	deallbutor
131			(check all that apply)	1		other:
			☐ 5-day 🔀 15-day	v Prod		
			l l	8 44	verse event term	L
			10-day period			oosis, Intracardiac thrombus,
			initial follow			lism, Cardiac arrest, Brain
			9. Mfr. report number	dam	age	
7 Other coloured history teature	ling presyleting medical goods	tions (e.g. ellergies	005287	ļ		
Other relevant history, include race, pregnancy, smoking a	and alcohol use, hepatic/renal	dysfunction, etc.)				
NI			E. Initial reporter			
			1. Name & address		phone#	
	11 11 .					
	JUL 2	2 9 2005			-	
				UNITED ST.	ATES	
_						
	sion of a report does ∩ot co l personnel, user facility, disi	nstitute an admission that tributor, manufacturer or product	2. Health professional ?	? 3. Occupation	on	4. initial reporter also sent report to FDA
THE STATE OF THE S	Paradiana, and maning, and		l l	1 0411-	alth Danfanaia	t sentieboutto tou

🔯 yes 🔲 no

caused or contributed to the event.

ALIC A 9 some

☐ yes ☐ no 🔯 unk



(∞ntinued)

n of a report does not constitute ion that medical personnel, user _____tributor, manufacturer or product caused or contributed to the event.

	EALTH AND HUMAN SERVICE e • Food and Drug Administratio
Mir report #	005287
UF/Dist repor	003201

Page 2 of 2

Additional Information

B5. EVENT DESCRIPTION (∞nt.)

MedWatch Case Comment:

Submission of this 15-day report does not constitute an admission that the reported event is an unlabeled event.

C1. Name (∞nt.)

Suspect Medication #1: Seasonale(LEVONORGESTREL, ETHINYLESTRADIOL) Tablet, 0.15/0.03mg

G3. Report source literature description

Journal: Virginia Pilot Newspaper 07/26/2005

Author: Mary Ann Bromley

Title: Unnecessary tragedies from the birth control patch

JUL 2 9 2005

FAX to:

1-800-FDA-0178

Mail to: MEDWATCH

5600 Fishers Lane

Rockville, MD 20852-9787

Health Professional? 3. Occupation

5. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

Method Examiner

Manufacturer

User Facility

Distributor/Importer

Yes No

U.S_Departme	ent of Health and Hum	an Services		- Fassiga h	y user-facili	lios		Ralava Inter	malional lac ET	DA Fecelmile Approvel: 30-JUN-19
			EDIO HELION			anufacturers	Jadr.	Report #		AT TOWNS APPROVED SUSCINETS
			MAH		TORY repo	rting	ļ	mporter Report #		GB-2006-00565
49540	00-3-00-01	i wa uriki filik 160 57111	ATION SER LEG		edex Inc.		5.7	mporter response		
	on vahorens			*	age 1 of 2					FDA Use On
A. PATIENT INF 1. Patient identifier						SPECT MEDI				
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micro-abscess	in several body ar	eas, e.g. lung	tissue) re	sulting in	1 1	tor, Medical A				3 Report Source
	ale patient in her 4	0's who was p	prescribed			nen_Heaton@ +1 973 487 29			j	Check all that apply)
levonorgestrei ((Mirena, IUS).						Surveillance,	P.O. Box 1	000 /	⊠ Foreign GBR
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	medical personnel, use caused or contributed t		и, manufa¢li	irer, or product			health care	professions		ant Report to FDA
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FOA Use Only



3 report does not constitute lat medical personnel, user distributor, manufacturer or or contributed to the event.

	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service - Food and Drug Administration
Report #	
/Importer R	open # GB-2006-00565€

Page 2 of 2

Additional Information

B5. EVENT DESCRIPTION (cont.)

levonorgestrel (Mirena) via intra-uterine route of administration for an unspecified indication.

On an unspecified date the patient developed a rapid course of septicaemia which was identified as an ascending genital infection via post-mortem. The post-mortem established a Group A Streptococcal sepsis with micro-abscesses in several body areas (e.g.lung tissue), resulting in death.

The patient died from the Group A Streptococcal sepsis on an unspecified date.

No additional information was provided. Further information requested and will be furnished upon receipt.

Reporter's Comment:

The reporter did not provide an assessment of the relationship of event to treatment of Mirena.

C1. Name (cont.)

Suspect Medication #1: Mirena(LEVONORGESTREL) IUS

C2. Dose, frequency & route used (cont.)

Suspect Medication #1: 20 µg/day, cont, Intra-uterine

U.S. Department of Health and Human Services Individual Safety Report use by user-facilities. stributors and manufacturers **WDATORY** reporting GB-2006-005658 UFAmporter Report # Berlex Inc. Page 1 of 3 FDA Use One A. PATIENT INFORMATION C. SUSPECT MEDICATION(S) 1. Patient identifier 2. Age at Time 4. Weight 3. Sex 1. Name (Give labeled strength & mfr/labeler, if known) 42 years of Event: 156,6 Female #1. Mirena(LEVONORGESTREL) (continued) Male of Birth UNK 71.0 in confidence 2. Dose, Frequency & Route Used **B. ADVERSE EVENT OR PRODUCT PROBLEM** Therapy Dates (if unknown, give duration) from/to (or best estimate) 1. Adverse Event and/or #1. 20 (continued) Product Problem (e.g., defects/malfunctions) #1. --/--/2003, duration UNK 2. Outcomes Attributed to Adverse Event #2. (Check all that apply) 4. Diagnosis for Use (Indication) Disability 5. Event Abated After Use #1. UNK Stopped or Dose Reduced? Death
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 Congenital Anomaly #1. Yes No Apply #2. Life-threatening Required Intervention to Prevent Permanent Impairment/Damage 6. Lot # (if known) 7. Exp. Date (# known) #2. Yes No Doesn't #1. UNK Hospitalization - initial or prolonged #1. UNK Other: Medically Significant 8. Event Reappeared After 3. Date of Event (mo/day/year) 4. Date of This Report (mo/day/year) #2. 9. NDC# (For product problems only) UNK #1. Yes No Apply 04/07/2006 #2. Yes No Doesn't 5. Describe Event or Problem Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) Group A streptococcal sepsis (unwell,lethargic, dizzy, lightheaded, flulike, diarrhea, temp 39, pulse 100, pulmonary edema, abscess on ovary with coccal bacteria)[Streptococcal sepsis] pelvic inflamatory disease (both ovaries oedematous and inflammed, G. ALL MANUFACTURERS fallopian tubes appear oedematous and inflammed, uterus 1. Contact Office - Name/Address (and Manufacturing Site inflammed)[Pelvic inflammatory disease] for Devices) +1 8882375394 peritonitis (peritoneal cavity contained purulent fluid, inflammation of Berlex Inc. peritoneum)[Peritonitis] Stephen Heaton, M.D. left ovary contained benign cystic teratoma[Dermoid cyst of ovary] Director, Medical Assessment 3. Report Source right ovary contained haemorrhagic cyst[Haemorrhagic ovarian cyst] Stephen_Heaton@Berlex.com (Check at that apply) right adrenal gland showed 20mm nodule[Adrenal mass] Fax: +1 973 487 2914 S Foreign GBR Global Med. Safety Surveillance, P.O. Box 1000 Montville, NJ 07045-1000 UNITED STATES Study Case Description: A health care professional reported on 14 continued in additional info section... Consumer 4. Date Received by Manufacturer(mo/day/yr) APR 1 0 2006 (A)NDA # NDA 21-225 03/31/2006 IND # User Facility RECEIVED 6. If IND, Give Protocol # PLA# Company Represent 6. Relevant Tests/Laboratory Data, Including Dates Body temperature 39 , Suppl. (1 Pre-1938 Yas Distributor 7. Type of Report Meart rate 100 , Suppl. ((Check all that apply) Other: 🕽 Blood pressure 120/80 , Suppl. (🛢 Yes ☐ 5-day
☐ 15-day 8. Adverse Event Term(s) 10-day Periodic Streptococcal sepsis, Pelvic inflammatory ☐ Initial 🔯 Follow-up #1 disease. Peritonitis. Dermold cyst of overy, Haemorrhagic overian 9. Manufacturer Report Number continued in additional info section... 7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, GB-2006-005656 egnancy, smoking and alcohol use, hepatic/renal dysfunction, eld #1 UNK concurrent condition, (continued) **E. INITIAL REPORTER** #2 --/-/1995 to --/--/1995 procedure, (continued) 1. Name and Address #3 --/-/1995 to UNK historical condition, (continued) Phone # Withheld Name and address withheld. #4 UNK, procedure, Caesarean section (continued) APR 0/2006 Submission of a report does not constitute an admission that 2. Health Professional? 3. Occupation medical personnel, user facility, distributor, manufacturer, or product 4. Initial Reporter Also caused or contributed to the event. Sent Report to FDA health care professional Yes No Yes No 🛭 Unk

FDA Use Ont



of a report does not constitute in that medical personnel, user riter, distributor, manufacturer or sed or contributed to the event.

	U.S. DEPARTMENT OF Public Health Sen	HEALTH AND HUMAN SERVICE: ice - Food and Drug Administration
Mir Report #	-	G8-2006-005656
UF/Importer (Report #	

Page 2 of 3

Additional Information

B5. EVENT DESCRIPTION (cont.)

occurrence of a rapid course of septicaemia (ascending genital infection identified via post-mortem, Group A Streptococcal sepsis with micro-abscess in several body areas, e.g. lung tissue) resulting in death in a female patient in her 40's who was prescribed levonorgestrel (Mirena, IUS).

The patient's past medical history, concurrent medical conditions, and concomitant medications were not reported. It was not reported if Mirena was used previously and tolerated.

On an unspecified date in 2003 the patient received levonorgestrel (Mirena) via intra-uterine route of administration for an unspecified indication.

On an unspecified date the patient developed a rapid course of septicaemia which was identified as an ascending genital infection via post-mortem. The post-mortem established a Group A Streptococcal sepsis with micro-abscesses in several body areas (e.g.lung tissue), resulting in death.

The patient died from the Group A Streptococcal sepsis on an unspecified date.

No additional information was provided. Further information requested and will be furnished upon receipt.

Suppl. (31Mar 2006): Additional information provided by the physician including the post-mortem report.

