ADVERSE EXPERIENCE (AE) COVER SHEET

(X)

CASE COMPLETED/CLOSED TO CENTRAL 0P 7/5/01 (Date/Initials) MAINTENANCE DATA COMPLETED/CLOSED TO CENTRAL _____ (Date/Initials)

CASE COMPLETED/CLOSED TO CENTRAL _____ (Date/Initials) MAINTENANCE DATA COMPLETED/CLOSED TO CENTRAL _____ (Date/Initials)

Routing: DM, AE, DB, JD, IG, BH, TH, RJ, DK, SK, JL, FM, GLM, RP, MS, RS, CY, MY, LEG

ADVERSE EXPERIENCE(S) REPORTED (FOR US CASES: NOTE PRIMARY AE, NOTE AE CLASSIFICATION AND GROUPING)

S/D See previous sheet

S/D

S/D

S/D

S/D

S/D

S/D

Redacted

PATIENT NAME OR INITIALS

MED WATCH TRIAGE #

PRODUCT ID/AEGIS FILE NO.

PRX20010140-2 2

SECT. V

DATE OF RECEIPT AT SB (PHILA) 7/5/01

FOLLOW-UP ACTIVITY

PHONE CALL BY MEDICAL MONITOR/USCS ☐

SITE VISIT BY MEDICAL MONITOR/USCS ☐

LETTER - CLINICAL SAFETY ☐

Logged to the FDA on: N/A

AWAITING RECEIPT OF REMAINDER OF REQUESTED INFORMATION ☐

CLOSE OUT ☐

US PI REPORT CLASSIFICATION

EXPEDITE ☐ (X)

PERIODIC ☐

MDS REPORT CLASSIFICATION: _____

DISTRIBUTION DECISION _____

SIGNATURE _____

DATE 7/5/01

COMMENTS FROM PHYSICIAN CLIN. DEV./US CLINICAL SAFETY PHYSICIAN/USCS PERSONNEL

X: letter unclaimed

FOLLOW-UP INFORMATION TO BE REQUESTED BY CLINICAL SAFETY

SOURCE TO BE CONTACTED

INFORMATION TO BE REQUESTED

DATES OF FOLLOW-UP LETTER #1 #2

FOLLOW-UP TELEPHONE CALLS #1 #2

COPY TO PRODUCT INFORMATION SERVICES DEPT. FOR PROCESSING OF ADDITIONAL INFORMATION Date_____ Initials_____

COPY TO QUALITY ASSURANCE - COMPLAINT NO. Date_____ Initials_____

PAR060290279

GlaxoSmithKline

GlaxoSmithKline
1250 South Collegeville Road
PO Box 5089
Collegeville, PA
19426-0989

Tel. 610 917 7000
Fax. 610 917 7707
www.gsk.com

June 13, 2001
PRX 2001014040-1
2001014040-2

Redacted

Dear Ms. Redacted

This is to acknowledge your e-mail to GlaxoSmithKline in which you reported that you were treated with Paxil® while pregnant. The pregnancy had to be terminated because the fetus developed Truncus arteriosis. We responded to your initial e-mail on June 6, 2001. This information has been forwarded to me.

In order to follow-up on your report, it is necessary that we have the details of your clinical course as it relates to your report. To obtain this, we need the name and address of your OB/GYN. For your convenience, I have enclosed an authorization form for you to sign and return to me.

We appreciate your cooperation. In the reply, please refer to our files numbered: 2001014040-1 and 2001014040-2, and use my mail code, UP-3410, in the mailing address.

Sincerely,

Deborah Pollak, R.N.
Assistant Clinical Safety Scientist

Enclosure
®SmithKline Beecham Pharmaceuticals

POST MARKETING
JUL - 5 2001
RECEIVED

Authorization for Release of Records

Re: [illegible]

I, _____, hereby authorize the following persons and/or institutions to provide to SmithKline Beecham Corporation, a copy of my medical records and/or other information regarding my medical status. I understand that any information provided may be forwarded to the FDA (Food & Drug Administration).

