README FILE FOR THE QUARTERLY DATA EXTRACT (QDE) FROM THE CFSAN Adverse Event Reporting System (CAERS)

U.S. Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
Office of Analytics and Outreach (OAO)

REVISED MAY 2016

TABLE OF CONTENTS

A. INTRODUCTION

You are viewing the README file that accompanies data extracted from the US Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS).

CAERS is a post-market surveillance system that collects reports about adverse events involving CFSAN-regulated products. The CAERS database receives both mandatory reports for dietary supplements as well as voluntary reports from both consumers and health care practitioners for dietary supplements, cosmetics, foods, and other products regulated by CFSAN. CAERS receives reports through MedWatch, emails, telephone calls, faxes, letters, and electronic transfers from the Office of Regulatory Affairs (ORA) District Offices' Field Accomplishments and Compliance Tracking System (FACTS).

Each data extract covers reports received by CAERS through the most recent quarter of the year. The posted data extracts contain information from adverse event reports associated with CFSAN-regulated products (foods, dietary supplements, and cosmetics). The CAERS extract provides a file of data in CSV format (delimiter separated text).

B. CAVEATS

The adverse event reports about a product and the total number of adverse event reports for that product in CAERS only reflect information **AS REPORTED** and do not represent any conclusion by FDA about whether the product actually 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 CAERS 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 in order to reduce over-reporting biases.

Because CAERS 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 CAERS 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:

Name of CAERS data field	**Description**
1. RA_Report #	The unique number that identifies each case.
2. RA_CAERS Created Date	The date on which the data were first entered into CAERS from an adverse event report.
3. AEC_Event Start Date	The reported date on which the consumer first experienced the adverse event.
4. PRI_Product Role	Suspect or concomitant (as reported)
5. PRI_Reported Brand/Product Name	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. PRI_FDA Industry Code	The FDA industry code associated with the type of product reported.
7. PRI_FDA Industry Name	The FDA industry description associated with the type of product reported. (Ice cream products, cosmetics, Coffee/Tea)
8. CI_Age at Adverse Event	The age of the consumer reported to have experienced the adverse event.
9. CI_Age Unit	The time unit (day, week, month, year) of the age provided in the CI_Age at Adverse Event data field for the consumer reported to have experienced the adverse event.
10. CI_Gender	The sex of the individual reported to have experienced the adverse event.

11. AEC_One Row Outcomes	Outcome(s) of the adverse event experienced by the injured consumer as specified by the reporter; each report may indicate one or more outcomes for each consumer.
12. SYM_One Row Coded Symptoms	The symptom(s) experienced by the injured consumer as specified by the reporter and coded by FDA according to the *Medical Data Dictionary for Regulatory Activities (MedDRA)*.[1] Each adverse event report may indicate one or more symptoms for each consumer.

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

E. QUESTIONS OR COMMENTS

Questions or comments may be directed to the US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Analytics and Outreach CAERS staff: CAERS@fda.hhs.gov