This 42 year-old female patient's medical history included an ovarian cystectomy while pregnant in 1995 and then had a caesarean delivery. There was no other record of any other significant gynecological or obstetric history. There was no other past history of note. The patient's body mass index (BMI) was 24.57. In April 2005 she was noted to have no problems with her IUD.

On this patient felt unwell, lethargic, dizzy, lightheaded, had complained of flu-like symptoms for the past 7 days and had diarrhea 4 times in 24 hours before she was seen by a doctor the day before she was found dead. The patient was seen by a physician the night before she died and was described as being fully alert and oriented with a temperature of 39, pulse of 100, blood pressure 120/80, her mouth was dry, her chest was clear, her abdomen was soft and non-tender, there was no neck stiffness or photophobia. A diagnosis of gastroenteritis was made by the physician and the following morning after a sudden deterioration in her health she was found dead at her home in bed on

Post mortem examination showed the patient died as a result of sepsis following Infection with Group A streptococcus. The infection appeared to have been primarily centered within the pelvis involving the uterus., fallopian tubes, and ovaries. As noted, the organism was also isolated from the IUD device.

The post mortem report stated it appeared most likely that the infection of the pelvic organs was a direct result of an ascending genital tract infection and death was directly attributable to Group A streptococcal sepsis which was secondary to pelvic inflammatory disease and peritonitis.

No additional information was reported.

APR 1 0 2006

Reporter's Comment:



of a report does not constitute n that medical personnel, user ter, distributor, manufacturer or ed or contributed to the event.

PURC He	ENT OF HEALTH AND HUMAN SERVICE alth Service - Food and Drug Administration
Mir Report # -	
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Page 3 of 3

The reporter did not provide an assessment of the relationship of event to treatment of Mirena.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
/ 1	UNK	concurrent condition Body mass index	Suppl. (31 Mar 2006): BMI = 24.57 (71 kg, 170 cm)
2	//1995 //1995	procedure Ovarian cystectomy	Suppl. (31 Mar 2006) Ovarian cystectomy whilst pregnant
3	//1995 UNK	historical condition Pregnancy	Suppl. (31 Mar 2006)
4	UNK	procedure Caesarean section	Suppl. (31 Mar 2006)

C1. Name (cont.)

Suspect Medication #1: Mirena(LEVONORGESTREL) IUS

C2. Dose, frequency & route used (cont.)

Suspect Medication #1: 20 µg/day, cont, Intra-uterine

G8. ADVERSE EVENT TERMS (cont.)

cyst, Adrenal mass

APR 1 0 2006



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The FDA Safety Information and

Adverse Event Reporting Program

OLUNTARY reporting adverse events, product problems and product use errors

Internet Submission - Page 1

Form Approved: OMB No. 0910-0291, Expires: 10/31/08 See OMB statement on reverse.

Distributor/Importer

	FDA USE ONLY	
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		•

A. PATIENT IN					SUSPECT PR		-				
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In confidence	20 Years	Male	or kg	<u> </u>							
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Interestions the last one six months before the death.) and idiopathic thrombocytopenic purpura; Past therapies included frincricio (0.0.5mg levonorgestre1/0.03mg ethiny1 estradio1/0.075mg levonorgestre1/0.04mg ethiny1 NONE OF THE ABOVE NONE OF THE ABOVE RECOVERED NONE OF THE ABOVE RECOVERED	MEDICAL HIS	TORY:																		
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IS RELEVANT TESTSHABORATION DATA None Provided. SILEMAN SUPPECT PRUGS INCOMES AND ACTIVE SUBSTANCE(8) 11 TRINORDIOL (LEVONORGESTREL/EPHINYL ESTRADIOL, TABLET) 12. DARY DOSE(5) 13. ROUTE(5) OF ADMINISTRATION 14. TOTAL 15. DARY DOSE(6) 16. ROUTE(5) OF ADMINISTRATION 17. NONCATIONS) FOR USE 17. INDICATIONS FOR USE 18. THERMAY DURATION 19. THERMAY DURATION 19. THERMAY DURATION 19. THERMAY DURATION 19. THERMAY DURATION 19. THERMAY DURATION 19. THERMAY DURATION 19. THERMAY DURATION 21. CONCOMINANT DRUGS AND DATES OF ADMINISTRATION (E-route from used to least enough (DANOTR) 22. CONCOMINANT DRUGS AND DATES OF ADMINISTRATION (E-route from used to least enough (DANOTR) 23. OTHER RELEVANT HISTORY (e.g. degrees in a subject, programmy with last movem of period, etc.) 24. OTHER RELEVANT HISTORY (e.g. degrees in a subject, programmy with last movem of period, etc.) PAST CONDITIONS: 25. OTHER RELEVANT HISTORY (e.g. degrees in a subject, programmy (LLT: Splenectomy) 26. DOWN (EVERY) (LLT: Normal birth); Idiopathic thrombocytopenic purpura); 17. INDICATION (E.G. DEGREE OF MANUFACTURER) 26. DOWN (E.G. DOWN (E.G. DEGREE OF MANUFACTURER) 27. DATE REPRESENCE NUMBERS. 28. NORMA AND ADDRESS OF MANUFACTURER (Include 20 Code) 19. WYETH PHARMACEUTICALS INC. 10. DOWN 76677 Philadelphia, PA 19101-7667 29. DATE RECEIVED 20. DATE RECEIVED 20. DATE RECEIVED 21. THERMAY DATE OF THE RECOULATION (LICENSE AUG 18 2006 21. THERMAY DATE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE SERVICE OF THE RECOULATION (LICENSE AUG 18 2006 DATE	thrombocyto	penic purpura.	Past th	erapie.	s incl	uded Tr	inordial	(0.05mg		_										
NONE PROVIDED. NO PROVIDED. RECOVERED				(co	nt'd)	ing ICVO	norgesti	e1/0.04m	g etni	JAT				╵╵	NOI	NE () 	HE AE	30V	Æ
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1. Supplet Drug(s) (include active substance(s))			No.	V	SÙSI	PECT DI	RUG(S)TI	FORMA	ION					 		C.	200			Charles
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17. INDICATION(S) FOR USE 19. Prophylaxis (LLT: Prevention) 18. THERAPY DATES (FROMTO) 19. THERAPY DURATION 11. 13-NOV-1995 / UNK 11. 13-NOV-1995 / UNK 11. 13-NOV-1995 / UNK 11. THERAPY DURATION 19. THERAPY DURATION 19. THERAPY DURATION 19. THERAPY DURATION 19. THERAPY DURATION 19. THERAPY DURATION 19. THERAPY DURATION 19. THERAPY DURATION 20. CONCOMINANT DRUGS AND DATES OF ADMINISTRATION (Exclude trace used to treat event) (DAMOYR) AUG 1 7 2006 20. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 23. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 24. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 25. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 26. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 26. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 26. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 27. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 28. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 28. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 28. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 28. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 29. OTHER RELEVANT HISTORY (e.g. diagnostica, allergics, pregnancy with last month of period, etc.) 29. OTHER RELEVANT HISTORY (e.g. diagnostica, pregnancy with last month of period, etc.) 29. OTHER RELEVANT HISTORY (e.g. diagnostica, pregnancy with last month of period, etc.) 29. OTHER RELEVANT HISTORY (e.g. diagnostica, pregnancy with last month of period, etc.) 29. OTHER RELEV	15. DAILY DOSE(S)		•				18. RO	UTE(S) OF AD	MINSTRAT	ION				{ ⊏] YES	6		NO	X	N/A
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### 13-Nov-1995 / UNK ### Unknown ### Unknown #### Unknown ##################################	18. THERAPY DATE	ES (FROM/TO)			19. TH	FRAPY DUE	ATION								_		┌ .			
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PAST CONDITIONS: Normal delivery(LLT:Normal birth); Idiopathic thrombocytopenic purpura(LLT:Idiopathic thrombocytopenic purpura); Infection(LLT:Infection); Splenectomy(LLT:Splenectomy) WAGNET-OFFREHORTS SUBMENCOBY MANUFACTURER 24a. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code) WYETH PHARMACEUTICALS INC. P. O. BOX 7667 Philadelphia, PA 19101-7667 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER REFERENCE NUMBERS: Regulatory Authority (HP) - 062587 Affiliate Ref Num - S06272 OTHER RE														Αt	ו גט(. 4	رن	JU		
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Manufacturer Control Number	er: SEWYE678311AUG06													
Indication for Tri CONCOMITANT THERAP Concomitant therap EVENT DETAILS: The patient experi stomach sickness o nausea, vomit, rea died on The cause of death embolism. Accordin	levonorgestrel/0.03mg ethinyl nordiol was prophylaxis. Thera	hydrochloride). onary embolism) on rest. All resus olism and the au th new and old	on the part of the	pati tion sy c	ent e in t	of of	The rienc home	pati ed a fail	lent ubdom	expe inal The	erie L pa pat	nced in, ient	i ,	

DSS AUG 1 8 2006



For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

7. Type of Report

007819

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?

