8-2 FACTS CONSUMER COMPLAINT REPORT

FACTS Version 4.9.01 - [Maintain Consumer Complaints]

Action Edit Options Navigate Tracing Window Help

Page 1 2

Maintain Consumer Complaints

Complaint Number: | Complaint Date: 10/26/2005 | Receiving Org: DFI | Accomp. District: | Status:

Complainant Name (Last, First): | Street Address:

City: | State: | Zip Code: | Province: | Mail Code: | Country:

Phone (Home): | Phone (Work):

How Received: | Complaint Source: | Source POC: | Source Phone:

Complaint Description:

Adverse Event Result: | Attended Health Professional? | Health Care Prov.

Adverse Event Date: | Emergency Room/Outpatient visit? | ER Info.

Required Hospitalization? | Hospital Info.

Injury / Illness:

Complaint Reported To?

Notify EO/EMOPS? | Notification Date: | Need addnl. FDA Contact?

Remarks: | Received By: Twohy, Christine

Complaint Symptoms

Symptoms	System Affected	Onset Time	Onset Time Unit	Duration	Duration Time Unit	Remarks

Add | Delete

Record: 1/1 | List of Values | <OSC> <DBG>

FACTS Version 4.9.01 - [Maintain Consumer Complaints]

Action Edit Options Navigate Tracing Window Help

Page 1 2

Product/Labeling

Brand Name: | Product Name: | Product Code: B

PAC: | Qty Size: | Unit of Measure: | Package: | Lot/Serial #: | Exp/Use by Date:

UPC: | Manufd. Date: | Purchase Date: | Product Used? | Amount Consum./Used: | Date Used: | Date Discont.:

Amount Remained: | Imported Product | Country of Origin: | Label Remarks:

Retail

Name:

Street Address:

City: | State: | Zip Code:

Province: | Mail Code: | Country:

Problem Ingredient Group

Name

Add | Delete

Manufacturer/Distributor of Product

FEI B	Firm Type	Name & Address	Home District

Add | Delete

Evaluation/Initial Disposition

Problem Keyword

Keyword	Details

Add | Delete

Initial Evaluation:

Initial Disposition:

Disposition Made By:

Disp Date:

Referrals

FACTS Org?	Org. Name	HHS Mail Code

Add | Delete

Init Disp Remarks:

Record: 1/1 | <OSC> <DBG>