



# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Fielisys International, Inc  
FDA Facsimile Approval: 15-JUN-1995  
Mfr report #  
UF/Dist. report #  
C1001000054

**A. Patient information**

1. Patient identifier: [redacted] 2. Age at time of event: UNK  
or Date of birth: UNK  
in confidence

3. Sex:  female  male  
4. Weight: UNK lbs or UNK 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: 02/15/2001 4. Date of this report: 02/23/2001

5. Describe event or problem:  
liver poisoning[Hepatocellular damage]  
yellow skin color[Yellow skin]  
bleeding internally[Haemorrhage NOS]  
vomiting blood[Haematemesis]  
tylenol poisoning[Therapeutic agent poisoning]

Case Description:  
A consumer reported that her husband (between 35-44 years of age) took NyQuil Adult, Version/Flavor Unknown Liquid (unspecified daily dose) for four days and developed very yellow skin color, vomited blood, and was bleeding internally beginning 15-FEB-2001. He was taken to the emergency room and was admitted to the critical care unit on 15-FEB-2001. The physicians said that NyQuil poisoned his liver. He had received thirteen pints of blood to treat the diagnosis of Tylenol poisoning. Her husband was still hospitalized and the symptoms were still present at the time of the initial report on 18-FEB-2001. Follow-up e-mail message received on 22-FEB-2001 revealed that her husband continued in additional info section...

6. Relevant tests/laboratory data, including dates: NI

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

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)  
# 1. NyQuil Adult, Version/Flavor Unknown (continued)  
# 2.

2. Dose, frequency & route used  
# 1. Unknown, Oral  
# 2.

3. Therapy dates (if unknown, give duration)  
# 1. duration 4 days 3 hrs  
# 2.

4. Diagnosis for use (indication)  
# 1. UNK  
# 2.

5. Event abated after use stopped or dose reduced  
# 1.  yes  no  doesn't apply  
# 2.  yes  no  doesn't apply

6. Lot # (if known) 7. Exp. date (if known)  
# 1. Unknown # 1. UNK  
# 2. # 2.

8. Event reappeared after reintroduction  
# 1.  yes  no  doesn't apply  
# 2.  yes  no  doesn't apply

9. NDC # - for product problems only (if known)  
# 1. # 2.

10. Concomitant medical products and therapy dates (exclude treatment of event): NI

**G. All Manufacturers**

1. Contact office - name/address (& mailing site for devices)  
Procter & Gamble Regulatory Affairs  
8700 Mason-Montgomery Road  
Mason, OH 45040 UNITED STATES

2. Phone number: 513-6222013

3. Report source (check all that apply):  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer: 02/18/2001

5. (A)NDA # (US) OTC:  
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):  
Hepatocellular damage, Yellow skin, Haemorrhage NOS, Haematemesis, Therapeutic agent poisoning

9. Mfr. report number: C1001000054

**E. Initial reporter**

1. Name & address: [redacted] phone # Unknown

2. Health professional?  yes  no

3. Occupation: Unknown

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.



\*3672504-0-00-02\*

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Procter & Gamble  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service - Food and Drug Administration  
Mfr report #

C1001000054

UF/Drat report #

(continued)

**Additional Information**

**B5. EVENT DESCRIPTION (cont.)**

had been moved to another section of the hospital. He had received ten pints of blood and several unspecified medications to treat the symptoms. She mentioned "lasting effects due to the over-the-counter use of NyQuil" and urged stronger warnings on the product. No further information was provided.

**C1. Name (cont.)**

Suspect Medication #1: NyQuil Adult, Version/Flavor Unknown(ETHANOL 10-25 %, PARACETAMOL 600-1000 mg, DEXTROMETHORPHAN HYDROBROMIDE 15-30 mg, PSEUDOEPHEDRINE HYDROCHLORIDE 60 mg, DOXYLAMINE SUCCINATE 7.5-12.5 mg) Liquid, 30mL

DSS

MAR 02 2001