README FILE FOR THE DATA EXTRACT FROM THE Human Foods Complaint System (HFCS)

U.S. Food and Drug Administration (FDA)
Human Foods Program (HFP)
Office of Surveillance Strategy and Risk Prioritization (OSSRP)

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TABLE OF CONTENTS

A. INTRODUCTION
B. CAVEATS
C. DATA FIELDS
D. QUESTIONS OR COMMENTS
E. NOTATION ON PRODUCT NAMES AND INDUSTRY CODES

A. INTRODUCTION

You are viewing the README file that accompanies data extracted from the US Food and Drug Administration (FDA) Human Foods Program (HFP) Human Foods Complaint System (HFCS).

HFCS is a post-market surveillance system that collects reports about adverse events involving HFP-regulated products. The HFCS database receives both mandatory reports for dietary supplements as well as voluntary reports from both consumers and health care practitioners for dietary supplements, foods, infant formula, and other products regulated by HFP. HFCS receives reports through the Safety Reporting Portal, MedWatch, emails, telephone calls, faxes, letters, and electronic transfers from the Office of Inspections and Investigations (OII) Compliance Management System (CMS).

This data extract covers reports received by HFCS January 1, 2004 through June 30, 2026. The posted data extracts contain information from adverse event reports associated with HFP-regulated products (foods, dietary supplements, and infant formula). The HFCS extract provides a file of data in xlsx format.

B. CAVEATS

The adverse event reports about a product and the total number of adverse event reports for that product in HFCS only reflect information **AS REPORTED** and do not represent any conclusion by FDA about whether the product caused the adverse events. For any given report, there is no certainty that a suspected product caused a reaction. Healthcare practitioners, firms, agencies, consumers, and others are encouraged to report suspected reactions; however, the event may have been related to a concurrent

underlying condition or activity or to co-consumption of another product, or it may have simply occurred by chance at that time.

The reports submitted to FDA vary in the quality and reliability of the information provided. Some reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions or used other products or medications at the same time. Reports may not include accurate or complete contact information for FDA to seek further information about the event, or complainants may choose not to participate in a follow-up investigation. When important information is missing from a report, it is difficult for FDA to fully evaluate whether the product caused the adverse event or simply coincided with it. There also may be duplicate reports in HFCS for the same adverse event because multiple people (such as an injured consumer and a healthcare provider who treated the individual) may have submitted reports. Efforts are made to identify these duplicate reports to reduce over-reporting biases. Because HFCS is constantly updated with new information, the number of reports for a given product and the content of individual reports may change over time.

Disclaimer: Submission of an adverse event report does not constitute an admission that a product caused or contributed to an event. The information in these reports has not been scientifically or otherwise verified as to a cause-and-effect relationship and cannot be used to estimate incidence (occurrence rate) or to estimate risk.

C. DATA FIELDS

Each HFCS data extract includes the following data fields; empty fields (missing data) indicate that the data are not available because they were not provided in the adverse event report submission:

TAB – PRODUCT-BASED (one row per CASE per PRODUCT view of data)

Name of CAERS data field	**Description**
1. Date_FDA_First_Received_Case	The date on which the case data was first received by the FDA.
2. Report_ID	The unique number that identifies each case.
3. Date_Event	The reported date on which the consumer first experienced the adverse event.
4. Product_Type	Suspect or concomitant (as reported)

5. Product*	The verbatim brands and/or product names indicated to have been used by the consumer reported to have experienced the adverse event. An adverse event report may specify consumption of a single product or multiple products.
6. Product_Code	The FDA industry code associated with the type of product reported.
7. Description	The FDA industry description associated with the type of product reported. (ice cream products, cosmetics, coffee/tea)
8. Patient_Age	The age of the consumer reported to have experienced the adverse event.
9. Age_Units	The time unit (day, week, month, year) of the age provided in the Age at Adverse Event data field for the consumer reported to have experienced the adverse event.
10. Sex	The sex of the individual reported to have experienced the adverse event.
11. Case_MedDRA_Preferred_Terms	The symptom(s) experienced by the injured consumer as specified by the reporter and coded by FDA according to the Medical Dictionary for Regulatory Activities (MedDRA).[1] Each adverse event report may indicate one or more symptoms.
12. Case_Outcome	Outcome(s) of the adverse event experienced by the injured consumer as specified by the reporter; each report may indicate one or more outcomes.

TAB – CASE-BASED (one row per CASE view of data)

Name of CAERS data field	**Description**
1. Date_FDA_First_Received_Case	The date on which the case data was first received by the FDA.
2. Report_ID	The unique number that identifies each case.
3. Date_Event	The reported date on which the consumer first experienced the adverse event.

4. Suspect_Products *	The verbatim Suspect brands and/or product names indicated to have been used by the consumer reported to have experienced the adverse event. An adverse event report may specify consumption of a single product or multiple products. Appended to the end of the product name in brackets is: **Product_Code** - The FDA industry code associated with the type of product reported **Description** - The FDA industry description associated with the type of product reported. (ice cream products, cosmetics, coffee/tea) If there are multiple Suspect Products, they are all listed in this field separated by a comma.
5. Concomitant_Products *	The verbatim Concomitant brands and/or product names indicated to have been used by the consumer reported to have experienced the adverse event. An adverse event report may specify consumption of a single product or multiple products. Appended to the end of the product name in brackets is: **Product_Code** - The FDA industry code associated with the type of product reported **Description** - The FDA industry description associated with the type of product reported. (ice cream products, cosmetics, coffee/tea) If there are multiple Concomitant Products, they are all listed in this field separated by a comma.
6. Patient_Age	The age of the consumer reported to have experienced the adverse event.
7. Age_Units	The time unit (day, week, month, year) of the age provided in the Age at Adverse Event data field for the consumer reported to have experienced the adverse event.
8. Sex	The sex of the individual reported to have experienced the adverse event.

9. Case_MedDRA_Preferred_Terms	The symptom(s) experienced by the injured consumer as specified by the reporter and coded by FDA according to the Medical Dictionary for Regulatory Activities (MedDRA).[1] Each adverse event report may indicate one or more symptoms.
10. Case_Outcome	Outcome(s) of the adverse event experienced by the injured consumer as specified by the reporter; each report may indicate one or more outcomes.

[1] MedDRA® the Medical Dictionary for Regulatory Activities terminology is the international medical terminology developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and used worldwide to classify adverse event symptoms.

D. QUESTIONS OR COMMENTS

Questions or comments may be directed to the US Food and Drug Administration, Human Foods Program, Food Cosmetics Information Center (FCIC) via the inquiry form found at: https://hfpinfo.my.salesforce-sites.com/Inquirypage

E. NOTATIONS ON PRODUCT, PRODUCT CODE AND DESCRIPTION VARIABLES

***PRODUCT:** FDA has made redactions in the Product column based on Exemption 4 of the Freedom of Information Act which protects trade secrets and commercial or financial information. See FDA's regulations at 21 CFR 20.111(c)(3).