



\*3417753-1-00-01\*

|                   |                 |
|-------------------|-----------------|
| Mfr report #      | PRUSA1999006640 |
| U/F/Date report # |                 |
| FDA Use Only      |                 |

| A. Patient information   |                                   |   |                                       |
|--|-----------------------------------|---|---------------------------------------|
| 1. Patient identifier<br>? - ?   | 2. Age at time of event:<br>25 yr | 3. Sex<br><input checked="" type="checkbox"/> female<br><input type="checkbox"/> male | 4. Weight<br>UNK lbs<br>or<br>UNK kgs |
| In confidence  |                                   |   |                                       |
| Date of birth: ??/??/??  |                                   |   |                                       |
| B. Adverse event or product problem  |                                   |   |                                       |
| 1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)  |                                   |   |                                       |
| 2. Outcomes attributed to adverse event (check all that apply)   |                                   |   |                                       |
| <input checked="" type="checkbox"/> death 22/222/22 (month/year)   |                                   | <input type="checkbox"/> disability   |                                       |
| <input type="checkbox"/> life-threatening  |                                   | <input type="checkbox"/> congenital anomaly   |                                       |
| <input checked="" type="checkbox"/> hospitalization - initial or prolonged   |                                   | <input type="checkbox"/> required intervention to prevent permanent impairment/damage |                                       |
| <input type="checkbox"/> other: _____  |                                   |   |                                       |
| 3. Date of event (month/year) ??/??/??   |                                   | 4. Date of this report (month/year) 12/02/99  |                                       |
| 5. Describe event or problem   |                                   |   |                                       |
| Report published in 1994 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 270). A 25-year-old patient (sex unspecified) died following intentional abuse of acetaminophen with codeine, and carisoprodol. Serum acetaminophen level 19 mcg/mL. Exposure to medication was chronic.  |                                   |   |                                       |
| Additional information received 29-NOV-99: This 25 year old female with a history of borderline diabetes presented unresponsive to the emergency department with the history that she had been chronically abusing acetaminophen with codeine and carisoprodol. She was found to be hypoglycemic and was treated with dextrose and started on N-acetylcysteine. Her initial vital signs were: blood pressure, 119/68 mmHg; heart rate, 136 beats/minute; and respiratory rate, 30 breaths/minute. Initial laboratory values included: acetaminophen level, 19 mcg/mL; blood pH, 7.06; SGOT, 1083 U/L; SGPT, 503 U/L; WBC, 42,000; glucose, 5 mg/dL; and prothrombin time, 23 sec. She was transferred to the liver transplantation (Cont.) |                                   |   |                                       |
| 6. Relevant tests/laboratory data, including dates (Lab data cont.)  |                                   |   |                                       |
| <b>DSS</b>   |                                   |   |                                       |
| DEC 10 1999  |                                   |   |                                       |
| ADVERSE EVENT REPORTING CENTER (Cont.)   |                                   |   |                                       |
| 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)   |                                   |   |                                       |
| History of borderline diabetes, chronic abuse of acetaminophen with codeine and carisoprodol.  |                                   |   |                                       |

| C. Suspect medication(s)  |  |   |  |
|---|--|---|--|
| 1. Name (give labeled strength & mfr/labeler, if known)   |  |   |  |
| #1 TYLENOL WITH CODEINE (unspecified) (ACETAMINOPHEN-   |  |   |  |
| #2 CARISOPRODOL (CARISOPRODOL) (Cont.)  |  |   |  |
| 2. Dose, frequency & route used   |  | 3. Therapy dates (if unknown, give duration) (month/year for best estimate)                                   |  |
| #1 oral   |  | #1 ??/??/??   |  |
| #2 oral   |  | #2 ??/??/??   |  |
| 4. Diagnosis for use (indication)   |  | 5. Event abated after use stopped or dose reduced   |  |
| #1 UNKNOWN  |  | #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply |  |
| #2 UNKNOWN  |  | #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply            |  |
| 6. Lot # (if known)   |  | 7. Exp. date (if known)   |  |
| #1  |  | #1  |  |
| #2  |  | #2  |  |
| 8. Event reappeared after reintroduction  |  |   |  |
| #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply |  |   |  |
| #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply            |  |   |  |
| 9. NDC # - for product problems only (if known)   |  |   |  |
| 10. Concomitant medical products and therapy dates (exclude treatment of event)                               |  |   |  |
| No Concomitant Products Reported  |  |   |  |

