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13-APR-1998-0690

VEIL CC
FORT

Individual Safety Report
3065100-X-00

FDA on 11/15/93

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or 64 yrs Date of birth [redacted]	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply)
(x) death 11/11/97 (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr) 10/29/97

4. Date of this report (mo/day/yr) 03/31/98

5. Describe event or problem

Consumer report of DEATH allegedly associated with an Extra Strength TYLENOL® acetaminophen product in her 62 y/o mother. Daughter reports mother was taking 3-4 Extra Strength TYLENOL at bedtime for approximately 4-5 months for tooth pain. On 10/29/97, patient appeared confused and disoriented; not like herself (CONFUSION). Daughter took mother to hospital later that same day and patient was admitted. Admitting diagnosis unknown. In hospital, patient had an elevated blood sugar (HYPERGLYCEMIA). Physician initially believed patient was suffering from a nervous breakdown. Later in the week, LFT's were reportedly abnormal (LIVER FUNCTION TESTS ABNORMAL) and patient was subsequently diagnosed with TYLENOL poisoning. Patient expired on 11/11/97. According to daughter, death certificate lists cause of death as acetaminophen toxicity, chronic. No further information was provided.

6. Relevant tests/laboratory data, including dates

blood work in hospital: blood sugar elevated (results not provided); liver function tests taken later in the week of hospitalization (results reportedly abnormal)

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

Crohn's disease, bipolar disorder; stents in heart 8/97

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Extra Strength TYLENOL product
#2

2. Dose, frequency & route used
#1 1500-2000 mg, hs, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 4-5 months
#2

4. Diagnosis for use (indication)
#1 tooth pain
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 Unknown
#2

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

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

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

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

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number
215-233-7820

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

4. Date received by manufacturer (mo/day/yr) 03/31/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

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

8. Adverse event term(s)
DEATH
CONFUSION
HYPERGLYCEMIA
LIVER FUNC ABNO

9. Mfr. report number
0957821A

E. Initial reporter

1. Name, address & phone #

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2. Health professional? ( ) Yes ( ) No

3. Occupation

4. Initial reporter also sent report to FDA ( ) Yes ( ) No ( ) Unk

FDA
Facsimile Form 3500A

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