Physician:

Name_____

Address_____

_____

Nurse, Pharmacist, or other Health Professional:

Name_____

Address_____

_____

Hospital:

Name_____

Address_____

_____

Date:_____

Signed: _____
(patient or legal guardian)

Relationship (if legal guardian): _____

Please Return To:

SB
SmithKline Beecham
Pharmaceuticals

U.S. Clinical Safety
Mailcode: UP-3420
1250 S. Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

PAR06029028I

GlaxoSmithKline

GlaxoSmithKline
[illegible] South Collegeville Road
PO Box 5089
Collegeville PA
19426 0989

Tel. 610 917 7000
Fax 610 917 7007
www.gsk.com

Redacted

RETURN TO SENDER

RTS

INSUFFICIENT ADDRESS
ATTEMPTED NOT KNOWN
NO SUCH NUMBER/ STREET
NOT DELIVERABLE AS ADDRESSED
UNABLE TO FORWARD

OTHER

A
C
S

PLACE STICKER AT TOP OF ENVELOPE
TO THE RIGHT OF RETURN ADDRESS
FOLD AT DOTTED LINE

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

[illegible] line in which you reported that you were treated
be terminated because the fetus developed
mail on June 6, 2001. This information has been

[illegible] that we have the details of your clinical course as
name and address of your OB/GYN. For your
for you to sign and return to me.

refer to our files numbered: 2001014040-1 and
[illegible] mailing address.

POST MARKETING

JUL - 5 2001

RECEIVED

PAR060290282

GlaxoSmithKline

T= 7/25

GlaxoSmithKline
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]

June 13, 2001
PRX 2001014040-1
2001014040-2

Redacted

Dear Ms. Redacted

This is to acknowledge your e-mail to GlaxoSmithKline in which you reported that you were treated with Paxil® while pregnant. The pregnancy had to be terminated because the fetus developed Truncus arteriosis. We responded to your initial e-mail on June 6, 2001. This information has been forwarded to me.

In order to follow-up on your report, it is necessary that we have the details of your clinical course as it relates to your report. To obtain this, we need the name and address of your OB/GYN. For your convenience, I have enclosed an authorization form for you to sign and return to me.

We appreciate your cooperation. In the reply, please refer to our files numbered: 2001014040-1 and 2001014040-2, and use my mail code, UP-3410, in the mailing address.

Sincerely,

Deborah Pollak, R.N.
Assistant Clinical Safety Scientist

Enclosure
®SmithKline Beecham Pharmaceuticals

PAR060290283

ADVERSE EXPERIENCE (AE) COVER SHEET

CASE COMPLETED/DISCLOSED TO CENTRAL 06/13/01 Date/Initials) MAINTENANCE DATA COMPLETED/DISCLOSED TO CENTRAL ... _____ (Date/Initials)

CASE COMPLETED/DISCLOSED TO CENTRAL .. .. Date/Initials) MAINTENANCE DATA COMPLETED/DISCLOSED TO CENTRAL . _____ (Date/Initials)

Routing: DM, AE, BB, JO, IC, SH, TH, AJ, DK, RK, JL, SW, SLM, RP, MS, RS, CY, MY, LEG

NAME OF REPORTER(S)

Redacted

PATIENT NAME OR INITIALS

ADVERSE EXPERIENCE(S) REPORTED (FOR US CASES: NOTE PRIMARY AE, NOTE AE CLASSIFICATION AND GROUPING)

(S/D) Pruritus arteriosis Ser/Ser

S/D

S/D

S/D

S/D

S/D

S/D

MED WATCH TRIAGE #

PRX

PRODUCT ID/AEGIS FILE NO.

