

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

ARMS#

13125



2 - LABEL SAMPLE

000001

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 27450

| | | | | | |
|---------------------------|-------------------------|--------------------------|----------------------------|----------------------|------------------------|
| Flag | Flag Remarks | | | | |
| Complaint Sample | MedWatch # 13125 | | | | |
| Episode Number | Origin | Basis | Sample Type | FIS Smpl Num | Status |
| | Domestic | Compliance | Official | 99921969 | Completed |
| FEI | Date Collected | Product Code | Responsible Firm | PAC | Hours |
| 3002675035 | 20-APR-99 | 54YEA99 | Dealer | 21008 | 8 |
| Related Smpl Num | Position Class | Sampling District | NDC Number | Permit Number | Storage Rqrmnt. |
| 27459 | INV | BLT-DO | | | Ambient |
| Dealer is Consumer | Crx/DEA Schedule | Recall Num | Consumer Compl. Num | Brand Name | |
| No | | | | Unknown | |

Product Description

See C/R # 27459

Product Label

Consumer is unsure of which tablets of her son's Ephedra containing tabs she took. No labeling collected.

Reason for Collection

MedWatch Complaint # 13125

MFG Codes

Expiration Date

Firm Legal Name

[REDACTED]

Address

[REDACTED]

Type of Firm

Dealer

Firm FEI

3002675035

FCE

Size of Lot

Est. Value

Rcpt Type

None

Date Shipped & Doc. Ref.

Description of Sample

Documents relating to consumer's MedWatch complaint # 13125

Method of Collection

Authorization for Medical Records Disclosure and the Adverse Event Questionnaire were collected from the consumer.

How Prepared

N/A

Collector's Identification on Package and/or Label

N/A

Collector's Identification on Seal

N/A

Sample Delivered To

Date Delivered

Orig C/R & Records To

BLT-DO

Lab w/Split Sample

Lab

Document Number

Document Date

Document Type

Document Remarks

Att.#1

11/10/1998

Other

CFSAN Assignment

Att.#2

03/05/1999

Other

Authorization for Medical Records Disclosure

Att.#3

03/05/1999

Other

Adverse Event Questionnaire

Exh.#1

03/08/1999

Other

Unpurged Medical Records on patient ID in MedWatch # 13125

Memorandum to Bridgette M. Wallace, ARMS Monitor, HFS-636

Remarks

This C/R is directly related to C/R # 27459

Payment Amount

Payment Method

704(d) Sample

702(b) Portion

Collector's Name

Date: 04/20/1999

Page: 1 of 2

000002

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 27460

| | | | | | |
|--|------------------|-----------|-----------|----------------------|-----------------------------|
| Name of Signer Gerald Mierle | No Charge | No | No | Gerald Mierle | Meaning Collector |
|--|------------------|-----------|-----------|----------------------|-----------------------------|