

Individual Safety Report



\*3665227-5-00-01\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Form Approved OMB No. 0910-0281 Expires 12/31/04 See OMB instructions on reverse

Mfr report # 01-0070  
 Off/Out report #  
 FDA Use Only

Page 1 of 1

**A. Patient information**

1. Patient identifier: unknown  
 2. Age at time of event: early 40's  
 or Date of birth:  
 3. Sex:  female  male  
 4. Weight: unkn lbs or kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g. defects/malfunctions)  
 2. Outcomes attributed to adverse event (check all that apply):  
 death  disability  
 life-threatening  congenital anomaly  
 hospitalization - initial or prolonged  required intervention to prevent permanent impairment/damage  
 other:  
 3. Date of event (mandatory): - November, 1999  
 4. Date of this report (mandatory):

5. Describe event or problem  
 A reporter called Watson Laboratories, Inc. regarding a patient who died after an overdose with Hydrocodone Acetaminophen 7.5/750 mg Tablets. The reporter stated that a woman in her early 40's underwent a bunionectomy and was prescribed a Hydrocodone Acetaminophen product for the pain. The reporter was initially unclear as to which product was involved, but she then indicated that the patient was prescribed Hydrocodone Acetaminophen 7.5/750 mg prior to the surgery and was instructed to take the medication before and after the surgery. She indicated that the doctor had prescribed 1-2 tablets every 4-6 hours, and the patient had taken 12 tablets in 24 hours. The reporter explained that the patient sustained toxic liver damage and died around November 17, 1999.

6. Relevant tests/laboratory data, including dates  
 Unknown

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

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/tablet, if known): Hydrocodone Acetaminophen Tablets 7.5/750 mg, Watson Laboratories, Inc.  
 #2  
 2. Dose, frequency & route used: #1 1-2 tabs po q4-6 hr #2  
 3. Therapy dates (if unknown, give duration, provide for each estimate): #1 unknown (12 tabs in 24 hr) #2  
 4. Diagnosis for use (indication): #1 pain #2  
 5. Event abated after use stopped or dose reduced: #1  yes  no  doesn't apply #2  
 6. Lot # (if known): #1 unknown #2  
 7. Exp. date (if known): #1 #2  
 8. Event reappeared after reintroduction: #1  yes  no  doesn't apply #2  
 9. NDC # - for product problems only (if known):  
 10. Concomitant medical products and therapy dates (exclude treatment given): Unknown

**G. All manufacturers**

1. Contact office - name/address (& mailing site for devices): Watson Laboratories, Inc. 311 Bonnie Circle Corona, CA 91720  
 2. Phone number: (909) 270-1400  
 3. Report source (check all that apply):  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other  
 news repo ter  
 4. Date received by manufacturer (mandatory): 01-11-2001  
 5. (A)NDA #: 81-083  
 IND #:   
 PLA #:   
 pre-1938  yes  
 OTC product  yes  
 6. If IND, protocol #  
 7. Type of report (check all that apply):  
 5-day  15-day  
 10-day  periodic  
 initial  follow-up #  
 8. Adverse event term(s): Death, Overdose, Liver Damage  
 9. Mfr. report number: 01-0070

**E. Initial reporter**

1. Name, address & phone # (Confidential)  
 DSS  
 FEB 14 2001  
 2. Health professional?  yes  no  
 3. Occupation: Reporter  
 4. Initial reporter also sent report to FDA:  yes  no  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.

FDA Form 3506A (8/03)



21 CFR 314.80(c)(2) Adverse Drug Experience Report

(ii)(a) Narrative Summary

A reporter called Watson Laboratories, Inc. regarding a patient who died after an overdose with Hydrocodone/Acetaminophen 7.5/750 mg Tablets. The reported stated that a woman in her early 40's underwent a bunionectomy and was prescribed a Hydrocodone/Acetaminophen product for the pain. The reporter was initially unclear as to which product was involved, but she then indicated that the patient was prescribed Hydrocodone/Acetaminophen 7.5/750 mg prior to the surgery and was instructed to take the medication before and after the surgery. She indicated that the doctor had prescribed 1-2 tablets every 4-6 hours, and the patient had taken 12 tablets in 24 hours. The reporter explained that the patient sustained toxic liver damage and died around November 17, 1999.

(ii)(b) Index

I. Manufacturer Control No:

01-0070

Patient Information

Initials: Unknown  
 Sex: Female  
 Age/DOB: early 40's  
 Weight: unknown

Adverse Reaction  
 Death, Overdose,  
 Liver Damage

(ii)(c) Narrative of Action Taken

We reviewed the FDA-approved package insert for Hydrocodone Bitartrate/Acetaminophen Tablets. The package insert states that the usual daily dosage of the 7.5/750 mg strength tablets is one tablet every four to six hours as needed for pain. It states 'the total daily dosage should not exceed 5 tablets'. Under the 'Overdosage' section of the package insert, it states 'In acetaminophen overdosage: dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect'. The insert states 'In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams, or fatalities with less than 15 grams.'

Limited information was received regarding this event. If any further information becomes available, it will be forwarded referencing Manufacturer Control No. 01-0070.

DSS

FEB 14 2001