



19-FEB-1998-0640



McNEIL CONSUMER  
FORT WASHIN

Page \_\_\_\_\_

Individual Safety Report



\*3032559-3-00\*

**A. Patient information**

1. Patient Identifier Case 215 In confidence	2. Age at time of event: 74 yrs or Date of birth:	3. Sex (X) female ( ) male	4. Weight unk lbs or kgs
--	--	----------------------------------	-----------------------------------

**C. Suspect medication(s)**

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

**B. Adverse event or product problem**

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage ( ) other:
2. Outcomes attributed to adverse event (check all that apply) (x) death (unknown) (mo/day/yr) ( ) life-threatening (x) hospitalization - initial or prolonged	
3. Date of event (mo/day/yr) unknown	4. Date of this report (mo/day/yr) 02/06/98

5. Describe event or problem  
Case # 215 received from the [redacted] 1996 case fatality data. See attached case report form provided by [redacted]

**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
4. Date received by manufacturer (mo/day/yr) 01/30/98		3. Report source (check all that apply) ( ) foreign ( ) study (x) literature ( ) consumer  (x) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:
6. If IND, protocol #		
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) initial ( ) follow-up #		(A) NDA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes
9. Mfr. report number 0929952A		8. Adverse event term(s) OVERDOSE INTENT    SYNCOPE HEMORRHAGE        BILIRUBINEMIA LIVER FAILURE      KIDNEY FAILURE DEATH

**E. Initial reporter**

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



19-FEB-1998-0641



\*3032559-3-01\*

**FATALITY: 1996**

---

Case Number: 215

Age: 74 yrs

Substances: Acetaminophen  
ethanol

Chronicity: Chronic

Route: Ingestion

Reason: Int Abuse

Pre-Hospital Arrest? No

A 74 year old female was admitted to ICU with decreased level of consciousness. She has a history of ETOH abuse and has been taking APAP on a chronic bases. Initial APAP level was 70 mcg/ml. The patient required intubation. She was oozing blood from all injection sites and her PTT was 7.2, bilirubin was elevated, LFT's high. She was given FFP and Vit K. She was also started on NAC per NG tube.

The patient was placed on a "Do Not Resuscitate" status due to history of hepatic and renal failure. She expired 2 days after admission to ICU. No autopsy was performed on the patient.