

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	
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

*Levonorgestrel
(FDA - more cases are being reported)*

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	
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	
5/20/2003 4114540-6	Uterine rupture	Mirena	25
5/28/2003 4119350-1	Uterine rupture	Mirena	
11/29/1997 3002759-7	Blindness	Trigoo	25
11/26/1997 3002759-7	Renal Artery-Blindness	Trigoo	
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	
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	42
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	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	

Levonorgestrel

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

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	
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	
5/20/2003	4114540-6	Uterine rupture	Mirena	25
5/28/2003	4119350-1	Uterine rupture	Mirena	
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	
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	42
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	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	

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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

12/1/1997	3058004-X	Triphasil-28	Pulmonary Embolism	
12/17/1997	3011767-1	Tri Levlen	Pulmonary Embolism	21
1/27/1998	3092371-6	Alesse	Pulmonary Embolism	38
2/6/1998	3110645-7	Norplant	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
6/8/1999	3278037-8		Ectopic	
6/14/1999	3282670-7	Norplant	Ectopic	19
6/23/1999	3289826-8			23
6/30/1999	3295104-3	Norplant	Ectopic	39
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	4150560-9	Levonell-2	Ectopic	35
8/19/2003	4174717-0	Mirena	Ectopic	38
8/28/2003	4181339-4	similar Plan b	Ectopic	

Levonorgestrel

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	
9/2/2005 4764187-3	Plan b	Ectopic	28
5/10/2006 4999818-6	Plan b	Ectopic	27

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

CERTIFICATE OF DEATH

Registration District No. 060-95 Local No. 2006003714

1. DECEDENT'S NAME (First, Middle, Last) NIKITA D SMOOTHORSON		2. SEX F	3. DATE OF DEATH (Month, Day, Year) August 10, 2006
4. SOCIAL SECURITY NUMBER 581-94-5037	5. AGE—Last Birthday (Years) 30	6. UNDER 1 YEAR Months Days	7. UNDER 1 DAY Hours Minutes
8. WAS DECEDENT EVER IN U.S. ARMED FORCES? (Yes or No) NO		9a. PLACE OF DEATH (Check only one) HOSPITAL: <input type="checkbox"/> Inpatient <input type="checkbox"/> ER/Outpatient <input type="checkbox"/> DCA OTHER <input type="checkbox"/> Nursing Home <input type="checkbox"/> Residence <input type="checkbox"/> Other (Specify)	
10. FACILITY NAME (If not institution, give street and number) CMC -UNIVERSITY		11. CITY, TOWN, OR LOCATION OF DEATH Charlotte	12. INSIDE CITY LIMITS? (Yes or No) Yes
13. COUNTY OF DEATH Mecklenburg Co.		14. MARRIAGE STATUS—Married, Never Married, Widowed, Divorced (Specify) Divorced	
15. SURVIVING SPOUSE (If wife, give maiden name)		16. DECEDENT'S USUAL OCCUPATION (Give kind of work done during most of working life. Do not use retired.) Park Entertainer	
17. KIND OF BUSINESS/INDUSTRY Amusement Park		18. RESIDENCE—STATE NC	
19. COUNTY Mecklenburg		20. CITY, TOWN, OR LOCATION Charlotte	
21. STREET AND NUMBER 6630 Pinta Court		22. INSIDE CITY LIMITS? (Yes or No) Yes	
23. ZIP CODE 28227		24. Was Decedent of Hispanic Origin? (Specify Yes or No. If yes, specify Cuban, Mexican, Puerto Rican, etc.) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Specify)	
25. RACE—American Indian, Black, White, Etc. (Specify) Blk		26. DECEDENT'S EDUCATION (Specify only highest grade completed) Elementary/Secondary (0-12) College (13-17+) 17+	
27. FATHER'S NAME (First, Middle, Last) Klevin Stouffer		28. MOTHER'S NAME (First, Middle, Maiden Surname) Sheila Moody	
29. INFORMANT'S NAME (Type/Print) Sheila Moody		30. MAILING ADDRESS (Street, City or Rural Route Number, City or Town, State, Zip Code) 753 Chris Dr, Mooles, NC 28082	
31. DATE AMENDED		32. Part I. Enter the diseases, injuries, or complications that caused the death. Do not enter the mode of dying. If appropriate, enter tobacco, alcohol, or drug use. List only one cause on each line. (PRINT or TYPE)	
33. IMMEDIATE CAUSE (Final disease or condition resulting in death) a. Pulmonary Emboli		34. DUE TO (OR AS A CONSEQUENCE OF):	
35. SEQUENTIALLY list conditions if any, leading to immediate cause. Enter UNDERLYING CAUSE (Disease or injury that initiated events resulting in death) LAST. b. Oral Contraceptive Use		36. DUE TO (OR AS A CONSEQUENCE OF):	
37. Part II. Other significant conditions contributing to death but not resulting in the underlying cause given in Part I, such as tobacco, alcohol, or drug use, diabetes, etc.		38. AUTOPSY? (Yes or No) If yes, were findings considered in determining cause of death?	
39. Was case referred to Medical Examiner? (Yes or No)		40. TIME OF DEATH	
41. NOTICE: STATE LAW REQUIRES THAT ALL DEATHS DUE TO TRAUMA, ACCIDENT, HOMICIDE, SUICIDE, OR UNDER SUSPICIOUS, UNUSUAL OR UNNATURAL CIRCUMSTANCES BE REPORTED TO, AND CERTIFIED BY A MEDICAL EXAMINER ON A MEDICAL EXAMINER'S CERTIFICATE OF DEATH. ANY DEATH FALLING INTO THESE CATEGORIES IS WITHIN THE MEDICAL EXAMINER'S JURISDICTION REGARDLESS OF THE LENGTH OF SURVIVAL FOLLOWING THE UNDERLYING INJURY.			
42. SIGNATURE AND TITLE OF CERTIFIER C. Dutton M.D.		43. DATE SIGNED (Month, Day, Year) 08/28/2006	
44. NAME AND ADDRESS OF PERSON WHO COMPLETED CAUSE OF DEATH (ITEM 20) (Type or Print) P.O. Box 560737 Charlotte, NC 28256			
45. METHOD OF DISPOSITION <input checked="" type="checkbox"/> Burial <input type="checkbox"/> Cremation <input type="checkbox"/> Removal <input type="checkbox"/> Donation <input type="checkbox"/> Other		46. PLACE OF DISPOSITION (Name of cemetery, crematory, or other place) Rutherford Park Cemetery	
47. LOCATION—City or Town, State, Zip Code Concord, NC		48. NAME OF FUNERAL DIRECTOR W. H. Bryant	
49. LICENSE NUMBER 1890		50. NAME OF EMBLIMER W. H. Bryant	
51. LICENSE NUMBER 1079		52. REGISTRAR'S SIGNATURE Earl Andrew Mobley MD	
53. DATE FILED (Month, Day, Year) 28 AUG 30 2006		54. REGISTRAR'S SIGNATURE W. H. Bryant	

