

RECEIVED AT DRUG SAFETY SURVEILLANCE



03-APR-1998-0762

McP

Individual Safety Report
3062745-8-00

Page ___ of ___

vised by FDA on 11/16/91

FDA use only

A. Patient information

1. Patient identifier: [redacted]
 2. Age at time of event: adult
 3. Sex: () female (X) 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):
 (X) death (12/28/95) () disability
 () life-threatening () congenital anomaly
 (X) hospitalization - initial or prolonged () required intervention to prevent permanent impairment/damage
 () other:

3. Date of event: 12/25/95
 4. Date of this report: 03/23/98

5. Describe event or problem:
 Notification via Summons & Complaint of DEATH allegedly associated w/the use of an acetaminophen product & hydrocodone APAP in adult male. According to Summons & Complaint, pt began experiencing cold/flu-like symptoms on 12/23/95. On 12/24/95, symptoms persisted & pt began experiencing back pain. That same day, pt had nothing to eat & declined alcoholic beverages. On 12/25/95, pt awoke & started VOMITING & c/o of upper ABDOMINAL PAIN. Pt taken to ER. Reported hx of taking over-the-counter acetaminophen. Pt sent home the same day w/hydrocodone APAP & instructions to return to hosp the next day for more tests. Returned to ER on 12/26/95 w/red appearance all over & yellow spots on skin & c/o vomiting & diarrhea. MD diagnosed toxic HEPATITIS likely caused by TYLENOL. Pt had LIVER FAILURE complicated by KIDNEY FAILURE & was transferred to 2nd hosp for dialysis/possible liver transplant. Pt went into COMA, suffered complete kidney failure & required respirator (APNEA). On 12/28/95, transferred to 3rd hosp for liver transplant. Died several hrs later.

6. Relevant test/laboratory data, including dates:
 12/25/95 a.m. blood work (results not provided); procedures undertaken reportedly ruled out gall bladder disease and indicated diminished liver function; 12/26/95 5 p.m. blood work (34 hours since first blood test) (See Sect B7)

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

Sect B6 con't: results interpreted by physician as probable viral hepatitis; 12/26/95 CT scan reportedly showed liver was very damaged, and that kidneys were not functioning properly

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 acetaminophen product (Perrigo)
 #2 hydrocodone APAP (McKesson)

2. Dose, frequency & route used
 #1 unknown dose, po
 #2 1-2 tablets, q4-6h prn, po

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
 #1 12/95
 #2 12/25/95-12/26/95; 1 day

4. Diagnosis for use (indication)
 #1 cold/flu and back pain
 #2 cold/flu and back 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 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
 () consumer
 () health professional
 () user facility
 () company representative
 () distributor
 (X) other: attorney

4. Date received by manufacturer (mo/day/yr)
 03/17/98

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 VOMITING
 PAIN ABDOMINAL HEPATITIS
 LIVER FAILURE KIDNEY FAILURE
 COMA APNEA

9. Mfr. report number
 0953961A

E. Initial reporter

1. Name, address & phone #
 [redacted] P.C.
 [redacted] Suite [redacted]
 [redacted]

2. Health professional?
 () Yes (X) No

3. Occupation
 attorney

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



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

APR 06 1998