2001014 040 - 2 SECT. # 1

DATE OF RECEIPT AT SB (PHILA)

FOLLOW-UP ACTIVITY

PHONE CALL BY MEDICAL MONITOR/USCS ☐

SITE VISIT BY MEDICAL MONITOR/USCS ☐

LETTER - CLINICAL SAFETY ☒

Logged to FDA 6/13/01

AWAITING RECEIPT OF REMAINDER OF REQUESTED INFORMATION ☐

CLOSE OUT ☐

US PI REPORT CLASSIFICATION

EXPEDITE ☒

PERIODIC ☐

MDS REPORT CLASSIFICATION: Ser

DISTRIBUTION DECISION B

SIGNATURE DPollet

DATE 6/13/01

COMMENTS FROM PHYSICIAN CLIN. DEV./US CLINICAL SAFETY PHYSICIAN/USCS PERSONNEL

FOLLOW-UP INFORMATION TO BE REQUESTED BY CLINICAL SAFETY

SOURCE TO BE CONTACTED

INFORMATION TO BE REQUESTED

DATES OF FOLLOW-UP LETTER #1 #2

FOLLOW-UP TELEPHONE CALLS #1 #2

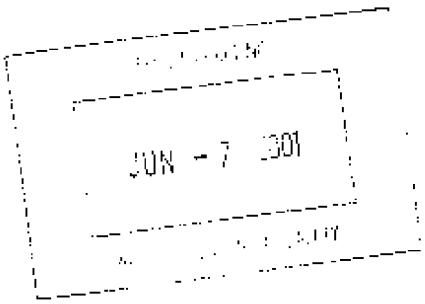
COPY TO PRODUCT INFORMATION SERVICES DEPT. FOR PROCESSING OF ADDITIONAL INFORMATION Date_____ Initials_____

COPY TO QUALITY ASSURANCE - COMPLAINT NO. Date..... Initials.....

uscrcweb@GlaxoWellcome.com on 07-Jun-2001 12:36

To: ww.clinical.safety-srg
cc:
Subject: FW: Paxil Use During Pregnancy GM

> -----Original Message-----
> From: US CRC Web Response Group Mailbox
> Sent: Wednesday, June 06, 2001 11:32 AM
> To: safety-srg@sbphrd.com
> Subject: FW: Paxil Use During Pregnancy GM
>
> Here's the newest reply from the customer. We have not responded to this
> email.
>
> > -----Original Message-----
> > From: [redacted]
> > Sent: Friday, June 01, 2001 10:04 PM
> > To: US CRC Web Response Group Mailbox
> > Subject: Re: Paxil Use During Pregnancy GM
> >
> > This response is in regards to an email that I had sent you preciously.
> I
> >
> > was asking to see if you have any, or are in the process of any clinical
>
> > trials for women who are currently on Paxil and pregnant. I wanted to
> > find
> > out information to see how many women were on Paxil during pregnancy and
> > if
> > they were able to succesfully have healthy babies.
> > I am in no way insinuating that your product did this to my child. I
> love
> >
> > the product and I don't think that I could have gotten through my panic
> > attacks without the wonderful help of this miracle drug.
> > I just want to start to try and get pregnant again soon. I DO NOT want
> to
> > put
> > my unborn child through anything that would hurt him/her.
> > Please, if you do not have information where is this information held?
> > Does
> > anyone do studies like this?
> > Please any information that you may give me would be great.
> > Thank you again for your help-
> >
> [redacted]



uscrcweb@GlaxoWellcome.com on 07-Jun-2001 12:36

To: ww.clinical.safety-srg
cc:
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> > >
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> > I just want to start to try and get pregnant again soon, I DO NOT want
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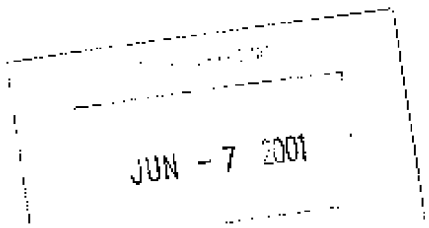
> > Please, if you do not have information where is this information held?
> > Does
> > anyone do studies like this?
> > Please any information that you may give me would be great.
> > Thank you again for your help-
> > [redacted]
>



uscrcweb@GlaxoWellcome.com on 07-Jun-2001 12:36

To: ww.clinical.safety-srg
cc:
Subject: FW: Paxil Use During Pregnancy GM

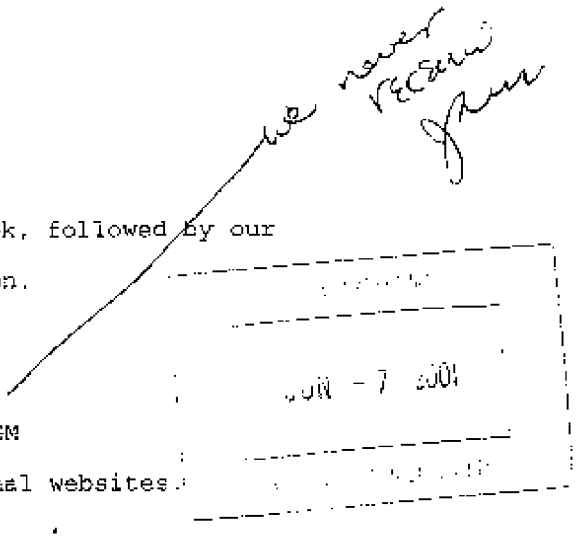
GSK
response

> -----Original Message-----
> From: US CRC Web Response Group Mailbox
> Sent: Wednesday, June 06, 2001 11:31 AM
> To: safety-srg@sbphrd.com
> Subject: FW: Paxil Use During Pregnancy GM
> Importance: High
>
> Here's the reply that was sent to the customer.
>
> > -----Original Message-----
> > From: US CRC Web Response Group Mailbox
> > Sent: Thursday, May 31, 2001 12:59 PM
> > To: Redacted
> > Subject: Paxil Use During Pregnancy GM
> >
> > Dear Ms. Redacted
> >
> > Thank you for your inquiry.
> >
> > We are attaching a copy of our current product information for Paxil®
> > (paroxetine HCL). Please review the section on USE DURING PREGNANCY.
> >
> >
> > Further questions about your treatment should be directed to the
> > physician, pharmacist, or healthcare provider who has the most complete
> > information about your medical condition. Because patient care is
> > individualized, we encourage patients to direct questions about their
> > medical condition and treatment to their physician.
> > We believe that because your physician knows your medical history, he or
> > she is best suited to answer your questions. Our Drug Information
> > department is available to answer any questions your physician or
> > pharmacist may have about our products. Your health care professional
> can
> > call our Drug Information department at 1-888-825-5249.
> > .
> >
> > Again, thank you for your inquiry to GlaxoSmithKline. If you should
> have
> > further questions concerning our company or our products, please feel
> free
> > to contact our Customer Response Center at 1-888-825-5249 during our
> > normal business hours, Monday through Friday, 8:00 am to 8:00 pm Eastern
> > Standard Time.
> >
> >
> >
> > Customer Response Center
> > 1-888-825-5249
> >
> >

JUN - 7 2001

uscrcweb@GlaxoWellcome.com on 07-Jun-2001 12:35

To: ww.clinical.safety-srg
cc:
Subject: FW: Paxil Potential Adverse Event GM



> -----Original Message-----
> From: US CRC Web Response Group Mailbox
> Sent: Wednesday, June 06, 2001 11:30 AM
> To: safety-srg@sbphrd.com
> Subject: FW: Paxil Potential Adverse Event GM
> Importance: High
>
> We are resending an email that came in last week, followed by our
> response,
> and then a new email reply from this same person.
>
> > -----Original Message-----
> > From: US CRC Web Response Group Mailbox
> > Sent: Thursday, May 31, 2001 12:57 PM
> > To: 'safety-srg@sbphrd.com'
> > Subject: Paxil Potential Adverse Event GM
> >
> > This e-mail was received by one of our external websites.
> >
> > Glenna/CRC
> >
> > Contact Name: [redacted]
> > Email Address: [redacted]
> > Questions/Comments: Please someone respond to me!!
> >
> > My name is [redacted] I was diagnosed with Panic Disorder about 4 1/2 years
> > ago. Since that time I have been taking Paxil(which is truly a miracle
> > drug). I have been Panic free with this drug and have been able to go
> on
> > with a normal life.
> > I was married in October of 2000. My husband and I found out that we
> were
> > pregnant at Christmas time. I was so excited, I love children. The
> only
> > problem is that I carried the baby to 6 months gestation and that had to
> > have a termination. The doctor's diagnosed my son with Truncheous
> > arteriosis. They said that he would not lead a normal childhood and
> would
> > most likely not make it through the open heart surgery that he would
> need
> > as soon as he was delivered(if he was able to make it to that time)
> > To say the least, I was absolutley distraut with this news. I thought
> > that it was something that I did. Was it because I stayed on the Paxil
> > for selfish reasons?? I wanted to know if you could direct me to any
> > information that you might have of any woman that have taken Paxil and
> > still had healthy babies. My husband and I are ready to try again to
> get
> > pregnant in the next month or two, I am so nervous. I don't want to
> stop
> > taking my miracle pill, but then again if there is a chance that this