Raisys Internet	onal Inc.	FDA I	Facsimile	Annerum	44 444	

er-facilities, and manufacturers		Reisys Inter	metonal, Inc., F	DA Facsimile Approval 11-JUI	N 16			
RY reporting	Mfr Repo	M#		00781				
	UF/Impa	Yer Report #			Ω.ι			
of 4		***		FDA Una	٠			
C. SUSPECT MEDICATION	V(S)			FDA Use	U.			
1. Name (Give tabeled strength &		, if known)	(Re	gimens Continued	· · ·			
#1. Plan B(LEVONORGES	TREL) (co	ontinued)	(1,70)	Amiena commiser) 			
#2. ORTHO TRI-CYCLEN I		inued)			_			
2. Dose, Frequency & Roule Us		3. There	py Dates (il	f unknown, give duration	n)			
#1 2 (continued)				o 02/10/2006				
#2. UNK, UNK, Oral		#2. 05/	31/2005,	duration UNK				
4. Diagnosis for Use (Indication)		*	5. Event	Abated After Use	_			
#1. Emergency contraception	nc			d or Dose Reduced?				
#2. Oral contraception 6. Lot # (If known) 7. Exp.	- 4 (% lyon)		" ''	es No Apply				
#1. T54395B #1. UN	Date (if knov IK	wn)	#2. 🔲 Y	es No Doesn	n INF			
#2. UNK #2. UN	ıĸ			Reappeared After				
9. NDC# (For product problems or			—	duction? es No Apply	rt			
	••		#2. Y	No Ooesn	ŕt			
ORAL CONTRACEPTIVE N UNK continued in additional info s G. ALL MANUFACTURERS 1. Contact Office - Name/Address for Devices)	section			2. Phone Number 2019303302				
Barr Laboratories 400 Chestnut Ridge Road Woodcliff Lake, NJ 07677-	····	IITED S1	[ATES	3. Report Source (Check all that apply) Foreign Study Uterabure				
4. Date Received by Manufacturer(mo/day/yr)	5. (A)NOA # 2	21-045		Health Professional				
08/16/2006	IND#			_				
. If IND, Give Protocol #				User Facility Company				
	PLA#			Company Representative				
Type of Report	Pre-1938	Yes	·]	Distributor				
(Check all that apply) ☐ 5-day ☐ 15-day	OTC Product	Yes		Other				
	8. Adverse				_			
	Urinary tra	act infect	tion, Influe	enza, Menorrhagia,				
Initial Follow-up #2	Pyrexia, C	Chills, Pe	elvic pain,	Abdominal				
	distension continued			section				

	ty intomiation a			
	nt Reporting Pro	gram		Pa
A. PATIENT INF				
1. Patient Identifier	of Event:	21 Years	3. Sex	4. Weight 125.0 lbs
in confidence	of Birth:		Male	56.7 kgs
B. ADVERSE EV	ENT OR PRODU	ICT PROBLEM		
1. Adverse Eve		Product Proble	m (e.g., defect	s/maifunctions)
2. Outcomes Attrib	uted to Adverse Eve	ent		
(Check all that ap	ply)	☐ Disability		
Death		Congenite	al Anomaly	
Life-threatening	(mo/day/yr)	Required Permaner	Intervention to	Prevent
Hospitalization	- initial or prolonged	Other:		
3. Date of Event (mo 02/2	o/day/year) 28/2006	4. Date of This	Report (mo/d 3/29/2006	lay/year)
5. Describe Event of Event Verbatim [Pi Urinary tract inf Flu[Influenza] ([Heavy, prolong: Pelvic pain[Pelv Bloating[Abdom Took unprescrib Cardiac arrhyth: Spotting[Metrori	REFERRED TERM) (ection[Urinary t Pyrexia], [Chills ed menstrual bl vic pain] sinal distension] bed Amphetami mla[Arrhythmia	s], (Headache]) eeding[Menorri ne[Drug use foi	[Dysuria], [nagia]	Haematuria])
Case Description of the contract	received regar B (levonorgest	rel tablets, 0.75	mg) for er	nergency

7. Other Relevant History, Including Preexisting Medical Condition race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) #1 UNK Historical Condition, (continued) Procedure, (continued) to UNK Historical Condition, (continued) o UNK Historical Condition, (continued) continued in additional info section ...

Comprehensive Drug Panel (continued)

Pregnancy test Negative

Rapid Flu test Negative

CDER/CDR

6. Relevant Tests/Laboratory Data, Including Dates



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Yes 🔀 No	Consume
----------	---------

Sent Report to FDA				
⊠ Yes		No		
1				

4. Initial Reporter Also

UNITED STATES

3. Occupation

Phone # 📆



Experience Report (continued)

Additional Information

n of a report does not constitute an authorism that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

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UF/Importer Report #	007819
	FDA Use Onto

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В	5. EVENT DESCRIPT	ION (∞nt.)			
no Od ai	of provided). It was reported the patient experienced heavy menstrual bleeding, a swollen, and a painful, inflamed pelvic area, on 101/2006. The patient developed fever, chills and headache, on 04/04/2006. On the patient expired due to cardiac hythmia.				
Pi 04 de ur pr pa	an B (dosage unknow 4/01/2006, the patient' escribed as bloating. nknown indication. Sh escribed unspecified r ttient expired. Patholo	n) was taken for contraceptives menstrual period started, de On 04/03/2006, the patient to e developed fever and chills on edications (never filled) and	protection, due scribed as a head of a single dose on 04/04/2006 as instructed her to cardiac arrhythm	to the antibiotic use, avy and prolonged flow of an unspecified am and started taking Tyler rest, as she may be	aking an unspecified antibiotic for a urinary tract of sexual intercourse in 02/2006 and 03/2006. On 02/28/2006 and again on 03/29/2006. On w and included pelvic pain and pelvic swelling phetamine (not prescribed for her) for an nol Cold and Sinus tablets. The campus clinic coming down with the flu." On the the eath. A Comprehensive Drug Panel report on has been requested.
1	7/07/2006-See attache				
07	/24/2006- Final autop:	sy report was received. See a	ittached report.		
08	/04/2006-	records received. M		nedication history con	rect dates (02/10/2006, 03/27/2006) and Lot
nu	mbers for Plan B were	provided.	, , , , , , , , , , , , , , , , , , ,		rest dates (02/10/2006, 03/2//2006) and Lot
03. Tri spa Ra	/04/2006. On 03/08/2 methoprim, therefore (otting on 03/29/2006, s	2006, the patient experienced to Clpro was prescribed on 03/08 secondary to Ortho Tri-Cylen ive. GuaiMax-D and Delsyn versions of the control	ourning on urina 3/2006. Pyridiur	a UTI started. Sulfar tion and hematuria. S n and Macrobid were	ob, the patient was examined for sore throat and methoxazole & Trimethoprim was prescribed on the was resistant to the Sulfamethoxazole & prescribed on 03/10/2006. The patient started a patient went to the clinic with flu symptoms. A ever filled. The patient expired on
Ме	dWatch Case Comme omission of this 15-da	int: y report does not constitute ar	n admission that	the reported event is	an unlab ele d event.
	B6. LABORATORY DAT # Date	'A Test / Assessment / Note	es es	Results	Normal High (1
	1	Comprehensive Drug		Positive	Normal High / Low
	報 で 売 ・ と ・ と ・	1- Amphetamines2- Pseudoephedrine3- Caffeine	059 ng/mL		
	B7. OTHER RELEVANT	HISTORY			DSS
_	# Start/Stop Date	Condition Type / Condition	Notes		AUG 8 1 2006
	1 UNK	Historical Condition Light smoking and light			7144
	• • • • • • • • • • • • • • • • • • •	al∞hol use			nia anno anno anno anno anno anno anno a
-:		Procedure	1-Early autoly for 24 hours)	tic changes, diffuse (e	explanation-due to body lying in warm room
			2- Pulmonary	∞ngestion, marked (explanation- could be due to a number of
			unspecified re	asons)	onic inflammation, periportal (explanation-
			possible early	viral hepatitis)	
		Autopsy raport Course of	non-significan	t) Annie 1909 BAuti (ex	planation-although high, the head of the AUG 3 0 2006
		Autopsy report-Cause of			AUG 3 1 2006



Experience Report (continued)

sion of a report does not constitute ission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

	U.S. DEPARTMENT OF HEALT Public Health Service - Fo	H AND HUMAN SERVICES and Drug Administrator
	Mil Report #	007819
į	UF/Imparter Report #	

DSS

'AUG 3 1 2006

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			Page 3 of 4
		death-cardiac arrythmia, Manner of Death-Natural	
3	UNK	Historical Condition Annual exam- normal	Received Rx for OrthoTri-Cyclen Lo
4		Historical Condition	Received Rx for Sulfamethoxazole &Trimethoprim #6 Received Rx for Cipro 500 mg x3 (03/08/06) for continuing symptoms of UTI
	UNK	Urinary tract infection	referred to family MD for continuing symptoms of UTI
5	UNK	Historical Condition Chlamydia	
3	UNK	Historical Condition Herpes	
7	UNK	Historical Condition Clinic visit	Sore throat, congestion Temp 98, BP 98/54
3	UNK	Historical Condition Clinic visit	Symptoms of burning on urination/hematuria, started on prescribed.
)	UNK	Historical Condition LMP	
0		Historical Condition	Urinary tract infection, last dose of Cipro Pyridium and Macrobid prescribed.
	UNK	Clilnic visit	Bp 124/78
1		Historical Condition	Vaginal spotting, for past week. Just started new pack of Ortho Tri-Cyclen Lo-dysfunctional uterine bleeding secondary to Ortho Tri-Cyclen Lo and
	UNK	Clinic visit	antiblotics.
2		Historical Condition	Complaining of Flu symptoms. Temp 98.6, BP 96/56.
	UNK	Clinic visit	GualMax-D and Delsiyn prescribed (never filled as per family).

C1. Name (cont.)

Suspect Medication #1: Plan B(LEVONORGESTREL) Tablet, 0.75mg

Suspect Medication #2: ORTHO TRI-CYCLEN LO()

C2. Dose, frequency & route used (cont.)
Suspect Medication #1: 2 Tablet, single, Oral

C10. CONCOMITANT MEDICAL PRODUCTS

TYLENOL COLD MEDICATION (CHLORPHENAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE) 04/01/2006 to

AMPHETAMINE UNK to UNK VITAMINS UNK to UNK

AUG 3 0 2006



Experience Report (continued)

2 4

mission of a report does not constitute idmission that medical personnel, user racinty, importer, distributor, manufacturer or product caused or contributed to the event.

