UNITED STATES FOOD & DRUG ADMINISTRATION

FDA Adverse Event and Products Experience Reporting Program (MedWatch);
Electronic Submissions

OMB Control No. 0910-0645

JUSTIFICATION MEMORANDUM FOR 83-C NON-SUBSTANTIVE CHANGE REQUEST; CFSAN SAFETY REPORTING PORTAL QUESTIONNAIRES

This information collection supports Food and Drug Administration (FDA, us or we) laws and regulations governing adverse event reports and product experience reports for FDA-regulated products; electronic submissions. The FDA Safety Reporting Portal (SRP) is one of the IT systems we employ to collect data electronically. The SRP enables industry, health professionals, consumers, and others to report adverse events or problems associated with regulated products by completing web-based rational questionnaires tailored to product categories. The information submitted through the SRP is routed to appropriate FDA components so that we have real time access to reports and are able to more rapidly analyze safety problems.

This non-substantive change request relates to rational questionnaires (RQ) used for submitting adverse event reports for the following CFSAN-regulated products: *dietary supplements, food, infant formula,* and *cosmetics*. Previously, we solicited public comment on two revised *dietary supplement* rational questionnaires (one mandatory and one voluntary), and three new voluntary rational questionnaires for *food, infant formula*, and *cosmetics*. We included a discussion of these changes in our ICR submission on February 29, 2016 (see pp. 5-6 of our Supporting Statement) and the ICR was approved by OMB. As we then discussed, however, the RQs were in the planning and development stage. Currently we are prepared to deploy the RQs and are including the screenshots for approval prior to implementation. Although we are simultaneously preparing a submission to renew all other elements of the ICR as well, in accordance with applicable regulations, we want to begin collection of the specific elements discussed here as anticipated in our previous submission. For ease of review, we have consolidated the screen shots into one PDF document.

Submitted: April 2019