

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12761



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Author: [REDACTED]

Date: 9/18/97 8:38 AM

Priority: Normal

TO: [REDACTED]

Subject: Internet incident report(ref to FDA)

Document # [REDACTED]

12761

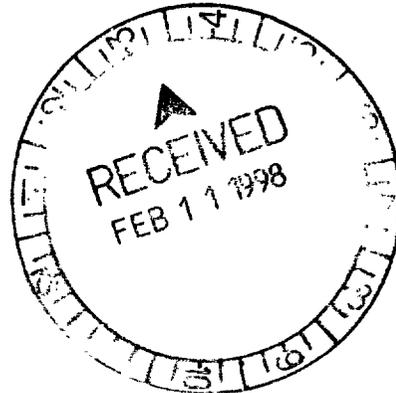
Wed Sep 17 21:58:29 EDT 1997

Name = [REDACTED]
 Address = [REDACTED]
 City = [REDACTED]
 State = [REDACTED]
 Zip = [REDACTED]
 Email = [REDACTED]
 Telephone = [REDACTED]
 Name of Victim = [REDACTED]
 Victim's Address = [REDACTED]
 Victim's City = [REDACTED]
 Victim's State = [REDACTED]
 Victim's Zip = [REDACTED]
 Victim's Telephone = SAME

Incident Description: MA HAUNG -" SAFE DIET" PILLS - ACCIDENT
 OVERDOSAGE, VICTIM TOOK
 4 PILLS AT THE SAME TIME. SIDE EFFECTS , RAPID HEARTBEAT , SEVERE
 CRAMPS , NAUSEA. PHYSICANS HAD NO COMMON KNOWLEDGE OF THE FACT+
 THAT THIS HERB HAS CAUSED 38 DEATHS. I'M CONCERNED THAT EVERYONE
 WILL BUY THIS PRODUCT BECAUSE THEY FEEL IT IS SAFE -BECAUSE
 IT IS SOLD IN HEALTH FOOD STORE.I JUST RECENTLY HAD READ UP
 IN THE "READER'S DIGEST ' (JAN 97) ABOUT THE SIDE EFFECTS. BUT
 NOT EVERYONE READS THAT BOOK AND THE GENERAL POPULATION DOES
 NOT HAVE ACCESS TO THE "WEB" . I PROMISE TO INFORM ALL THAT
 I KNOW ABOUT THIS INCIDENT . PLEASE TELL ME WHEN THIS PRODUCT
 WILL BE TAKEN OFF THE SHELVES AND WHAT ELSE CAN I DO TO PREVENT
 SOMEONE ELSE FROM BEING ILL OR EVEN DIE FROM THIS HERB!!

[REDACTED]

Victim's age = 15
 Victim's sex = Female
 Date of incident = 9/16/97
 Product involved = MA HUANG - EPHEDRA
 Product brand name/manufacturer =
 Product involved still available = Yes
 Product model and serial number =
 Date product purchased =



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DALLAS DISTRICT OFFICE

memorandum



Date: April 13, 1998
From: Connie Hannon-Rabel, Investigator
DHHS/FDA/DAL-IB
Subject: Follow-up on Adverse Event Report #12761
To: Mr. Robert Deininger, DAL-DIB

[Redacted]

Several attempts have been made to contact the complainant at the phone number given in the assignment. There has been no answer at the number, nor a recording/Messaging device. Telephone information revealed only one listing in the area for [Redacted] which is different from the number contained in the assignment. When this number was contacted, the individual stated she had not made a complaint. Efforts to collect the label for the suspect product, Ma Huang, have been fruitless.

On 3/25/98, A letter was sent to the address provided in the assignment (attached). Eighteen days have passed since mailing the letter with no response.

Since the letter was mailed, two additional contacts have been attempted via telephone both yielding no results.

Connie Hannon Rabel
Connie Hannon Rabel

To: Ms. Bridgette M. Wallace, ARMS Monitor
HFS-636

Date: 4/13/98

FROM: Paul Perdue, Jr.; ASCSO
Investigations Branch (HFR-SW150)

Several attempts were made to contact the above-referenced consumer via telephone and U.S. mail to collect labeling of the Ma Huang product. All attempts to make contact with the consumer were unsuccessful, therefore, this assignment could not be completed.

Paul Perdue, Jr.
Paul Perdue, ASCSO

[Redacted]

Attachment

O: DAL-DO; cc: HFS-636; cc: [Redacted]

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