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VALTREX (VALACICLOVIR HYDROCHLORIDE) UNK to UNK CIPRO 03/08/2006 to UNK SULFAMETHOXAZOLE W/TRIMETHOPRIM (SULFAMETHOXAZOLE, TRIMETHOPRIM) 03/04/2006 to UNK

G8. ADVERSE EVENT TERMS (∞nt.)
Drug use for unknown indication, Arrhythmia, Metrorrhagia, Dysuria, Haematuria

Block C - Additional Dosage Regimens

Suspect Product 2. Dose, Frequency & Routé Used 3. Therapy dates

ed 3. Therapy dates 6. Lot # (if unknown, give duration) (if known)

7. Exp. Date wn) (if known)

#1 Plan B Regimen #2 2 Tablet, single, Oral 03/27/2006 to 03/27/2006

T54395C

UNK

DSS AUG 8 1 2006 S. Department of Health and Human Services

MEDWATCH

For VOLUNTARY reporting of adverse events, produc product use e

reporting of		FDA	USE DIALT	
t problems and	Triage unit sequence #			
TOUR				
SUSPECT PRODU	CT(S)			
Name, Strangth, Manufact #1 Levonorgestrel		Moduci seceli Moduci seceli	chter, Lt	d. and
e2 Duramed Pharma	ceutical	s, Inc.		Route
Dose or Amount		Frequency		
#1 0.75 m.g.		one time	นยe	oral
#2 0.75 m.g.		one time		oral
5. Dates of Use (If unknown best estimate)	, give durati	an) from 4a (ar		L Dote Hearicag
02/28/2006			at Yes	
#2 03/29/2006			#2 TYes	Ho Dogent
4. Diagnosis or Resson fo	r Use (India	stion)	B. Event Res	ppsared After
#1 Emergency Con	tracepti	ve	Reinfrodu	ction?
22 Emergency Con			N1 Yes	No Li Apply
	7. Explisi	on Date	#2 Yes	No Doesn't
6. Lot #			B. NDC # or	
<u> 11 </u>	<u> </u>		-	
12	12	UCE.	<u></u>	
E. SUSPECT MED	CAL DE	VICE		
1. Brand Name				
2. Common Device Nam	•			
3. Manufacturer Name, (Olly and Sta	10		
3.				
		ot #	7	5. Operator of Device
4. Model #	1			Health Professional
Catalog # Expiration Date (non/dd/yyyy) Lay User/Pate				Lay Usen/Patient
Π				Other:
Serial # Other #				
6. If implented, Give Di	te (markid)	7777) 7. If	Explanted, Giv	e Date (mm/dd/yyyy)
			and Reven	on a Patient?
8. In this a Single-use	Device that	WINE HODIOCOC	MI GOOD LINES .	
9. If Yes to Rem No. 8,	Enter Name	and Address	Reprocesso	
8. It Ass to tests up. a.				
· 1				Ţ
			N DEODU	TS.
F. OTHER (CO!	COMITA	owide bee	ment of event)	
		3~a 16 t	o event di	ate
Ortho Tricycl Tylenol cold	and sim	us 04/01/2	006 to ev	ent date
]]				
G. REPORTER	(See co	ntidentiality	section on	back)
1, Hurse and Address	3			
	يحاصي			
Pax:				
			mell	
Phone #				le die France de
2. Health Professio	nal? 3. 0c	cupation		4. Also Reported for
☐ Yes ☑ N	•	Healthcare Pro		Menutecturer User Facility
5. If you do NOT w	ent your ide	ntity disclosed	П	Distributor/Importer
to the manufacti	wer, place t		AL II	

he FDA Safety information and Page dverse Event Reporting Program A. PATIENT INFORMATION 4. Weight Petiant identifier 2. Age at Time of Event, or Date of Birth: 115 b · 7 Female ☐ Male in confidence ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Product Problem (e.g., defects/mattunctions) Product Use Error Problem with Different Manufacturer of Same Medicine . Outcomes Attributed to Adverse Event (Check all that apply) Disability or Parmanent Demage Death: _ (mm/dd/yyyy) Congunital Anomaly/Birth Defect Life-threatening Other Serious (Important Medical Events) Hospitalization - initial or prolonged

5. Describe Event, Problem or Product Use Error

). Date of Event (mm/od/yyyy)

Following 2nd time pills were taken on 3-29-06 patient experienced heavy menstrual bleeding, pelvic area was swollen, painful and inflamed starting 04/01/2006; chills, fever and headache started on 04/04/2006 and eventual death concern with lack of long tarm erody of sugment product easiety and possible term study of suspect product safety and possible serious side effects not adequately described in the product label or other materials.

4. Date of this Report (mar/dd/yyyy)

06/26/2006

Required Intervention to Prevent Permanent Impalment/Demage (Devices)

Patient was healthy prior to taking 2nd dose, and family and friends that knew her and saw her prior to her death are convinced that her death is directly related to her use of the drug.

6. Relevant Tests/Laboratory Data, including Dates

See attached autopsy report/blood toxicology screen

Other Relevant History, Including Preexisting Sedical Conditions (e.g., altergles, race, programcy, amoking and alcohol use, lived/sichey problems, etc.)

Light smoking and light alcohol use

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: Immirriment

ATTACHMENT ISR # 5095100-X DATE.



La LIVEU

DEPARTMENT OF PATHOLOGY

AUTOPSY REPORT

NAME:

AGE: 21

SEX: F

PROSECTOR: Assistant:

AUTOPSY NO:

DATE:

TIME: 8:30 am

CORONER: 1

ANATOMIC FINDINGS

1. Early autolytic changes, diffuse

2. Pulmonary congestion, marked

3. Hepatic congestion and mild chronic inflammation, periportal

TOXICOLOGY

Pseudoephedrine 1059 ng/ml (Ther 200-800)

CAUSE OF DEATH

Consistent with cardiac arrhythmia

MANNER OF DEATH

Natural

Forensic Pathologist

COMPLETED:



CIRCUMȘTANTIAL SUMMARY

. !

was a 21 year old white female found dead in her room at a Sorority on the morning of According to investigators from the Police Department and Coroner, she had been complaining of an upper respiratory infection and had visited the student health center. She had also apparently taken OTC cold medication, and remarked to a friend that she intended to take a large quantity of Adderal to help her finish a school project. No signs of foul play were noted at the scene. Due to the circumstances of the death, the Coroner was notified and an autopsy authorized.

DOCUMENTS AND EVIDENCE EXAMINED

Telephone and additional conversations with

IDENTIFICATION

On the second of

CLOTHING AND VALUABLES

The deceased is received wearing a black fleece jacket, black t-shirt, gray sweat pants, and white socks. Valuables included a white metal with white stone ring on the left middle finger, a small white metal nose stud in the left side, and a metal and plastic navel stud. A woven and plastic bracelet is on the left wrist and a green and blue braided bracelet is on the left ankle.

EXTERNAL EXAMINATION.

The body is that of a well developed, well nourished, white female adult appearing the stated age of 21 years. The body length is 62 inches and the estimated body weight is 125 pounds. Scalp hair is bleached blonde with dark roots. Jaundice is not present in the skin or sclerae.

The head is normocephalic. The irides are green and the sclerae are white. The pupils are equal in diameter. There are no contact lenses present and there are no conjunctival petechiae. The nose is normal. There is blood in the nares and mouth. Teeth are present. There is no denture. Oral hygiene is good. The ears are pierced.

There is no significant increase in the anteroposterior diameter of the chest. The breasts are symmetrical without palpable masses. The abdomen is not distended. The external genitalia are those of a shaved female adult. The anus is not dilated and has no evidence of injury. The extremities are symmetric and there are no significant deforming injuries.

The following scars, nevi and tattoos are present: there is a pigmented nevus on the right knee.

SIGNS OF DEATH: Rigor mortis is generalized and post mortem lividity is purple and fixed on the



anterior surface of the body.

ARTIFACTS: No artifacts of medical or post mortem care are present.

No artifacts of putrefaction are present.

INJURIES

No external or internal injuries are identified.

INTERNAL EXAMINATION

SEROUS CAVITIES: The body cavities are opened with a standard Y- shaped incision. The cranial cavity is opened with a coronal incision of the scalp and removal of the calvarium. An odor like alcohol is not apparent in the body cavities. The lungs are well aerated and fill the pleural cavities. There is no evidence of pneumothorax. There is no blood or effusion in either pleural cavity. There are no pleural adhesions. There is no blood or excess fluid in the pericardial sac. There is no evidence of pericarditis. There is no evidence of peritonitis. There is no blood in the peritoneal evidence of pericarditis. There is no evidence of the organs from the body, inspection of the serous cavity. There is no ascitic fluid. After removal of the organs from the body, inspection or pelvic cavities reveals no evidence of fracture of the ribs, sternum, clavicles, vertebral column or pelvic bones. Contusion hemorrhage is not present in the body walls.

NECK ORGANS: The larynx and trachea are in the midline. No significant hemorrhage is present in the skin, fat or sternocleidomastoid muscles of the anterior neck. The thyroid gland is symmetrical and composed of reddish-brown parenchyma.

There is no hemorrhage in the intrinsic muscles of the larynx. There is no obstruction of the respiratory tract in the nasopharynx, larynx or trachea. There is scant mucus in the larynx. The mucosa of the hypopharynx, larynx and trachea is smooth and glistening without ulceration or mucosa of the hypopharynx, larynx and trachea is smooth and glistening without ulceration or tumor. Cervical lymph nodes are appropriate for age. No fractures or dislocations of the cervical vertebrae are detected.

HEART: The 240 gram heart is in usual position with respect to the great vessels and chest cavity. The left ventricle is not significantly hypertrophied and the cardiac chambers are not dilated. On opening the aorta and pulmonary trunk, there is no evidence of air embolism and there is no evidence of pulmonary thromboembolism. There is no evidence of pericarditis. The circumflex coronary artery arises from the left main coronary. The coronary arteries are examined by multiple cross-sections. There is no significant atherosclerotic plaque in the major coronary arteries.

Thrombosis of the coronary arteries is not present. The cardiac valve leaflets are delicate. The circumferences of the cardiac valves are within normal limits for age and heart size. There is no softening or mottling of the myocardium due to recent myocardial infarction or necrosis. There is no myocardial fibrosis. There is no myocardial contusion. There are no defects in the atrial or ventricular septae. Autolysis is mild to moderate.

VASCULAR SYSTEM: The aorta and its main branches show mild yellow streak atherosclerosis. There is no evidence of aneurysm, coarctation, dissection or laceration of the aorta. The renal arteries are not stenotic.



LUNGS: The combined weight of the lungs is 1260 grams. The trachea is complete, without malformation, from the larynx to the carina. There is no aspirated gastric material and no aspirated blood in the trachea. The distal bronchi contain scant mucus. The pleural surfaces are smooth and glistening. No petechiae are visible. The lungs and hilar nodes are not significantly anthracotic and there is no bullous emphysema. On cut section, there is no aspirated blood apparent in alveoli. Pneumonia is not recognized. There is no focal consolidation and no tumor. There is mild passive congestion of the lungs. There is no evidence of pulmonary edema. There is no pulmonary contusion. Pulmonary thromboemboli are not present. There is no putrid gas cavitation.