> > might hurt or affect the baby I want to know upfront and I will somehow
> > stop taking it for the timebeing. Please contact me as soon as
> possible.
> > I love everything that this drug has done for me and I am so thankful
> that
> > your company had this available for me. I just want to continue to have
> a
> > normal life, and have the child that I have always wanted.
> > Please contact me as soon as possible.
> >
> >
> >
> >
> >
> > Please don't forget about me...
> > THank you in advance for your time.
> >
>

Redacted

AECENASS AE GATHERING INFORMATION SYSTEM AECEN
Centrally Labeled / Distributed

Distribution Assessment

Case 2001014040-2 DES LOCUS Date 31-MAY-2001 Typ I TypRep SU SERIOUS UNEXP
Drug PAXIL Memo Initial Information TypCen SU SERIOUS UNEXP

Distribute? B Decision Date 13-JUN-2001 Due to Central Site 05-JUN-2001
B = ALL COUNT Scheduled Date 13-JUN-2001 Sent to Central Site 13-JUN-2001
Actual Date Due for 05-JUN-2001

Case Assessment

Cen Type Report SU SERIOUS UNEX Identifiable Source Y Identifiable Patient Y
Valid ICH Case Y SB Drug Y Adverse Experience Y
EMEA Class Professional Source N

Adverse Experiences

Term	Pr	Code	Central IB	MDS	EMEA	Loc	Onset		Clear		Sr	Oc	Ord
TRUNCUS ARTERIOSIS	Y	UNC		N		N	-	-	-	-	Y	X	
							-	-	-	-			
							-	-	-	-			
							-	-	-	-			
							-	-	-	-			

FRM-40400: Transaction complete -- 3 records posted and committed.
Count: *1 <OSC><DBG><List><Replace>

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

SMITHKLINE BEECHAM PHARM
1250 SOUTH COLLEGEVILLE ROAD
PO BOX 5089
COLLEGEVILLE PA 19426-0989 US
1-800-877-7074

Approved by FDA on 12/1/1993

Mfr report #: 2001014040-2

UF/Dist report #:

A. Patient Information

1. Patient Identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
(in confidence)		☐ female ☒ male	____ 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 (mo/day/yea)
- ☐ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☒ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yea)

4. Date of this report: 06/13/2001 (mo/day/yea)

5. Describe event or problem

Report 2001014040-2 describes the occurrence of Truncus arteriosis in a fetus whose mother was treated with paroxetine (Paxil) for panic disorder. This report was received from the mother and has not been confirmed by a physician or other healthcare professional.

The mother's concurrent medications and medical conditions were not specified. Four and a half years ago, the mother started Paxil (dose unknown). The mother discovered she was pregnant in December 2000 while being treated with Paxil. However, she reported that at six months gestation, the pregnancy had to be terminated because the fetus was diagnosed as having Truncus arteriosis. The mother was told by the physician that the child "would not lead a normal childhood and would most likely not make it through the open heart surgery that he would need as soon as he was delivered (if he was able to make it to that time)". The mother noted, "I am in no way insinuating that this product [Paxil] did this to my child".

Additional information has been requested.

See report 2001014040-1 for information regarding the mother.

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.)

The mother's concurrent medications and medical conditions were not specified.