UNOFFICIAL

DHHS 1872
Revised 3/03
Review 3/08
VITAL RECORDS

over

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.

A. Patient Information			
1. Patient identifier [REDACTED]	2. Age at time of event: 19 YR or Date of birth: Unknown	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
In confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> life-threatening	<input type="checkbox"/> required intervention to prevent permanent impairment/damage	<input checked="" type="checkbox"/> other: serious	
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> recovered		
3. Date of event (mo/day/yr) 04 / 10 / 97	4. Date of this report (mo/day/yr) 06 / 25 / 97		
5. Describe 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 relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
None provided			

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.) #2			
2. Dose, frequency & route used #1 1 TABLET ONCE DAILY ORAL #2		3. Therapy dates (if unknown, give duration) #1 1 YEAR #2	
4. Diagnosis for use (indication) #1 Unknown #2		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)			
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) WYETH-AYERST LABORATORIES 170 RADNOR CHESTER ROAD ST. DAVIDS, PA. 19087 KAREL F. BERNADY, PH.D.		2. Phone number (610) 902-3760	
4. Date received by manufacturer (mo/day/yr) 06 / 24 / 97		5. (A)NDA # 19-192 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
6. If IND, protocol #		3. Report source (check all that apply) <input checked="" type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #		8. Adverse event term(s) CEREBRAL THROMBOSIS VOMITING DIARRHEA HEADACHE	
9. Mfr. report number 8-97176-003N			

E. Initial reporter			
1. Name, address & phone # [REDACTED] FRANCE 4			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation N/A	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> unk	

DATE SENT TO FDA
NOV 25 1997 19970380

WYETH
RECEIVED AT DRUG SAFETY SURVEILLANCE

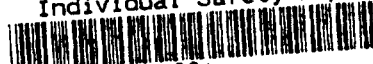


01-DEC-1997-2085

N

ICAL 1

Individual Safety Report



3056829-8-00

11/10/93

76-003N

ST. DAVIDS, PA. 19087

Page

FOA 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

Individual Safety Report

WYETH-AYERST LABORATORIES

THE FDA MEDICAL PRODUCTS REPC

170 RECEIVED AT DRUG SAFETY SURVEILLANCE



3058001-4-00

ST.



01-DEC-1997-5265

1 of 2

FDA Use Only

A. Patient Information

1. Patient identifier [redacted] in confidence	2. Age at time of event: or Date of birth: 23 YR [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 129 lbs or kgs
--	---	---	-----------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input checked="" type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening (mo/day/yr)	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 04 / 14 / 97

4. Date of this report (mo/day/yr) 04 / 28 / 97

5. Describe event or problem

The patient, with Down's Syndrome, presented to the ER unresponsive with CPR in progress. Her color was dusky-blue, petechia were present on face, skin cool and she had orange-red emesis coming from her mouth. Suctioning and intubation were attempted; intubation was unsuccessful and the patient subsequently died. The provisional autopsy report revealed an ACUTE PULMONARY EMBOLUS.

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.)

Down's Syndrome; hypothyroidism; used Depo-Provera in the past (q 3 months from [redacted] to [redacted]) with weight gain 101 lb. [redacted] to 125 lb. [redacted]. No previous history of T. Upjohn has been notified of this adverse event.

DATE SENT TO FDA
12/28

Submission of a report does not constitute an admission that

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TRIPHASIL-28 TABLETS

#2

2. Dose, frequency & route used

#1 1 TABLET ONCE DAILY ORAL

#2

3. Therapy dates (if unknown, give duration)

#1 08 / 08 / 96 to 04 / 14 / 97

#2

4. Diagnosis for use (indication)

#1 REGULATE MENSES/DYSMENORRHEA

#2

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # - for product problems only (if known)

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)

WYETH-AYERST LABORATORIES
170 RADNOR CHESTER ROAD
ST. DAVIDS, PA. 19087

KAREL F. BERNADY, PH.D.