LIVER: The 1410 gram liver has a smooth capsular surface. On cut section, the parenchyma is reddish-brown and has a lobular architecture. The liver is mildly passively congested. Metastatic tumor is not present. The hepatic duct is patent. The gallbladder is present. There are no gallstones. Autolysis of the liver is mild.

PANCREAS: The pancreas is appropriate in shape and size with respect to total body fat stores. On cut surface, it is lobular with interspersed fat without focal calcification, fibrosis, hemorrhage or fat necrosis. Autolysis is mild.

GASTROINTESTINAL SYSTEM: The esophagus is lined with glistening white mucosa. The stomach is coarsely rugated. The stomach contains 25 ml of particulate food matter. There is no odor like alcohol in the stomach. No pills or pill residues are present. There are no erosions or ulcers in the stomach or duodenum. The small bowel and colon are intact without perforation, diverticula or palpable tumors. The vermiform appendix is present.

SPLEEN: The 250 gram spleen is composed of red and white trabecular pulp. There is no laceration of the splenic capsule. Autolysis is not significant.

ADRENALS: Two adrenals are present with golden brown cortex and white medulla. No cortical nodules are present in either adrenal. Autolysis is not significant.

URINARY TRACT: The right kidney weighs 130 grams, the left kidney 110 grams. The two kidneys, ureters and bladder are present in their usual positions without dilatation. The kidneys are symmetrical in shape and size. The capsules strip from the cortices with ease and the cortical surfaces are smooth. On cut section, the cortex appears of ample thickness and the medulla appears surfaces are smooth. The kidneys are congested. There are no stones or tumors in the kidneys, pelves, ureters or ample. The kidneys are congested. There are no stones or tumors in the kidneys, pelves, ureters or bladder. Autolysis of the kidneys is not significant. The bladder contains scant yellow urine.

REPRODUCTIVE SYSTEM: The uterus, fallopian tubes and ovaries are present. They are of usual size and shape for age. No tumors are present. There is no evidence of current pregnancy.

CENTRAL NERVOUS SYSTEM: There is no hemorrhage in the scalp or galea. The dura, removed by stripping from the calvarium and base of the skull, shows no epidural or subdural hemorrhage. The cerebral and cerebellar hemispheres of the 1340 gram brain are symmetrical. The leptomeninges are transparent and can be stripped with ease. There is no subarachnoid hemorrhage. There is no flattening of the gyri and no widening of the sulci. The major vessels at the base of the There is no flattening of the gyri and no widening of the sulci. The major vessels at the base of the brain have a usual anatomic distribution and there is no significant atherosclerosis. The cranial brain have a usual anatomic distribution and there is no evidence of herniation at any of the portals of the nerves are symmetrical and intact. There is no evidence of contusion, edema, brain. On serial coronal sectioning of the brain, there is no evidence of contusion, edema,



hemorrhage, tumor, atrophy, infection or infarction in the cerebrum, cerebellum and brain stem. There are no fractures of the convexity or base of the skull. The craniocervical junction demonstrates a usual range of motion. The spinal cord is not examined.

PHOTOGRAPHS: Autopsy photography is taken by the Police Department and the County Coroner's Office.

SPECIMENS FOR FIREARMS EXAMINATION OR TRACE EVIDENCE: None.

SPECIMENS FOR TOXICOLOGY: Blood (central) and Urine.

MICROSCOPIC EXAMINATION

HEART: Heart sections are histologically within normal limits.

LUNGS: Pulmonary sections show congestion.

LIVER: Hepatic sections demonstrate the presence of mild periportal inflammatory infiltrates, chronic, without additional pathologic change.

SPLEEN: Splenic sections show depletion of white pulp elements..

ADRENALS: Adrenal sections are histologically within normal limits.

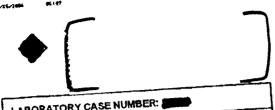
KIDNEYS: Renal sections are histologically within normal limits.

PANCREAS: Pancreatic sections show autolysis but are otherwise histologically within normal limits.

THYROID: Thyroid sections are histologically within normal limits.

CENTRAL NERVOUS SYSTEM: Representative CNS sections are histologically within normal limits.





LABORATORY CASE NUMBER:

Client Account

Physician:

Report To:

CORONER-IN

Subject's Name:

Agency Case #

Date Of Death:

Test Reason: Not given

investigator:

Date Received:

Date Reported:

Laboratory Specimen No:

Container(s) Received:

01: Red Top Bottle Blood, AUTOPSY

Date Collected:

70510

Test(s) Requested: Comprehensive Drug Panel (5508)

Analyte Name Result Cut-off Units Therapeutic Range Loc AMPHET AMINES POSITIVE 50 ng/mL Pseudoephedrine POSITIVE 50 ng/mL Pseudoephedrine. Quant 1059 1 ug/mL BARBITURATES Negative 150 ng/ml BENZODIAZEPINES Negative 20 ng/ml CANNABINOIDS Negative 50 ng/ml COCAINE/METABOLITES Negative 1 ng/ml FENT ANYL Negative 50 ng/ml METHADONE Negative 20 ng/ml OPIATES Negative 20 ng/ml OPIATES Negative 20 ng/ml OPIATES Negative 50 ng/ml OPIATES Negative 50 ng/ml PHENCYCLIDINE Negative 50 ng/ml PHENCYCLIDINE Negative 100 ng/ml PHENCYCLIDINE Negative 100 ng/ml SALICYLATES Negative 10 ug/ml TRICYCLIC ANTIDEPRESSANTS Negative 0.02 % (wh) STIMULANTS POSITIVE
Analyte Name AMPHET AMINES Positive Pseudoephedrine Pseudoephedrine. Quant Pseudoephedrine. Quant Pseudoephedrine. Quant Pseudoephedrine. Quant Pseudoephedrine. Quant Negative BENZODIAZEPINES Negative CANNABINOIDS Negative COCAINE/MET ABOLITES Negative Negative Negative Negative OPIATES OXYCODONE/MET ABOLITE Negative PHENCYCLIDINE PROPOXYPHENE SALICYLATES Negative Negative Negative Negative 100 ng/ml Negative 100 ng/ml Negative 100 ng/ml Negative 100 ng/ml Negative 100 ng/ml Negative 100 ng/ml Negative TRICYCLIC ANTIDEPRESSANTS Negative Negative
AMPHET AMINES Pseudoephedrine
Caffeine POSITIVE NARCOTICS Negative SEDATIVES/HYPNOTICS Negative ANTIDEPRESSANTS Negative ANALGESICS Negative Negative



H/25/396

Laboratory Specimen No:

Date Collected:

Test(s) Requested:

Container(s) Received: 01: Red Top Tube Vitreous

70570

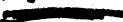
Autopsy Panel, Volatiles (550V1)

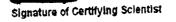
Loc Therapeutic Range Units Cut-off Result Analyte Name 0.02 % (w/v) Negative **ALCOHOLS** % (w/v) 0.02 Negative Methanol 0.02 % (WN) Negative Ethanol 0.02 % (w/v) Negative Acetone % (w/v) 0.02 Negative Isopropanol

The Specimen Identified by this Laboratory Specimen Number has been handled and analyzed in accordance with all applicable requirements.

Laboratory Case #: I

Print Date/Time:





Page: 2 of 2



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Subjective	
Chief Complain	ation: Ortho Tange to Shuperfor LMP: 2 wh
Current medic	ation: Ortho Trange 60 Shugerfu LMP: 2 wh
Med allergles:	NKDA CI:
General:	□ No Sx Fever of Fatigue of Myalgia □ Dizziness/lightheadedness A Headache (1 Appetite
Ears:	No Sx □ Pain - R L □ Fullness - R L □ Hearing loss - R L □ Popping - R L
Nose:	□ No Sx Stuffy © Drainage Sneezing □ Itching
Facial Pain:	No Sx Maxillary – R L Frontal – R L Between eyes Upper teeth Worse bending
Throat:	No Sx Pain Swollen glands Post nasal drainage Itching Scratchy
Chest:	□ No Sx (Cough - dry prod both □ SOB □ Wheeze □ Tightness □ Pain
PMH:	□ No Sx to Cough → dry prod both □ Sob □ Whitezer □ Hydrau / Cun foliary □ Asthma □ Abn Heart valve □ +PPD (Cigarettes _ ppd x _ yrs. □ Mono □ Envir Allergy
	□ Recurrent strep □ Flu shot □ H/O GERD □ H/O Ent Surgery
Other Hx:	At think are has Flu
-	
If PMHx of	Asthma complete section below.
	Age of onset date of most recent asthma episode Nighttime
	C. Activity. D. Posts infection. D. Other
	Derenal hest U Souce use
	Home PEF:
	☐ Anti-histamine ☐ Other ☐ Hospitalization ☐ Intubated ☐
<i>:</i>	() And-historiale () onto
	URI/ASTHMA FORM
	[\forall] = Present [] = Absent + PPD = Not asked or not applicable



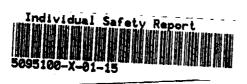
: Objective VS:	96 6 BP_Glot 18 P RRPEF Pred. PEF Distress - Rone mild mod sev [] O ₂ Sat(RA) .
Ear Canal:	R - OF NL Red Swollen Exudate Wax L - A NL Red Swollen Exudate Wax Red Swollen Retraction
Ear Drum:	n later Greet G Effusion G Retraction
Nasal:	□ NL □ Red □ Pale □ Swollen Scharge Color Clear □ Sinus tenderness
Throat:	□ NL □ Red □ Lymphold hypertrophy □ Ulcerations ☑ Discharge Color
Tonsils:	□ NL □ Absent Small □ Moderate □ Large □ Exudate
Neck:	NL Accessory muscle use Decreased ROM
Cerv. Nodes	: INL Enlarged CL Tender - R L AC I PC
Chest:	NL Wheezing Rales Rhonchi Clears w/cough Other
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Other PE	
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又 ASTHM	
plan C	TOBID!
del	sep- 10 ml 10 BID 1 BT De Ameline
🗇 Pt. edi	ucation given
Call if	not improving in / well - Appointment Asthma educ. Referral
) A	Fluids 🗆 Call for test results 🗀 Additional Dictation Signature
1	



