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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM COPY

CIBA Consumer Pharmaceuticals

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Form Approved by FDA on: 01/05/94

MW report # 00876134

Manufacturer report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event; or Date of birth:	3. Sex	4. Weight
LP In confidence	Unknown Unknown	☒ female ☐ male	____ lbs ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defect/malfunction)

2. Outcome attributed to adverse event (check all that apply)

- ☒ death 10/7/95 (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization-initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other: _____

3. Date of event (mo/day/yr): 6/9/95

4. Date of this report (mo/day/yr): 03/13/96

5. Describe event or problem

PERDIEM Fiber: 3/12/96 - Received report of esophageal blockage with Perdiem Fiber requiring surgery to remove the blockage; the patient died four months later. Additional information requested.

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

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

#1 PERDIEM-PSYLLIUM 4.03GM/TGP-CIBA

#2

2. Dose, frequency & route used

#1 Unknown/Unk/PO

#2

3. Therapy dates (if unknown, give duration)

#1 Unknown

#2

4. Diagnosis for use (indication)

#1 Unknown

#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)

#1 98865

#2

7. Exp. date (if known)

#1 10/31/96

#2

8. NDC # — for product only (if known)

N/A

9. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

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

Unknown

G. Manufacturer

1. Contact office — name/address (& mfrng site for devices)

CIBA Self-Medication, Inc.
581 Main St.
Woodbridge, NJ 07095

2. Phone number: 908-602-6730

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☒ other: FDA # attorney

4. Date received by manufacturer (mo/day/yr): 03/12/96

5. (A) NDA # N/A
IND #
PLA #
pre-1938 OTC product ☐ yes ☒ yes

6. If IND, protocol #: N/A

7. Type of report (check all that apply)

- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☒ initial ☐ follow-up # ___

8. Adverse event term(s)

ESOPHAGEAL STRICTURE (ESOPHAGEAL BLOCKAGE), DEATH

9. Mfr. report number: 00876134

F. Initial reporter

1. Name, address & phone #

Paul Perantinides, Esq.
Nukes Perantinides & Nolan Co., LPA
300 Courtyard Square 80 So. Summit St.
Akron, OH 44308-1719

2. Health professional? ☐ yes ☒ no

3. Occupation: N/A

4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☐ unk

FDA

Facsimile of FDA Form 3500A

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