UNITED STATES FOOD & DRUG ADMINISTRATION

Applications for FDA Approval to Market a New Drug

OMB Control No. 0910-0001

**Request for Non-substantive, non-material change**:

Changes to Form FDA 3331a: *NDA/ANDA Field Alert Automated*

As part of the FDA Adverse Event Reporting System (FAERS) II Modernization Priority, the CDER/OPQ/Office of Surveillance/DQSA/QDAB is recommending an update to the FORM FDA 3331a Field Alert Report (FARs). The revision of the form improves efficiency in collecting and using the data and adds information to help identify, verify, and archive documents in each appropriate FAR. (Draft attached). The form is available for electronic submission. No database changes are required.

We believe these revisions allow for a more streamlined approach for accepting data.

Form Revisions:

This field currently exists in the form:

1. Box 8 (Lot numbers and expiration dates): Also include the Batch Size and number of Consumer Complaints on Batch. This information assists with evaluating potential risk with product quality defects.

New fields to be added:

1. Manufacturer Control Number (MCN) – a number assigned by the Manufacturer to each initial individual case safety report submission. The same MCN is assigned by the manufacturer and is used for the initial and any follow-up submissions. Use of the same MCN standardizes the identification of serial reports for a single event.
2. Field # 12: Coded quality issue/defect: uses standard MedDRA terminology to provide the most specific quality issue/defect description.
3. Field # 13: Reported specific quality issue/defect.

As a result of these limited adjustments/changes, we do not anticipate any adjustment will be required to the cumulative burden for submission.

**Submitted: February 2020**