Subjective	
Chief Complaint	pouthout congestation Today
Current medica	tion: arthor Tri Cycle Lo
Med allergies:_	NKDA CI:
General:	□ No Sx □ Fever A Fatigue Myalgia □ Dizziness/lightheadedness A Headache A Appetite
Ears:	No Sx Pain - R L D Fullness - R L D Hearing loss - R L D Popping - R L
Nose:	□ No Sx Stuffy S Drainage S Runny □ Sneezing □ Itching
Facial Pain:	□ No Sx □ Maxillary − R L □ Frontal − R L □ Between eyes □ Upper teeth □ Worse bending
Throat:	□ No Sx
Chest:	□ No Sx ★ Cough
РМН:	□ No Sx McCough Gird prod both □ SOB □ White 20 □ High Rest of the State of t
	☐ Recurrent strep ☐ Flu shot ☐ H/O GERD ☐ H/O Ent Surgery
Other Hx:	
	
If PMHx of A	sthma complete section below:
	Age of onset date of most recent asthma episode
	Resp Sx freq: Daytime Dighttime
	Trigger:
•	Home PEF:
	PIEVIOUS TA. III Steroid Statisticality
	□ Anti-histamine □ Other □ Hospitalization □ Intubated □
	11:48AM

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6 Present



ibjective S:	BP 54T 98 P RR PEF Pred. PEF Distress - none mild mod sev D O2Sat (RA)					
ar Canal:	R - NL Red Swollen Exudate Wax L - KNL Red Swollen Exudate Wax					
ar Drum:	R - NL Red Effusion Retraction					
lasal:	□ NL □ Red □ Pale □ Swollen SCDischarge Color_Clean□ Sinus tenderness					
hroat:	□ NL OXRed □ Lymphoid hypertrophy □ Ulcerations Dy Discharge Color Clean					
onsils:	□ NL □ Absent Small □ Moderate □ Large □ Exudate					
leck:	NL Accessory muscle use Decreased ROM					
lerv. Nodes:	□ NL OXEnlarged - QQ □ Tender - R L UXAC □ PC					
:hest:	NL U Wheezing U Rales U Rhonchi U Clears w/cough U Other					
ardiac:	NL D NE D Irregular rhythm D Irregular rate D Murmur Other					
)ther PE						
n-office Tx:	□ None □					
.ab/ Testing						
Assessment	nsillitis/Pharyngitis 🗆 Sinusitis 🗅 Acute bronchitis 🗅 Allergic rhinitis 🗅 Other					
] ASTHMA - □ acute exacerbation □mild intermittent □ persistent = mild moderate severe; □ OM = L R						
van busines D = PO BID #20						
	on given Handout Cold Influenza Vaccine					
Call if not in	mproving in / wk - Appointment Asthma educ. Referral					
) Push Fluid	S Call for test results Additional Dictation Signature					



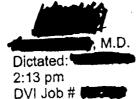
SUBJECTIVE: I saw on 1 and at that time she had had a cough for 4-5 days. I thought it was viral and symptomatic care was recommended. She was given a script for Tussionex to use at bedtime. She comes in today stating that the cough is more frequent. She has paroxysms of coughing, sometimes 20-30 minutes at a time, and sometimes will vomit after coughing. Occasionally there is some mucus produced, but it is mostly clear. She has noticed fatigue, does not know if she has had a fever. She still has some nasal congestion, but denies sinus pain. The patient has no history of asthma, but has used an inhaler before when she has been ill.

OBJECTIVE: Peak flow 400, predicted 430. She appears in no distress. TMs are normal. Nose real red with swollen turbinates. Throat clear. Neck no adenopathy. Chest has good expansion and clear to auscultation. No wheezes, rales or rhonchi heard.

ASSESSMENT: BRONCHITIS.

PLAN:

- 1. Z-Pak.
- 2. Advair 100-50, 1 puff b.i.d., #3.
- 3. She is to let me know if this not improving in 5-6 days.



J:	of To: PN Pt state Juntil 2- lak yesterlay Continues
	Alvain i juffhid - Not seeing quest ingurrenet. Still noting cough-
<u></u>	was it is love but undle to court us gotum. No fever Dilaret
	rest a great deal over weekend lucks rough. a segur consulted
	A. advised 2- lak at M working up to ~ 10 day. Continue Alvan + proff hid.
,— <u> </u>	tx Thrainer Typ 12 to 1 tay glo go cough -m refells. Non weit
<u> </u>	12. 1 + Cod all No Trans dedictors.
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A CONTRACT SAFETY REPORT

The FDA Safety Information and Adverse Event Reporting Program

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Ulfr Report #	
	CA-2006-03539
JF/Importer Report #	

A. PATIENT IN	FORMATION					C. SUSPECT MEDIC	ATION(S	1			PDA Use O
1. Patient Identifier	2. Age at Time of Event:	26 years	3.	Sex	4. Weight	1. Name (Give labeled st			known)		
	or Date	20 years	🛭	CD	XXDER	#1. Mirena(LEVONC	RGESTR	REL) (cor	ntinued)		•
in confidence	of Birth;	UNK		Male	UNK kas	#2.					
B. ADVERSE E	VENT OR PRO	DUCT PROB	LEM			2. Dose, Frequency & R	loute Used		3. Therapy	Dates (if	unknown, give duration) timate)
1. Adverse Eve				e.g., defects	/malfunctions)	#1. 20 (continued)		1	#1. UNK		
2. Outcomes Attrib	outed to Adverse E	vent				#2			#2.		
(Check all that a	pply)	☐ Di	isability			4. Diagnosis for Use (In	dication)		5.		bated After Use
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	n - initial or prolonge	od [] Ot	ther:			#2.	#2.		8.		eappeared After
3. Date of Event (n		4. Date	of This Re	port (mo/d 0/2006	ay/year)	9. NDC# (For product pro				Reintrod I. [] Ye	duction?
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5. Describe Event of Event Verbatim IF	or Problem PREFERRED TERM	() (Related symp	otoms if any	separated	hy commas)	10. Concomitant Medica	1 Beadwas	4 75		_	
ruptured cereb						No Concomitant Med	ication Ut	and inera NK to UN	ipy Dates (I K	:xclude ti	realment of event)
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in a 26 year-old	d female patie	nt who was	prescrib	ed levor	orgestrel	G. ALL MANUFACTI					
(Mirena, IUS).	This report wa	s received	on 14 No	ov 2006	from a	Contact Office - Name for Devices)	/Address (s	ind Manuf	acturing Si	æ	2. Phone Number +1 8882375394
patient and has	s not been ver	ified by a ph	nysician	or other	health care	Berlex Inc.					
professional.					!	Claudia Schoenig-D	-				
T					į	Director, Medical As					3. Report Source
There was no						Claudia_Schoenig@Berlex.com (Check all that apply) Fax: +1 973 487 2914					
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tolerated.	was not report	eu ir iviirema	was use	a previo	usiy and	Montville, NJ 07045	i-1000 U	NITED S	TATES		Study
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On an unspeci	ified date the p	oatient recei	ived the	first dos	e of	4. Date Received by	5.				Consumer
levonorgestrel	(Mirena) at 20	µg/day, cor	nt via inti	ra-uterin	e route of	Manufacturer(mo/day/y)NDA#U	S:NDA 21	-225	Heelth Professional
administration (11/14/2006 IND # User Facilit					Uses Seeling
continued in ad	iditional info s	ection			İ	6. If IND, Give Protocol #	}				_
6. Relevant Tests/Li	aboratory Data, In	cluding Dates		·····				LA#			Company Representative
NI					ŀ	7. Type of Report	م ا	re-1938	Yes		Distributor
	•					(Check all that apply)	g	TÇ	☐ Yes		Other:
						5-day 15-day	ļ				
					1	10-day Periodic			erebral a		n
						☐ Initial ☐ Follow-up	*			•	
						9. Manufacturer Report N	umber				
7. Other Relevant Hi	istory, including P smoking and alcoho	reexisting Medi	ical Conditi	lons (e.g. a	Mergies,	CA-2006-035391					
NI	amonally and accord	a deat troperactive	гна оуыолс	suori, etc.)		E. INITIAL REPORTE	B				
						1. Name and Address	K				
						Name and address	withheld	Phon	• # Withh	eld	
										DS	SS
						N.			A 14		
	Submission of a	anot doss set	constitut-	an admire	ion that			*********	N(JV 2	2 2006
	Submission of a r medical personne caused or contrib	d, user facility,	distributor,			2. Health Professional?	3. Occup	∎tion nv sales			itial Reporter Also ent Report to FDA

representative

☐ Yes ☐ No 🔯 Unk

Yes No

a report does not constitute tat medical personnel, user comp, composition, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 2

Berlex Inc. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service - Food and Drug Administration

Public Health Service - Food and Drug Administration
Milr Report # CA-2006-035391

Ulf Importer Report #

FDA Use Only

Experience Report (continued)

Additional Information

B5. EVENT DESCRIPTION (cont.)

On an unspecified date the patient developed a ruptured cerebral aneurysm, resulting in death.

The patient died from ruptured cerebral aneurysm. It was not reported if an autopsy was performed. Death occurred on an unspecified date, after treatment with Mirena was started.

The dosage of Mirena was not changed. Dechallenge for Mirena was not applicable. Rechallenge for Mirena was not applicable.

Further information will be requested by the sales representative.

C1. Name (cont.)

Suspect Medication #1: Mirena(LEVONORGESTREL) IUS

C2. Dose, frequency & route used (cont.)

Suspect Medication #1: 20 µg/day, cont, Intra-utenne

DSSNOV 2 2 2006

ment of Health and Human

MEDWATC..



