Individual Safety Report

3549368-9-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: adult or Date of birth:
3. Sex: (X) female ( ) male
4. Weight: 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)
( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: none

3. Date of event (mo/day/yr): unknown
4. Date of this report (mo/day/yr): 11/30/99

5. Describe event or problem

Consumer alleges that the use of one of our Extra Strength TYLENOL® acetaminophen products and PERCOCET® was associated with LIVER FUNCTION TESTS ABNORMAL (test showed elevated liver enzymes). According to consumer, she takes both PERCOCET and TYLENOL on a daily basis for pain. Consumer reports a routine lab test performed by her physician on an unspecified date revealed an elevation in her liver enzymes. The physician reportedly did not recommend any change in therapy.

6. Relevant tests/laboratory data, including dates

unknown

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

osteoarthritis; several unspecified drug allergies

C. Suspect medication(s)

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

2. Dose, frequency & route used
#1 unknown dose, po
#2 unknown dose, po

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

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

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

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

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

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

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

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

G. All manufacturers

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

2. Phone number
215-273-7303

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)
11/30/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

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

8. Adverse event term(s)
LIVER FUNC ABNO

9. Mfr. report number
1277788A

E. Initial reporter

1. Name, address & phone #

AUG - 9 2000

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.

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