



19-FEB-1998-0674



McNEIL CONSUMER
FORT WASH

Page _____



3031725-0-00

A. Patient information

1. Patient identifier Case 194 In confidence	2. Age at time of event: 41 yrs or _____ Date of birth: _____	3. Sex (X) female () male	4. Weight unk lbs or _____ kgs
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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	() disability
() life-threatening	() congenital anomaly
(x) hospitalization - initial or prolonged	() required intervention to prevent permanent impairment/damage
() other: _____	

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 02/09/98 (mo/day/yr)

5. Describe event or problem

Case # 194 received from the █████ 1996 case fatality data. See attached case report form provided by █████

C. Suspect medication(s)

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

#1 unknown acetaminophen product

#2 _____

2. Dose, frequency & route used

#1 "high doses", daily, po

#2 _____

3. Therapy dates (if unknown, give duration from/to for best estimate)

#1 unknown dates or duration

#2 _____

4. Diagnosis for use (indication)

#1 viral illness and abdominal 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)

See attached case report form provided by █████

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
(x) literature
() consumer
(x) health professional
() user facility
() company representative
() distributor
() other:

4. Date received by manufacturer (mo/day/yr)
01/30/98

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)

OVERDOSE LIVER FAILURE
BRAIN SYND ACUT ACIDOSIS
HEPATORENAL SYN COAGULATION DIS
DEATH

9. Mfr. report number
0929666A

E. Initial reporter

1. Name, address & phone #

██████████ MD
██████████ Centers
Suite ██████████ Avenue
██████████

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

3. Occupation
physician

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

FEB 11 1998



19-FEB-1998-0675



3031725-0-00

[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 194

Age: 41 yrs

Substances: Acetaminophen

Chronicity: Chronic

Route: Ingestion

Reason: Int Misuse

Pre-Hospital Arrest? No

This 41 year old female presented to a local Emergency Department with a 1-day history of a viral illness and abdominal pain, for which she was taking high doses of acetaminophen daily. She is known to use alcohol, but had no known history of ethanol abuse. On admission, she was found to be in fulminant hepatic failure with hepatic encephalopathy and acidemia. She was transferred to a regional transplant and poison treatment center for evaluation, and was confirmed to be in hepatorenal failure. On admission, her serum pH was 7.18 with a PCo₂ of 23; admission LFT's were an AST of 5524 u/L, ALT > 4,250 u/L, ammonia 237 micromoles/L, total bilirubin 3.7, creatinine 5.3, PT 44.7 seconds and acetaminophen 44 mcg/ml. The patient was immediately started on intravenous N-acetylcysteine at the time of admission, and was placed on the priority liver transplant list. However, the patient's status deteriorated rapidly and she developed multi-organ failure with severe coagulopathy. She expired on the day following admission due to fulminant hepatic failure. Antigens and antibodies for hepatitis A, B, and C were all negative. The patients' family refused permission for autopsy.