Releys Int	emelional,	Inc., FDA	Facelmile	Approvet;	11-JUN-1	999

Mfr Report #	
	012396
UF/Importer Report #	
	FOA Use Only

The FDA Safe	-					_
Adverse Even		, co B c s c	n			Р
A. PATIENT INF	ORMATION					
t. Patient Identifier	2. Age at Time of Event:	31 Y	'ears	- 1	Sex	4. Weight UNK 16
	or			_]⊵	Female	
in confidence	Date of Birth:			,	Male	UNK kg
B. ADVERSE EV	ENT OR PRO	DUCT	PROBLE	M		
1. Adverse Ever	nt and/or		Product Pr) melda	s.g., defect	s/malfunctions)
2. Outcomes Attribu (Check all that ap		Event	☐ Disa	bility		
Death Death			Cong	genital A	nomaly	
Life-threatening	(mo/day/yr)				ervention to	
Mospitalization	- initial or prolong	je d	Othe			
3. Date of Event (m	o/day/year)		4. Date of		port (mo/ 4/2007	day/year)
5. Describe Event of Event Verbetim [P Stroke[Cerebro Passed out[Los Blood clot in ne Multiple blood of Pressure in bra Swelling of brai	REFERRED TER evascular acc ss of conscio eck[Thromboack] dots in brain ain[Intracrania	cident] usnes sis] [Cereb al pres	s] oral thror	nbosis	s]	f by commas)
Case Description Information was prescribed Sea oral contracept reported the paunspecified data blood clot in he brain causing s	s received re isonique (levi ion. Therapy itient passed te. At the hos ir neck. It wa	onorge y dates out ar spital, as disc	estrel, et s and do nd was to it was di overed t	hinyl e sages aken t iscove he clo	estradiol are unk o the ho red the t had sp) tablets for known. It was spital on an patient had bread to her

surgery to relleve the pressure on her brain by having the continued in additional info section... 6. Relevant Tests/Laboratory Data, Including Dates 7. Other Relevant History, including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

01 2				FDA Use Only	
C. SUSPECT MEDICA	TION(S)				
1. Name (Give labeled stre	ngth & mfr/labeler.	if known)			
#1. Seasonique(LEVONORGESTR (continued)					
		00110100	-		
#2.					
2. Dose, Frequency & Ros	ite Used	3. There	py Date	s (if unknown, give duration) t estimate)	
#1. UNK, UNK, Oral		#1. UN			
#2.		#2.			
4. Diagnosis for Use (India	*			nt Abated After Use oped or Dose Reduced?	
#1. Oral contraception				Yes No Apply	
#2, 6. Lot # (if known) 7.	Exp. Date (if kno	·***			
	•	****,	#2.	Yes No Doesn't	
#1. UNK #	1. UNK		R Eve	nt Reappeared After	
#2. #:	2.		Rein	troduction?	
9. NDC# (For product probl	ems only)		#1.	Yes No Apply	
			#2.	Yes No Doesn't	
1					
10. Concomitant Medical	Products and The	erapy Date	s (Exclu	de treatment of event)	
141					
G. ALL MANUFACTU			04-	14 Ab Number	
Contact Office - Name/A for Devices)	Wordes (and Man	uracturing	ane	2. Phone Number 2019303446	
Barr Laboratories					
Anthony Oladipo, Ph	armD, MPH				
VP, Drug Safety and	Risk Manager	nent		3. Report Source	
400 Chestnut Ridge				(Check all that apply)	
Woodcliff Lake, NJ 0	7677 -7668 U	NITED S	TATES	Foreign	
				Study	
				Literature	
4 Data Received by	5.			Consumer Consumer	
4. Date Received by Manufacturer(mo/day/yr)		21-840		Health Professional	
04/11/2007					
6, If IND, Give Protocol #	IND#			User Facility	
	PLA#			Company Representative	
7 7	Pre-1938		3	Distributor	
7. Type of Report (Check all that apply)	i	_		Other:	
5-day 🕅 15-day	OTC Product		•		
	8. Advers	e Event To	erm(s)	.1	
10-day Periodic				nt, Loss of	
☐ Initial ☐ Follow-up	#conscio	ușness, 1	Chromb	osis, Cerebral	
9. Manufacturer Report Nu				pressure	
012396	continue	ed in addi	tional i	nfo section	
1	ļ				
E. INITIAL REPORTER	₹				
1, Name and Address		none# U	NK		
	Ľ.				
UNITED STATES					
2. Health Professional?	3. Occupation			4. Initial Reporter Also Sent Report to FDA	
	Consumer				
Yes 🔀 No				Yes No 🛭 Unk	

APR 2 5 2007.

DSS

Experience Report (continued)



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administrative

FDA Use Only

# Report #	 	
		012396
JF/Importer Report #		

Page 2 of 2

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-			ш	1117	,	FBF	ш	111	M 5	ш	

B5. EVENT DESCRIPTION (cont.)

right half of her skull removed. It was reported the patient was induced into a coma to stop the blood flow and three unspecified surgeries were performed. Multiple clots were found on the left side of her brain. The brain swelling continued and the patient was on life support. She subsequently died on the left side of death was stroke. Additional information was requested.

MedWatch Case Comment:

Submission of this 15-day report does not constitute an admission that the reported event is an unlabeled event.

C1. Name (cont.)

Suspect Medication #1: Seasonique(LEVONORGESTREL, ETHINYLESTRADIOL) Tablet

G8. ADVERSE EVENT TERMS (cont.) increased, Brain oedema

APR 2 5 2007

The FDA Safety Information and

Y reporting of uct problems and e errors

Triage unit sequence s

Adverse Event Reporting Program	Page 1 of 1 (900)
A. PATIENT INFORMATION	D. SUSPECT PRODUCT(S)
- 20vo 17 vote 9	hight 1. Name, Strength, Manufacturer (from product label) 150 b kg Seasonale
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	12
Check all that apply:	2. Dose or Amount Frequency Route
Adverse Event Product Problem (e.g., delects/mailunctions) Product Use Error Problem with Different Manufacturer of Same Me	edicine #2
2. Outcomes Attributed to Adverse Event	
(Check all that apply) [7] Death: Disability or Permanent Damage (mm/dd/yyy)	3. Dates of Use (If unknown, give duration) from/to (or bast astimate) 1 11/05-1/1/06 (5-6 wks)
Life-threatening Congenital Anomaly/Birth Defe	Description of the control of the co
Hospitalization - initial or prolonged Other Serious (Important Medic	4. Diagnosis of Reason for Use (Indication)
Pequired Intervention to Prevent Permanent (mpelment/Damage (Devices)	8. Event Respected After 8. Event Respected After 8. Event Respected After
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyy) 07/20/2007	#1 Yes No Doesn't Apply
5. Describe Event, Problem or Product Use Error	6. Lot # 7. Expiration Date #2 Type Tipe Toosan't
Safety Evaluator Follow-up Report for ISR#	#1 P1 P1 P1 P1 P1 P1 P1 P1 P1 P1 P1 P1 P1
5060812-0-00-01. Contact Providing Pollow-up information:	#2 #2
(consumer). Date contacted:	
11/27/2006. PT term from original ISR:Deep voin thrombosis. Follow-up information: Started Seasons	·
	2. Common Device Name
complications. Brought to ER & pronounced dead. St	ne l
went on a long plane flight on her honeymoon previously been on long plan flights (Africa, Chir with no problems. Attachment: follow-up letter.	13. Manufecturer Name, City and State
الله الله الله الله الله الله الله الله	4. Model # Lot # 5. Operator of Device
E	Health Professional
<u> </u>	Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient
	Serial # Other # Other:
PLEASE TYPE	8. If Implented, Give Date (mm/dd/yyyy) 7. If Explanded, Give Date (mm/dd/yyyy)
II.	8. is this a Single-use Device that was Reprocessed and Reused on a Patient?
	9. If Yes to Item No. 8, Enter Name and Address of Perrotes for V
6. Relevant Teste/Laborstory Data, including Dates	JUL 2 3 2007
	MEDIMATORIOTI
	MEDWATCH CTU
	F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
	Product names and therapy dates (exclude treatment of event)
	None
 Other Relevant History, including Preexisting Medical Conditions (e.g., allengrace, pregnancy, smoking and sloohol use, liver/kidney problems, etc.) 	G. REPORTER (See confidentiality section on back)
No previous pregnancies, births or complications.	No 1. Name and Address
family history of clotting events. in 'perfect hea	U.S.
• • • • • • • • • • • • • • • • • • • •	1
	Phone # E-mail
	2. Health Professional? 3. Occupation 4. Also Reported to:
C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA)	Yea No Manutecturer
	5. If you do NOT want your identity disclosed User Facility
Yes No Returned to Manufacturer on:	

FORM FDA 3500 (10/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

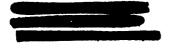
DSS



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration Silver Spring, MD 20993 September 11, 2006



RE: Case Number

Dear Ms.

I recently received a report you submitted to MedWatch of fatal deep vein thrombosis associated with the use of Seasonale. Additional clinical information would be useful in evaluating your report; to assist you in making your response, a copy of the report is included. The privacy of reporting persons and institutions as well as patients is protected from public disclosure. For your convenience, space has been provided for any information that is available on the following subjects; alternatively, providing a copy of the hospital discharge summary (if you were hospitalized) or any other relevant medical records would be appreciated. Or, you may ask your health care provider to complete this letter.

1. What were the exact dates of Seasonale therapy in relation to the adverse event?

My day ghter States taking Seasonale in Nov. 2005 - She

died was your daughter receiving other drugs concomitantly? If so, please provide the dates of

therapy and the indication for use for these drugs.

She was on no other drugs.

3. If your daughter previously used hormonal contraceptives, please list the brand names, dates of therapy and reason for discontinuation.

buth cartral. She used no previous

4. Please list your daughter's previous gynecologic history, including the number of pregnancies, the number of births, and any complications during pregnancy.

pregnancies, bioths or complications of any kind.

5. How was the deep vein thrombosis diagnosed and treated?

She was brought into the ER + pronounced dead.



6.	Does your daughter have any previous history of clotting events? Is there a family history of
	colotting events? There is no family history & my daughter was in perfect health as bou as we knew.
	was in perfect health as how agree 100000
•	ou so we when.

7. Does your daughter have any other medical history that might be relevant to this event? Please provide your daughter's height and weight.

She was 5'7''

Bo pas so beautiful!

8. Did your daughter have any prolonged travel, physical trauma, bed rest or inactivity prior to the event? Please describe her smoking history.

She what on a long plane light on her long house on the house previous long plane lights (africa, China) with no problems.

I appreciate your assistance and am truly interested in as much of the requested information as you can provide. You may provide your response via facsimile at 301-796-9721 or <u>mail at the address listed below</u>.

1.