2. Phone number (610) 902-3760

3. Report source (check all that apply)

foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (mo/day/yr) 04 / 24 / 97

5. (A)NDA # 19-190

IND #

PLA #

pre-1938 yes

OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day
 10-day periodic
 initial follow-up #

8. Adverse event term(s)
PULMONARY EMBOLUS

9. Mfr. report number
8-97118-249N

DEC 01 1997

E. Initial reporter

1. Name, address & phone #
[redacted]

2. Health professional? Pharmacist

3. Occupation

4. Initial reporter also sent report to FDA

00006



MEDWATCH

Approved by the FDA on 11/10/93

WYETH-AYERST LABORATORIES

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

170 RECEIVED AT DRUG SAFETY SURVEILLANCE

ST.



01-DEC-1997-5266

2 of 2

Mfr report # 8-97118-249N

UF/Dist report #

FDA Use Only

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)

LEVOTHYROXINE 0.075 mg
IRON SUPPLEMENT

Individual Safety Report



3058001-4-00

DEC 01 1997



ADVERSE EXPERIENCE REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS [REDACTED]	1a. COUNTRY Denmark	2. DATE OF BIRTH Day [REDACTED] Month [REDACTED] Year [REDACTED]	2a. AGE UNITS 33Yr	3. SEX F	4-6. EXPERIENCE Day 20 Month APR Year 2001	8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
7. DESCRIBE EXPERIENCE(S) PULMONARY EMBOLISM						<input checked="" type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> NONE OF THE ABOVE <input type="checkbox"/> RECOVERED
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. Medical history was not provided. The dose regimen was 1 tablet daily. It is unknown if the patient was taking concomitant therapy. The patient experienced pulmonary embolism (pulmonary embolism) on [REDACTED] and was hospitalized. Her treatment was unspecified. The patient died on [REDACTED].						
13. RELEVANT TESTS/LABORATORY DATA None Provided.						

II. SUSPECT DRUG(S) INFORMATION

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? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> N/A
15. DAILY DOSE(S) #1 1 Tablet 1x per 1 Day	16. ROUTE(S) OF ADMINISTRATION #1 Oral	
17. INDICATION(S) FOR USE #1		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A
18. THERAPY DATES (FROM/TO) #1 00-UNK-1997 / 20-Apr-2001	19. THERAPY DURATION #1 3 Yr	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event) (DA/MO/YR)
Unknown

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
UNK

RECEIVED
JUN 18 2001
CDR/CDEP

IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER

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 (RP) (via Schering AG) 01/01922-CDS	
Local Marketing No NDA 13-668	24b. MFR CONTROL NO. HQ2066414JUN2001	<p style="text-align: right;">DSS JUN 19 2001</p> <p style="text-align: right;">JUN 15 2001 DATE SENT TO FDA</p>	
24c. DATE RECEIVED BY MANUFACTURER 14-Jun-2001	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> CONSUMER <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> REGULATORY AUTHORITY <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> LICENSE		
Date of this report 15-Jun-2001	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP		

Individual Safety Report



4412805-1-00-02

Experience Report
(continued)

of a report does not constitute
in that medical personnel, user
agency, distributor, 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

Adverse report #	
UIF/Out report #	K200400695
FDA Use Only	

Page 2 of 3

Additional Information

B5. EVENT DESCRIPTION (cont.)

13JAN2004. The patient's mother reported that her daughter experienced right sided pain on 27MAR2004. She denied having fallen or knocked it. The patient took two unspecified pain killers and went to bed. The next day she reported feeling better but that it still hurt slightly. On [REDACTED], she returned from school due to pain. That evening the patient reported feeling better. The mother was unable to make an appointment with her general practitioner and took the patient to the emergency department on [REDACTED]. On the way to the emergency department, the mother reported that the patient experienced difficulty breathing and that it hurt to cough. The patient presented to the emergency department with a six day history of right-sided chest pain, which was dull with sharp exacerbations, and associated non-productive cough. She denied any history of trauma, expectorating blood, fever, or shortness of breath. An examination did not reveal any abnormalities. The right chest wall was mildly tender along the fourth, fifth, and sixth ribs with no associated swelling or skin changes noted. Her pulse was 76, blood pressure 119/57 mmHg, respiratory rate 20, and her oxygen saturation was 100% on room air. There was equal expansion of both lung fields and good air entry bilaterally. An electrocardiogram was performed and nothing abnormal was detected. The patient was diagnosed with a soft tissue injury to the rib. She was discharged on diclofenac and paracetamol and advised to follow-up with her general practitioner if the pain persisted. Levonorgestrel/ethinyl estradiol was discontinued. During the subsequent week, the patient continued to experience pain and difficulty breathing. On [REDACTED], the patient complained to her mother of feeling unwell and later that evening she vomited. On [REDACTED], she was observed sleeping at 9 am and 1:30 pm by her parents. At 5:30 pm, the mother was unable to awaken her daughter and observed that she was pale and did not appear to be breathing. The patient died on [REDACTED]. A post mortem examination revealed a large thrombotic pulmonary embolus mainly affecting the right pulmonary artery and the right pulmonary tree. There were also smaller amounts of thrombotic emboli present in the left lung. There was a wedge shaped pulmonary infarct in the right lower lobe overlying the area of hemorrhage on the right parietal pleura. There was also bilateral pulmonary edema and a small pericardial effusion. There was no evidence of pneumonia or lung tumors. Paracetamol was within the therapeutic range at 4 mg/l and does not support acute paracetamol overdose as a cause of death. There was no obvious evidence of liver toxicity that might have followed a previous overdose. No other drugs were detected in the blood. The pathologist commented that the pulmonary infarct in the right lung was not acute and probably occurred one to two weeks previously, secondary to a small embolus, and was likely to have been the cause of the chest pain. The large pulmonary embolus was very recent. The pathologist stated that the right calf was slightly larger at 40 cm diameter than the left calf at 38 cm diameter and may well have been the source of the pulmonary embolus. The cause of death was 1) thrombotic pulmonary embolus and 2) pulmonary infarct. The coroner concluded that the death was due to natural causes.

Follow-up information was received by King Pharmaceuticals, Inc. on 14JUL2004 via fax from Berlex Laboratories. Additional events, event details, past medical history, medical records, laboratory and diagnostic test results, and post mortem examination results were provided. The date and cause of death were updated.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
7	[REDACTED]	Electrocardiogram	Nothing abnormal detected	
8	[REDACTED]	Post mortem	Summary of pathological findings were: 1. Large thrombotic pulmonary embolus 2. Peripheral pulmonary infarction right lung 3. Right pleural granulation tissue reaction with inflammation 4. Pulmonary edema 5. Small pericardial effusion	
9	[REDACTED]	Paracetamol level	4 mg/l	6 2
		No other drugs were detected in the blood.		

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	[REDACTED] UNK	Historical Condition Ligament injury NOS	Left ankle injury: rupture of lateral collateral ligament.

JUL 27 2004

DSS

Individual Safety Report



4412885-1-00-03
Experience report
(continued)

ion 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

Mfr report #	
UF/Dist report #	K200400685
FDA Use Only	

Page 3 of 3

2	UNK	Historical Condition Foot fracture	Right closed fracture metatarsal 5th
3	Ongoing	Historical Condition Tonsillitis	Sore throat with swollen red tonsils. Occasional dizziness and fever and feeling tired. No nodes. Treated with penicillin, sore throat symptom ongoing 3/52. Recurrence of symptoms noted on 13JAN2004.
5	UNK	Current Condition Overweight	Body mass Index = 27.7 (70 kg, 159 cm)

C1. Name (cont.)
Suspect Medication #1: NORDETTE -21(LEVONORGESTREL, ETHINYL ESTRADIOL) Tablet

G8. ADVERSE EVENT TERMS (cont.)
Pericardial effusion

JUL 27 2004

DSS

JUL 28 2004



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

user-facilities,
manufacturers for
FDY reporting
King Pharmaceuticals, Inc.

Relays International, Inc.
FDA Electronic Approver: 31JUN-1999

Mfr report #	
LR/Dist report #	K200400695
FDA Use Only	

A. Patient Information			
1. Patient identifier UNK	2. Age at time of event: 16 Years or Date of birth: UNK	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
In confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunction)			
2. Outcomes attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other:			
3. Date of event 03/31/2004	4. Date of this report 05/18/2004		
5. Describe event or problem Event Verbatim (PREFERRED TERM) (Related symptoms if any separated by commas) Pulmonary embolism[Pulmonary embolism]			
Case Description: This report was received by King Pharmaceuticals, Inc. on 10MAY2004 via fax from Berlex Laboratories. A regulatory authority reported that a 16 year-old female patient received oral levonorgestrel/ethinyl estradiol 1 tablet daily started 13JAN2004 for oral contraception. There were no concomitant medications or significant past medical history. On [redacted], after the initiation of levonorgestrel/ethinyl estradiol therapy, the patient experienced a pulmonary embolism and died. There was no post mortem examination performed. The probable cause of death was listed as pulmonary embolism.			
6. Relevant tests/laboratory data, including dates None			
7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) NI			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1. NORDETTE -21(LEVONORGEST (continued))			
#2.			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration)	
#1. 1 tablet, qd, Oral		#1. 01/13/2004 to 03/31/2004	
#2.		#2.	
4. Diagnosis for use (Indication)		5. Event abated after use stopped or dose reduced	
#1. Oral contraception		#1. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2.		#2. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot# (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction	
#1. UNK	#1. UNK	#1. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2.	#2.	#2. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC# - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event) NI			

G. All Manufacturers			
1. Contact office - name/address (& mfrng site for devices)		2. Phone number	
King Pharmaceuticals, Inc.		9196537005	
501 Fifth Street Bristol, TN 37620 UNITED STATES		3. Report source (check all that apply)	
		<input checked="" type="checkbox"/> foreign GBR	
		<input type="checkbox"/> study	
		<input type="checkbox"/> literature	
		<input type="checkbox"/> consumer	
		<input checked="" type="checkbox"/> health professional	
		<input type="checkbox"/> user facility	
		<input type="checkbox"/> company representative	
		<input type="checkbox"/> distributor	
		<input checked="" type="checkbox"/> other: Manufacturer	
4. Date received by manufacturer 05/10/2004	5. (A)NDA # 18-668		
6. If IND, protocol #	IND #		
	PLA #		
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes		
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	OTC product <input type="checkbox"/> yes		
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	8. Adverse event term(s) Pulmonary embolism		
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #			
9. Mfr. report number K200400695			

E. Initial reporter			
1. Name & address		phone #	
[redacted]		[redacted]	
[redacted] UNITED STATES		DSS	
2. Health professional?		3. Occupation	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		Other Manufacturer	
4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			



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



4363772-0-00-02

M

E

(continued)

Report does not constitute
medical personnel, user
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

Mfr report #	K200400695
UF/Dial report #	
FDA Use Only	

Page 2 of 2

Additional Information

C1. Name (cont.)

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

DSS

MAY 21 2004

MAY 19 2004



4902505-3-00-01*

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

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

The FDA Safety Information and Adverse Event Reporting Program

Page 1 of 2

Mfr Report #	006392
UFI/Importer Report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient Identifier UNK	2. Age at Time of Event UNK or Date of Birth: UNK	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight UNK lbs or UNK kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input checked="" type="checkbox"/> Death UNK (mo/day/yr)		<input type="checkbox"/> Disability	
<input type="checkbox"/> Life-threatening		<input type="checkbox"/> Congenital Anomaly	
<input type="checkbox"/> Hospitalization - initial or prolonged		<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage	
<input type="checkbox"/> Other: _____			
3. Date of Event (mo/day/year) UNK		4. Date of This Report (mo/day/year) 02/01/2006	
5. Describe Event or Problem Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Severe neutropenia[Neutropenia] Anemia[Anaemia] Leukopenia[Leukopenia]			
Case Description: Information regarding an adverse event associated with Nordette was derived from scientific literature. The article, A Trial of Contraceptive Methods in Women with Systemic Lupus Erythematosus, was obtained from The New England Journal of Medicine. It discussed findings from a single blind clinical trial involving 162 women with systemic lupus erythematosus, who were randomly assigned to combined oral contraceptives, a progestin-only pill, or a copper intrauterine device (IUD). The combined oral contraceptive regimen consisted of 30 µg of ethinyl estradiol plus 150 µg of levonorgestrel (Nordette). The progestin-only pill contained 30 µg of levonorgestrel (Microlut, Schering Mexicana). The continued in additional info section...			
6. Relevant Tests/Laboratory Data, including Dates #1 Anemia, Leukopenia 500 (neutrophils 55%)			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) #1 UNK, Historical Memo, History of drug related leukopenia (Azathioprine)			

C. SUSPECT MEDICATION(S)	
1. Name (Give labeled strength & mfr/labeler, if known)	
#1. Nordette 21 Day(LEVONORGE (continued))	
#2. AMOXICILLIN(AMOXICILLIN) (continued)	
2. Dose, Frequency & Route Used	3. Therapy Dates (if unknown, give duration from/to (or best estimate))
#1. UNK, UNK, Oral	#1. duration 183 days
#2. 1.5 g, qd, Oral	#2. UNK
4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1. UNK	#1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
#2. Upper respiratory (continued)	#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
6. Lot # (if known)	7. Exp. Date (if known)
#1. UNK	#1. UNK
#2. UNK	#2. UNK
8. Event Reappeared After Reintroduction?	
#1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply	
#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply	
9. NDC# (For product problems only)	
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) NI	

G. ALL MANUFACTURERS	
1. Contact Office - Name/Address (and Manufacturing Site for Devices) Barr Laboratories 400 Chestnut Ridge Road Woodcliff Lake, NJ 07677-7668 UNITED STATES	2. Phone Number 2019303302
3. Report Source (Check all that apply)	
<input type="checkbox"/> Foreign	
<input type="checkbox"/> Study	
<input checked="" type="checkbox"/> Literature	
<input type="checkbox"/> Consumer	
<input checked="" type="checkbox"/> Health Professional	
<input type="checkbox"/> User Facility	
<input type="checkbox"/> Company Representative	
<input type="checkbox"/> Distributor	
<input type="checkbox"/> Other: _____	
4. Date Received by Manufacturer (mo/day/yr) 01/26/2006	5. (A)NDA # 18-668
6. If IND, Give Protocol #	IND #
7. Type of Report (Check all that apply)	PLA #
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	Pre-1938 <input type="checkbox"/> Yes
<input type="checkbox"/> 10-day <input type="checkbox"/> Periodic	OTC Product <input type="checkbox"/> Yes
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Follow-up #1	8. Adverse Event Term(s) Neutropenia, Anaemia, Leukopenia
9. Manufacturer Report Number 006392	

E. INITIAL REPORTER			
1. Name and Address		Phone # UNK	
[Redacted Name and Address]			
2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Physician	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk	



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



4982585-3-00-02

ion of a report does not constitute
sion that medical personnel, user
security, importer, 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

MR Report #	006392
UF/Importer Report #	
FDA Use Only	

(continued)

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 neutropenia.

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-Perpita M, Lara-Reyes P, Seuc AH, Cravioto MD

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

Volume: 353 Year: 2005 Pages: 2539-2549

Individual Safety Report



4065974-X-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only H Pad

Triage unit
sequence # 187724

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

CDER
CDER

A. Patient information

1. Patient Identifier [redacted] In confidence	2. Age at time of event: 40 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 153 lbs or kgs
--	--	---	-----------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 2-20-03

4. Date of this report (mo/day/yr) 2-21-03

5. Describe event or problem

Pulmonary Embolus - patient had been on Ortho Novum 150 for an unspecified time period, & was recently Δ'd to Nordette 21 day - presented with PE on 2-20-03

6. Relevant tests/laboratory data, including dates

DSS
FEB 28 2003

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

∅ smoking
∅ alcohol

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) (from to (or best estimate))	
#1 Nordette 21 day	#1 1 po QD	#1 Ortho Novum 150 2 weeks	
#2 Ortho Novum 150 28 day	#2 1 po QD	#2 unknown	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
4. Diagnosis for use (indication)		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#1 menorrhagia		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 menorrhagia		8. Event reappeared after reintroduction	
6. Lot # (if known)		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#1 N/A		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
7. Exp. date (if known)		9. NDC # (for product problems only)	
#1 N/A		#2	
10. Concomitant medical products and therapy dates (exclude treatment of event)			

D. Suspect medical device

1. Brand name		4. Operator of device	
2. Type of device		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:	
3. Manufacturer name & address		5. Expiration date (mo/day/yr)	
6. model #		7. If implanted, give date (mo/day/yr)	
catalog # FEB 28 2003		8. If explanted, give date (mo/day/yr)	
serial # MEDWATCH CTU		9. Device available for evaluation? (Do not send to FDA)	
lot #		<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)	
other #		10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)

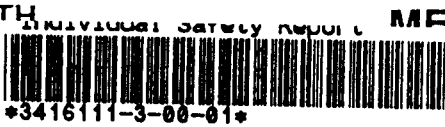
1. Name, address & phone # [redacted] PharmD			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PharmD	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

WVETH
 TM WAY
 WYETH-AYER
 BOX 8299
 PHILADELPHIA



MEDWATCH

REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # 8-99180-072A

UF/Dist report #

FDA Use Only

A. Patient Information

1. Patient identifier UNK in confidence	2. Age at time of event or UNK Date of Birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or kgs
---	---	---	-----------------------------------

B. Adverse event or product problem

1. Adverse event Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input checked="" type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization-initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) UNK

4. Date of this report (mo/day/yr) 11/23/1999

5. Describe event or problem

STROKE. Information has been received from an attorney, regarding an unidentified female patient (age unspecified) who had been prescribed Triphasil-28 therapy (dates unspecified). Medical history included long-term heavy bleeding with her menses resulting in persistent iron deficiency anemia. Concomitant drug therapy was not provided. The patient was given a pack of pills in the physician's office, and over the next 12 days the patient took 4 tablets. The interval at which the patient took the tablets is unknown. Twelve days after receiving Triphasil-28 therapy the patient suffered a stroke and died. No further information was provided.

6. Relevant tests/laboratory data, including dates

None Provided.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

OTHER MEDICAL HISTORY:
 Long-term heavy bleeding with her menses and persistent iron deficiency anemia.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

1 TRIPHASIL-28

2

2. Dose, frequency & route used

1 Tablet 1x per 1 Day, Oral

2

3. Therapy dates (if unknown, give duration)

1 12 Day

2

4. Diagnosis for use (indication)

1 UNK

2

5. Event abated after use stopped or dose reduced

1 yes no doesn't apply

2 yes no doesn't apply

6. Lot # (if known)

1

2

7. Exp date (if known)

1

2

8. Event reappeared after reintroduction

1 yes no doesn't apply

2 yes no doesn't apply

9. NDC # - for product problems only (if known)

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

G. All manufacturers

1. Contact office - name/address

WYETH LABS (RA)
 170 Radnor Chester
 St. Davids, PA 19087

2. Phone number

6109023760

3. Report source (check all that apply)

foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (mo/day/yr)

06/22/1999

5. (A)NDA 19-190
 IND #
 PLA #

pre-1938 yes
 OTC product yes

6. If IND, protocol #

7. Type of report

5-day 15-day
 10-day periodic
 initial follow-up #

8. Adverse event term(s)

Cerebrovascular accident NOS

9. Mfr. report number

8-99180-072A

E. Initial reporter

1. Name & address phone #

[REDACTED]

2. Health professional?
 yes no

3. Occupation

4. Initial reporter also sent report to FDA
 yes no unk

Individual Safety Report



3846168-3-00-01

ADVERSE EXPERIENCE REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS	1a. COUNTRY France	2. DATE OF BIRTH Day Month	2a. AGE UNITS 38Yr	3. SEX F	4-6. EXPERIENCE Day Month Year	8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
---------------------	-----------------------	-------------------------------	-----------------------	-------------	-----------------------------------	---

7. DESCRIBE EXPERIENCE(S)
 THROMBOTIC THROMBOCYTOPENIC PURPURA

Information was received on 08-DEC-2000, from a Literature abstract (Zenut, et al. Fatal thrombocytopenic purpura: Role of oral contraceptives? Therapie 2000; 55: Abstract; 42b) concerning a 38 Yr old female patient who had taken therapy with TRINORDIOL (0.05MG LEVONORGESTREL/0.03MG ETHINYL ESTRADIOL/0.075MG LEVONORGESTREL/0.04MG ETHINYL ESTRADIOL/0.125MG LEVONORGESTREL/0.03MG ETHINYL ESTRADIOL) (equivalent to Triphasil) for an 18 month duration (therapy dates and indication were unspecified). Her medication history included prior use of the oral contraceptive Adepal (levonorgestrel and ethinyl estradiol). Concomitant therapy included occasional use of TYLENOL (PARACETAMOL). The patient was casually noted to have severe thrombocytopenia (10 giga/L). Some time following the initial diagnosis, the patient was hospitalized. On admission, a clinical examination revealed purpura, large ecchymoses, cephalalgia and eyeground minor bleeding. A cranial

(cont'd)

- PATIENT DIED
- INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY
- LIFE THREATENING
- NONE OF THE ABOVE
- RECOVERED

13. RELEVANT TESTS/LABORATORY DATA
See following page.

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (INCLUDE ACTIVE SUBSTANCE(S)) #1 TRINORDIOL (0.05MG LNG/0.03MG EE/0.075MG LNG/0.04MG EE/0.125MG LNG/0.03MG EE, TABLET)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A
15. DAILY DOSE(S) #1	16. ROUTE(S) OF ADMINISTRATION #1 Unknown	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A
17. INDICATION(S) FOR USE #1	19. THERAPY DURATION #1 Unknown	
18. THERAPY DATES (FROM/TO) #1 Unknown		

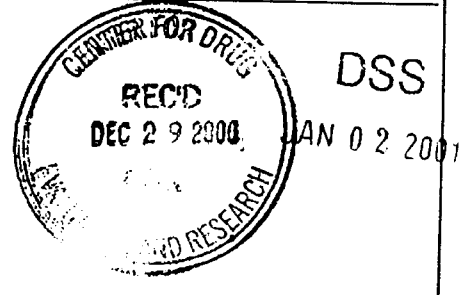
III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event) (DA/MO/YR)
 TYLENOL (PARACETAMOL), Unknown

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
 UNK

IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code) WYETH LABS (RA) 201 King of Prussia Sixth Floor Radnor, PA 19087-5114	
Local Marketing No. NDA 19-192	24b. MFR CONTROL NO. HQ4722412DEC2000
24c. DATE RECEIVED BY MANUFACTURER 20-Dec-2000	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> CONSUMER <input checked="" type="checkbox"/> LITERATURE <input type="checkbox"/> REGULATORY AUTHORITY <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> LICENSE



DEC 28 2000 DATE SENT TO FDA	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP
---------------------------------	---

DEC 29 2000



3648168-3-88-82

YES

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)

<i>Test Name</i>	<i>Date</i>	<i>Result</i>	<i>Normal Range</i>
Laboratory test abnormal NOS			
		Autopsy showed diffuse capillary thrombi involving most organs and confirmed diagnosis of thrombotic microangiopathy.	-
Platelet count decreased			
		10 aiga L	-

DSS

JAN 02 2001

DEC 29 2000

Individual Safety Report



3840160-3-00-03

RECEIVED

DEC 07 2000

GSSE/RESS

1788434

<13>

Unique Identifier
203439

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/l) 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.
On

admission, she presented with purpura and large ecchymoses,
cephalalgia

and eyeground minor bleeding otherwise clinical examination and
cranial

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
the

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 18 old girl on low dose oral progestatives (CAILLARD S., 1998).

DSS

JAN 02 2001

DEC 29 2000

Individual Safety Report



MED WATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

Facsimile FDA Form 3500A
Printed by
BERLEX Laboratories
Wayne, NJ

Approved by FDA, Oct. 15th, 1990

Mfr report # 00/01147-GBD

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient initials [redacted] in confidence	2. Age at time of event: 34 years or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 70 kgs
--	---	---	----------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem e.g., (defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input checked="" type="checkbox"/> death (add Mon yyyy)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (dd Mon yyyy) 10 Apr 2000

4. Date of this report (dd Mon yyyy) 24 Jan 2001

5. Describe event or problem

The initial and four(4) follow-up reports for this case involving Mirena have been submitted to IND 22,697. The initial case was submitted on 24 Jul 00 (serial no. 056); follow-up #1 on 23 Aug 00 (serial no. 061); follow-up #2 on 15 Sep 00 (serial no. 068); follow-up #3 on 24 Oct 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).

Physician's report via sales rep on 20 Jul 00 and phone call on 21 Jul 00:

34 year-old patient who was on Mirena since Aug 99 collapsed in bathroom. Resuscitation without success. Pt died. Autopsy was not performed. No risk factors. Physician is not informed about further details. However, although he does not see any causal relationship to Mirena, he will send a written report.

Suppl. (16 Aug 00):
<continued>

8. Relevant tests/laboratory data, including dates
None reported

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunctions, etc.)
Patient has asthma in history, no risk factors, multipara (2 children), allergy to penicillin. No clotting disorder in known.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeled, if known)-
#1 MIRENA (levonorgestrel)
#2

2. Dose, frequency & route used
#1 <continued>
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 238 days
#2

4. Diagnosis for use (indication)
#1 Contraception
#2

5. Event abated after use stopped or dose reduced
#1 yes no doesn't apply
#2 yes no doesn't apply

6. Lot # (if known) #1 Unknown #2
7. Exp. date (if known) #1 #2

8. Event reappeared after reintroduction
#1 yes no doesn't apply
#2 yes no doesn't apply

9. NDC # - for product problems only (if known)
#1 #2

10. Concomitant medical products and therapy dates (exclude treatment of event)
Unknown

G. All manufacturers

1. Contact office - name/address & mfring site for devices
Berlex Laboratories, Inc.
300 Fairfield Road
Wayne, NJ 07470
USA