| G. All manufacturers  |  |
|---|--|
| 1. Contact office - name/address (& mailing site for devices)   | 2. Phone number                          |
| R.W. JOHNSON PHARM. RES. INST. USA<br>DIV. OF ORTHO PHARMACEUTICAL CORP.<br>920 U.S. Route 202<br>P.O. Box 300<br>Raritan NJ 08869<br>USA<br>( Informing Unit ) | 908-704-4504                             |
| 3. Report source (check all that apply)   |  |
| <input type="checkbox"/> foreign  |  |
| <input type="checkbox"/> study  |  |
| <input checked="" type="checkbox"/> literature  |  |
| <input type="checkbox"/> consumer   |  |
| <input checked="" type="checkbox"/> health professional   |  |
| <input type="checkbox"/> user facility  |  |
| <input type="checkbox"/> company representative   |  |
| <input type="checkbox"/> distributor  |  |
| <input type="checkbox"/> other: _____   |  |
| 4. Date received by manufacturer (month/year)   | 5. (AN)DA #                              |
| 11/29/99  | 85-055                                   |
| 6. If IND, protocol #   | IND # _____                              |
|   | PLA # _____                              |
| 7. Type of report (check all that apply)  | pre-1938 <input type="checkbox"/> yes    |
| <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day   | OTC product <input type="checkbox"/> yes |
| <input type="checkbox"/> 10-day <input type="checkbox"/> periodic   |  |
| <input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1  |  |
| 8. Adverse event term(s)  |  |
| 1) DEATH  |  |
| 2) HEPATIC FAILURE  |  |
| 3) RENAL FAILURE ACUTE  |  |
| 4) HYPOGLYCAEMIA  |  |
| 5) DRUG ABUSE   |  |
| 9. Mfr. report number   |  |
| PRUSA1999006640   |  |

| E. Initial reporter  |               |  |  |
|--|---------------|--|--|
| 1. Name, address & phone #   |               |  |  |
| Dr. Toby Litovitz<br>National Capital Poison Center<br>Georgetown University Hospital<br>3800 Reservoir Road NW<br>Washington, DC 20007<br>USA |               |  |  |
| 2. Health professional?  | 3. Occupation | 4. Initial reporter also sent report to FDA  |  |
| <input checked="" type="checkbox"/> yes <input type="checkbox"/> no  | Physician     | <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> 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.

P.O.  
Rarid  
USA



\*3417753-1-00-02\*

Continuation Sheet for FDA 3500A Form

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Mfr. report #: PRIUSA1999006640

Date of this report: 12/02/99

**B. Adverse event or product problem**

**B.5 Describe event or problem (Cont...)**

center. She developed fulminant hepatic failure and renal failure, despite N-acetylcysteine therapy. She was determined not to be a candidate for liver transplantation. The patient expired on day three. No autopsy was performed.

**B.6 Relevant tests/laboratory data, including dates (Cont...)**

**Lab Result:**

| Sl.No. | Test date | Test name                   | Test result                         | Normal value |
|--------|-----------|-----------------------------|-------------------------------------|--------------|
| 1      | ??/??/??  | DRUG LEVEL<br>acetaminophen | 19 mcg/mL<br>(microgram/milliliter) |              |

**C. Suspect medication (Cont...)**

Seq No. : 1  
C.1 Suspect medication : TYLENOL WITH CODEINE (unspecified) (ACETAMINOPHEN/CODEINE)

**Source of report (Literature):**

Seq No. : 1  
Author : Toby Litovitz  
Journal title : 1994 Annual Report of the American Association of  
Poison Control Centers National Data Collection  
System  
Year : 95  
Edition : 13(5)  
Page number : From 551 To 597  
Article title : American Journal of Emergency Medicine

**DSS**

**DEC 09 1999**

DEC 10 1999

ADVERSE EVENT REPORTING