Sincerely yours,

Pharm.D.
Food and Drug Administration

Food and Drug Administration
Office of Drug Safety
10903 New Hampshire Ave Bldg
WO22 Rm 3487; Mallstop 3411
Silver Spring, MD 20993-0002

10:24 PAGE 2/3 RightFAX 11/11/99 Wyeth Ayers: HOLVICOAL SATULY RODOL Page: 1 ot 2 ADVERSE EXPERIENCE REPORT REACTION INFORMATION CHECK ALL APPROPRIATE TO ADVERSE REACTION 2. DATE OF BIRTH 4-6 EXPERIENCE I PATIENT 2a. AGE la COUNTRY UNITS INITIALS 27 Yr 0.0 UNK 1999 7 DESCRIBE EXPERIENCE(S) PATIENT DIED INTRA-UTERINE DEATH; Unintended pregnancy; Multiple pregnancy Information was received on 03-Nov-1999 from a healthcare professional via Schering AG Germany concerning a 27 yr old female patient. The patient's concurrent history includes Multiparity. Therapy with MICROGYNON (equivalent to Nordette-21) (1 tablet daily) for Contraception NOS began in FEB-1999 and ceased on 8-OCT-1999. Concomitant therapy included NONE. The patient became pregnant (Unintended pregnancy) with triplets in SEP-1999 and death of one embryo (Intra-uterine death) was suspected. An Ultrasound antenatal screen confirmed a gestational age of 4-5 weeks. Schering Ref. #-99/00886-CDS. INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY LIFE THREATENING NONE OF THE ABOVE 13 RELEVANT TESTS/LABORATORY DATA RECOVERED See following page. SUSPECT DRUG(8) INFORMATION 20. DID REACTION ABATE 14 SUSPECT DRUG(S) (INCLUDE ACTIVE SUBSTANCE(S)) * NORDETTE-21 TABLET (LEVONORGESTREL, ETHINYL ESTRADIOL) AFTER STOPPING DRUG? YES NO X NA 16. ROUTE(S) OF ADMINSTRATION 15 DAILY DOSE(S) #1 1 Tablet 1x per 1 Day 21. DID REACTION REAPPEAR 17 INDICATION(S) FOR USE AFTER REINTRODUCTION? #1 Contraception NOS YES NO X NA 19. THERAPY DURATION 18 THERAPY DATES (FROM/TO) #1 CC-Feb-1999 / 08-Oct-1999 #1 8 Mth CONCONITANT DRUG(S) AND HISTORY 22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event) (DAMOYR) NONE, Unknown (cont'd. 23 OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.) CONCURRENT CONDITIONS: FREGNANCY: LMP: 10/08/1999 IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER 24a, NAME AND ADDRESS OF MANUFACTURER (Include Zip Code) OTHER REFERENCE NUMBERS: Business Partner (BP) (via Schering AG) - 99/00886 WYETH LABS (RA) 170 Radnor Chester 3c. Davids, PA 19087 24b, MFR CONTROL NO. HQ4 57 230 4 NOV 1999 Local Marketing No NDA 18-668 ぶんしいしょ かん ノム 24d. REPORT SOURCE 24c DATE RECEIVED CONSUMER STUDY BY NOV 1 2 1993 REGULATORY AUTHORITY MANUFACTURER LITERATURE HEALTH X PROFESSIONAL X LICENSE 33-Nov-1999 25m. REPORT TYPE NOV1 1 1999 FOLLOWUP X INITIAL

DATE SENT TO FDA

Wyeth Ayus India	Sarety Report	_	0:24	PAGE	3.	/3	F	ligh	tF/	X	_		P	'age:	2	of
• 33 36.		;		·												
ADVERS	RIENCE REPORT	•			1			T	T	Τ	Τ	Τ			T	T
anulacturer Con.	HQ4572304NOV1999	····	· ····································										-			
Box # 13 - 181.	ESTS/LABORATORY DATA		(Contin	uation)								········				
Test Name Dat:	R esult				Nor	mal	Rang	<u>le</u>				,				
Ultrasouri . 00-00	:1 screen Gestational age is 4-5 y	veeks.										•				
ox ∤ 23 – C ::.	JANT HISTORY	(Co	ntinuati	.on)								·				
Conception D Delivery Dat																
Confirmat:60	: Ultrasound															
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Adverse Event Reporting System (AERS)

ISR Information Report for ISR #(s)

5337347-0

STEPPER Date Run: Run by:

06/01/2008

Total ISRs:

FDA - Adverse Event Reporting System (AERS)

ISR Information Report for ISR #5088172-X

•	•				
ation:	5088172-X	5926485	Expedited (15-Day)	FDA Rcvd. Date: 08/24/2006	НО
ISR Information:	ISR#:	Case #:	ISR Type:	FDA Revd. D	Outcome(s): HO

Initial or Follow-up ISR:	Verbatim Follow-up #:
	٠
Yes	Yes
Best Rep. ISR:	eSub ISR:

Information.	AMIOI MEGIOTIC
Manufacturer	

ABBOTT Sender Mfr:

Follow-up

GB-ABBOTT-05P-167-0317426-00 Mfr. Rcvd. Date: 08/15/2006 Mfr. Control #:

Primary Suspect (A)NDA/PLA #:

Reporter Information: Patient Information:

Patient ID: UNKNOWN

Reporter Name:

77.45 YR

Female Gender: DoB: Age:

65 Kilogram

Reporter Phone:

Reporter Zip:

Reporter Street: Reporter Org.:

Reporter City: Health Prof.:

05/05/2005

Event Start

Date:

Weight:

YES

Reporter Country: Reporter State:

Occupation: OTHER HEALTH PROFESSIONAL

UNITED KINGDOM

Therapy End Date Therapy Start Date 05/09/2003 RHEUMATOID Indication(s) NDC# Lot# Route Dosage Text Role Product(s) HUMIRA

ReC

DeC

1st Dose to Event Interval

SUBCUTANEOU UNKNOWN S

ARTHRITIS

ReC

ACTH STIMULATION TEST ABNORMAL

Reaction(s)

BLOOD POTASSIUM INCREASED

Relevant Laboratory

Result 165

Body height

Potassium

05/05/2005 05/05/2005

Test Name

Test Date

Unit Ğ

Normal Low Range

Normal High Range

Info Avail Y/N

Relevant Medical History

The patient has a history of rheumatoid arthritis since 1993, hypertension since 1996, and peptic ulcer disease since 2003. BSRBR patient number: 0002999 Long Synacthen test

Increased

06/01/2008

Continuing

End Date

Start Date

Disease/Surgical Procedure

HYPERTENSION

PEPTIC ULCER

Medical History Product(s)

Start Date

Reaction(s)

Event/Problem Narrative

End Date

Indication(s)

FILED SYRINGE therapy for rheumatoid arthritis. On the patient was hospitalized for increased blood potassium level and long synacthen test. The events of increased blood potassium level and long synacthen test were not related to HUMIRA PRE-FILLED SYRINGE therapy. Follow-up information received on 15 Aug 2006: This case was determined to be a duplicate of AER 06P-167-0339103-00, which will be invalidated. Information from both cases will be combined into this case. Report from the United Kingdom of increased blood potassium level and long synacthen test coincident with ADALIMUMAB (HUMIRA PRE-FILLED SYRINGE) therapy. On 09 May 2003, the patient began HUMIRA PRE-

Study Report?:

Study Name: Study Type:

Sponsor Study #:

Protocol #:

Literature Text:

FDA - Adverse Event Reporting System (AERS)

ISR Information Report for ISR #5337347-0

ISR Information:	mation:					Manufacture	Aanufacturer Information:
ISR#:	5337347-0		Best Rep. ISR:	No	Initial or Follow-up ISR: Initial	Sender Mfr:	BERLEX
Case #:	6321897	,	oC.,h ICD.	\ \ \ \	V/		223010 2000 aa aiis aa
ISR Type:	ISR Type: Expedited (15-Day)		cono row.	3	verbattii follow-up #:	Mir. Control #:	MIT. Control #: BK-SHK-BK-200/-0189//
FDA Revd.	FDA Rcvd. Date: 05/29/2007					Mfr. Rcvd. Date: 05/22/2007	. 05/22/2007
Outcome(s): DE	: DE					Primary Suspect (A)NDA/PLA #:	021225

	Reporter State:	Reporter Country: BRAZIL	Occupation: CONSUMER OR OTHER NON HEALTH PROFESSIONAL
Reporter Information: Reporter Name:	Reporter Org.: Reporter Street:	Reporter Zip: Reporter Phone:	Reporter City: Health Prof.: NO Occupation: CONSU PROFE
Patient Information: Patient ID:	Age: 41 YR DoB:	r: Female	weignt: Event Start Date:

Product(s)	Role	Dosage Text	Route	Lot#	NDC#	Indication(s)	Therapy Start Date	Therapy End Date	Interval 1st Dose	DeC ReC	ReC
MIRENA	ď	20 Âμg/day, cont	INTRA- UTERINE				09/01/2002				
Reaction(s) DEATH				ReC							÷
Relevant Laboratory											
Test Date	Test Name		Result	<u>.</u>	Unit	Normal Low Range		Normal High Range		Info Avail V/N	

Reaction(s) Comment Continuing Indication(s) End Date End Date Start Date Start Date Disease/Surgical Procedure Medical History Product(s)

Relevant Medical History

This report describes the occurrence of unspecified death in a 41 year-old female who had levonorgestrel (Mirena, IUS) inserted. This report was received on 22 May 2007 via patient support program from a company representative and has not been verified by a physician or other health care professional. The company became aware of this case after receiving back the patient support program magazine from the Post Office. They informed that it could not be delivered because the patient died. There was no medical history, concurrent conditions or concomitant medications reported. It was not reported if Mirena was used previously and tolerated. In Sep-2002 the patient received the first dose of levonorgestrel (Mirena) at 20 µg/day, cont via intra-uterine for an unspecified date the patient experienced unspecified death. The patient died from Event/Problem Narrative

06/01/2008

Page

unspecified death. It was not reported if an autopsy was performed. Death occurred on an unspecified date, after treatment with Mirena was started.

Study Report?:

OTHER STUDIES Study Name:
Study Type:
Sponsor Study #:

Protocol #:
IND #:

Literature Text: