



19-FEB-1998-0624



McNEIL CONSUMER  
FORT WASHIN

Individual Safety Report



\*3032528-3-00\*

Page \_\_\_\_\_

**A. Patient information**

|  |  |                                      |                                   |
|--|--|--------------------------------------|-----------------------------------|
| 1. Patient Identifier<br><br>Case 211<br>In confidence | 2. Age at time of event:<br>or<br>Date of birth:<br>37 yrs | 3. Sex<br>(X) female<br><br>( ) male | 4. Weight<br>unk lbs<br>or<br>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 (unknown) (m/d/y)                | ( ) disability   |
| ( ) life-threatening                       | ( ) congenital anomaly   |
| (x) hospitalization - initial or prolonged | ( ) required intervention to prevent permanent impairment/damage |
| ( ) other:                                 |  |

|  |   |
|--|---|
| 3. Date of event<br>(m/d/y)<br>unknown | 4. Date of this report<br>(m/d/y)<br>02/06/98 |
|--|---|

5. Describe event or problem

Case # 211 received from the [redacted] 1996 case fatality data. See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

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

See attached case report form provided by [redacted]

**C. Suspect medication(s)**

|   |                         |   |  |
|---|-------------------------|---|--|
| 1. Name (give labeled strength & mfr/labeler, if known) |                         | 3. Therapy dates (if unknown, give duration) from/to (or best estimate)         |  |
| #1 unknown acetaminophen product                        |                         | #1 over several days  |  |
| #2 ethanol  |                         | #2 over several days  |  |
| 2. Dose, frequency & route used                         |                         | 5. Event abated after use stopped or dose reduced                               |  |
| #1 "large amount", po                                   |                         | #1 ( ) Yes ( ) No (X) N/A   |  |
| #2 unknown dose, po                                     |                         | #2 ( ) Yes ( ) No (X) N/A   |  |
| 4. Diagnosis for use (indication)                       |                         | 8. Event reappeared after reintroduction  |  |
| #1 intentional abuse                                    |                         | #1 ( ) Yes ( ) No (X) N/A   |  |
| #2 intentional abuse                                    |                         | #2 ( ) Yes ( ) No (X) N/A   |  |
| 6. Lot # (if known)                                     | 7. Exp. date (if known) | 10. Concomitant medical products and therapy dates (exclude treatment of event) |  |
| #1 Unknown  | #1 Unknown              | See attached case report form provided by [redacted]                            |  |
| #2 unknown  | #2 unknown              |   |  |
| 9. NDC # - for product problems only (if known)         |                         |   |  |

**G. All manufacturers**

|  |  |   |
|--|--|---|
| 1. Contact office - name/address (& mfrng site for devices)  |  | 2. Phone number   |
| McNeil Consumer Products Company<br>Medical Affairs<br>7050 Camp Hill Road<br>Ft. Washington, PA 19034 |  | 215-233-7820  |
| 4. Date received by manufacturer (m/d/y)   |  | 3. Report source (check all that apply)   |
| 01/30/98   |  | ( ) foreign<br>( ) study<br>(x) literature<br>( ) consumer<br><br>(x) health professional<br>( ) user facility<br><br>( ) company representative<br>( ) distributor<br>( ) other: |
| 6. If IND, protocol #  | 5. (A) NDA # 17-552<br>IND #<br>PLA #<br>pre-1938 ( ) Yes<br>OTC product (X) Yes                             |   |
| 7. Type of report (check all that apply)   | 8. Adverse event term(s)   |   |
| ( ) 5-day (X) 15-day<br>( ) 10-day ( ) periodic<br>(X) initial ( ) follow-up #                         | HYPOTENSION ACIDOSIS<br>CREATININE INC LIVER FUNC ABNO<br>PROTHROMBIN INC CONFUSION<br>HEMATOMA SUBDUR DEATH |   |
| 9. Mfr. report number  |  |   |
| 0929802A   |  |   |

**E. Initial reporter**

|  |               |   |
|--|---------------|---|
| 1. Name, address & phone #   |               |   |
| [redacted] MD<br>[redacted] Centers<br>Suite [redacted] Avenue<br>[redacted] |               |   |
| 2. Health professional?  | 3. Occupation | 4. Initial reporter also sent report to FDA |
| (X) Yes ( ) No   | physician     | ( ) Yes ( ) No (X) Unk                      |



Facsimile Form 3600A

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



19-FEB-1998-0625



\*3032528-3-01\*

**[REDACTED] FATALITY: 1996 [REDACTED]**

Case Number: 211  
Age: 37 yrs  
Substances: Acetaminophen  
ethanol  
Chronicity: Chronic  
Route: Ingestion  
Reason: Int Abuse  
Pre-Hospital Arrest? No

A lethargic 37 year-old female was brought to the emergency department by ambulance after it was learned that she had ingested a large amount of acetaminophen and alcohol over several days. The patient had a history of pancreatitis and chronic liver disease. On admission her BP was 110/60, her pulse 120, her respiratory rate 18 breaths/minute, and her temperature 96° F. An arterial blood gas on admission was pH 7.20, pCO<sub>2</sub> 26, pO<sub>2</sub> 124. An acetaminophen level was <2 mcg/mL and an ethanol level was 75 mg/dL. The patient's creatinine was 2.9 mg/dL, BUN 19 mg/dL, ammonia 56 IU/L. The ALT was 25,300 the AST 18,000 the LDH 64,900 the bilirubin 9.1 mg/dL. The PT was 39.5 sec and the PTT 127 sec. The patient was intubated and was started on 140mg/kg N-acetylcysteine (NAC-PO) via NG tube. NAC-PO was continued at 70 mg/kg every 4 hrs until the hepatic transaminases approached normal. Approximately 72 hours after admission the patient became progressively lethargic and confused. A CT scan revealed a subdural hematoma. The patient continued to deteriorate and expired on the eighth day of hospitalization. The medical examiner declined the case.