2. Phone number (888) 237-5394

3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (dd Mon yyyy) 20 Jul 2000

5. similar to: (A)NDA # 21-225
IND #
PLA #
pre-1938 yes
OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)
 5-day 15-day
 10-day periodic
 initial follow-up #

8. Adverse event term(s)
EMB PULM
THROMBOPHLEB DEEP
CONVULS
HEART ARREST

9. Mfr. report number
00/01147-GBD

E. Reporter

1. Name, address & phone #
[redacted]
[redacted]
Country of origin: Germany

DSS
JAN 25 2001

2. Health professional? yes no

3. Occupation Physician

4. Initial reporter also sent report to FDA yes no unk



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

JAN 25 2001

Individual Safety Report



MED WATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Facsimile FDA Form 3500A
Printed by
BERLEX Laboratories
Wayne, NJ

Approved by FDA, Oct. 19th, 1993

MIR report #	00/01147-GBD
UF/DIR report #	-
FDA Use Only	

Continuing Page

B.5. Describe event or problem

Gynecologist's written report:

Patient suffered from cardiac arrest in [REDACTED]. Patient died.
No further information obtainable.

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 [REDACTED] 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. Patients husband refused an autopsy.

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

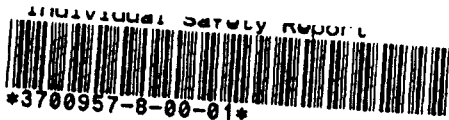
DSS

JAN 26 2001



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

JAN 25 2001



Facsimile FDA Form 3500A
Printed by
BERLEX Laboratories
Wayne, NJ

Mir report # 01/00393-GBD
UF/Dial report #
Approved by FDA, Oct 15th, 1996
FDA, Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information
1. Patient Initials: _____
2. Age at time of event: 45 years
or Date of birth: Unknown
3. Sex: female male
4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem
1. Adverse event and/or Product problem e.g., (defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
 death 2001 (dd Mon yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (dd Mon yyyy) 2001
4. Date of this report (dd Mon yyyy) 6 Apr 2001

5. Describe event or problem
Gynecologist's report:
Pt has been taking Miranova for approximately five years. Pt had a history of hypertension prior to intake of Miranova. Pt could not work for three weeks in Jan 01 due to cardiovascular problems. Gynecologist saw the pt in [redacted] for the last time and examination was unremarkable. At this time blood pressure was 150/ 90 mm Hg (the same value as it was the years before). Pt did not have a varicosis. Some days ago pt died suddenly while teaching in school. Physician did not arrange for an autopsy, but pt's relatives did. At time of event pt was still under Miranova.

Pathologist's report to gynecologist: Autopsy results are not clear yet. Pt had a hypertrophy of the right heart. No embolism and no cerebral infarction could be found. Pathologist told the reporting gynecologist that an intoxication might be possible. Neither gynecologist nor pathologist see a causal relationship between exitus and Miranova in this pt.
<continued>

6. Relevant tests/laboratory data, including dates
Diagnostic Investigation: Autopsy was performed: No embolism, no cerebral infarction, pt had hypertrophy of the right heart. Intoxication might be possible.
Suppl. ([redacted]): Autopsy result: acute heart failure rt because of heart valve hypertrophy which was not known.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunctions, etc.)
Pt had a history of hypertension prior to intake of Miranova.

C. Suspect medication(s)
1. Name (give labeled strength & mfr/labeler, if known)
#1 MIRANOVA (levonorgestrel, ethinylestradiol)
#2 _____
2. Dose, frequency & route used
#1 1 coated tablet p.o.
#2 _____
3. Therapy dates (if unknown, give duration) (month) (or best estimate)
#1 1996 - approx. 5 years
#2 _____
4. Diagnosis for use (indication)
#1 Unknown
#2 _____
5. Event abated after use stopped or dose reduced
#1 yes no doesn't apply
#2 yes no doesn't apply
6. Lot # (if known)
#1 Unknown
#2 _____
7. Exp. date (if known)
#1 _____
#2 _____
8. Event reappeared after reintroduction
#1 yes no doesn't apply
#2 yes no doesn't apply
9. NDC # - for product problems only (if known)
#1 _____
#2 _____
10. Concomitant medical products and therapy dates (exclude treatment of event)
Unknown

G. All manufacturers
1. Contact office - name/address & mfring site for devices
Berlex Laboratories, Inc.
300 Fairfield Road
Wayne, NJ 07470
USA
2. Phone number (888) 237-5394
3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other: _____
4. Date received by manufacturer (dd Mon yyyy) 26 Mar 2001
5. Similar to: (A)NDA # 20-860
IND # _____
PLA # _____
pre-1938 yes
OTC product yes
6. Adverse event term(s)
HEART FAIL RIGHT
7. Type of report (check all that apply)
 5-day 15-day
 10-day periodic
 initial follow-up # 1
8. Mir. report number 01/00393-GBD

E. Reporter
1. Name, address & phone #
[redacted]
Country of origin: Germany
2. Health professional? yes no
3. Occupation Physician
4. Initial reporter also sent report to FDA yes no unk



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