C. Suspect Medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 PAXIL
SMITHKLINE BEECHAM
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unk, give duration)
#1
#2

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

D. All manufacturers

1. Contact office - name/address(&mailing site for devices)
Ms. Jane A. Nieman UP 3410
SMITHKLINE BEECHAM PHARMACEUTICALS
1250 SOUTH COLLEGEVILLE ROAD
COLLEGEVILLE PA 19426-0989 US

2. Phone number
1-610-917-5475

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

4. Date r'cvd by manufacturer
05/31/2001 (mo/day/yea)

5.
(A)NDA # 20-031
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)
TRUNCUS ARTERIOSIS

9. Mfr. report number
2001014040-2

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

FDA Form 3500A
Facsimile

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

PAR060290291

GlaxoSmithKline

15-DAY ALERT REPORTS

GlaxoSmithKline
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]
www.gsk.com

JUN 13 2001

NDA 20-031 (Paxil®)

FDA, Central Document Room
12229 Wilkins Avenue
Rockville, MD 20852

Dear Sir/Madam:

Enclosed please find two copies of an initial 15-day alert report concerning a fetus whose mother had been treated with Paxil® therapy during pregnancy.

Patient 2001014040-2 – Truncus arteriosis:
FDA Form 3500A.

Thank you for your attention to this matter.

Sincerely,

Patricia Kauffman, M.D.
Associate Director
Global Clinical Safety and Pharmacovigilance

PK:dp
Enclosure

PAR060290292

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

SMITHKLINE BEECHAM PHAR
1250 SOUTH COLLEGEVILLE ROAD
PO BOX 5089
COLLEGEVILLE PA 19426-0989 US
1-800-877-7074

Page 1 of 1

Approved by FDA on 12/1/1993

Mfr report #: 2001014040-2

DF/Dist report #:

A. Patient Information

1. Patient Identifier: in confidence

2. Age at time of event: or Date of birth:

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 ____ (mm/dd/yyyy)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☒ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ____

3. Date of event (mm/dd/yyyy):

4. Date of this report (mm/dd/yyyy): 06/13/2001

5. Describe event or problem

Report 2001014040-2 describes the occurrence of Truncus arteriosis in a fetus whose mother was treated with paroxetine (Paxil) for panic disorder. This report was received from the mother and has not been confirmed by a physician or other healthcare professional.

The mother's concurrent medications and medical conditions were not specified. Four and a half years ago, the mother started Paxil (dose unknown). The mother discovered she was pregnant in December 2000 while being treated with Paxil. However, she reported that at six months gestation, the pregnancy had to be terminated because the fetus was diagnosed as having Truncus arteriosis. The mother was told by the physician that the child "would not lead a normal childhood and would most likely not make it through the open heart surgery that he would need as soon as he was delivered (if he was able to make it to that time)". The mother noted, "I am in no way insinuating that this product [Paxil] did this to my child".

Additional information has been requested.

See report 2001014040-1 for information regarding the mother.

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.)

The mother's concurrent medications and medical conditions were not specified.

C. Suspect Medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1 PAXIL
SMITHKLINE BEECHAM
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unk, give duration)
#1
#2

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

D. All manufacturers

1. Contact office - name/address (&mfrlng site for devices)
Ms. Jane A. Nieman UP 3410
SMITHKLINE BEECHAM PHARMACEUTICALS
1250 SOUTH COLLEGEVILLE ROAD
COLLEGEVILLE PA 19426-0989 US

2. Phone number
1-610-917-6475

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

4. Date r'cvd by manufacturer
05/31/2001 (mm/dd/yyyy)

5. (A)NDA # 20-031
IND #
PLA #

6. If IND, protocol #

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

pre-1938 ☐ yes
OTC product ☐ yes

8. Adverse event term(s)
TRUNCUS ARTERIOSIS

9. Mfr. report number
2001014040-2

E. Initial Reporter

1. Name, address & phone #
Redacted

JUN 13 2001

2. Health Professional?
☐ yes ☒ no

3. Occupation

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

FDA Form 3500A
Facsimile

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

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