## INSTRUCTIONS FOR FILLING OUT AND SUBMITTING FORM FDA 3331a – FIELD ALERT REPORT

Use Form FDA 3331a to submit Field Alert Reports (FARs) for CDER- or CBER-regulated drug products that are approved under a new drug application (NDA) or abbreviated new drug application (ANDA). Save a copy of Form FDA 3331a to your computer and then follow the instructions below. As used in Form FDA 3331a, the term "problem" refers to the incident (see 21 CFR 314.81 (b)(1)(i)) or possible/actual quality issue (see 21 CFR 314.81 (b)(1)(ii)) that is the subject of the FAR.

### Section I: Filling Out the Form

**On page ii:**

Select the FDA Office of Regulatory Affairs (ORA) district office responsible for the facility where the problem occurred. See Field 1 below for additional information. For foreign facilities, select the district office responsible for the location where your authorized U.S. agent is located. Note: Page 2 check-box selections allow for only one jurisdictional office to be designated as the recipient of your Form 3331a. Firms may manually add other district office's email address to the "TO" line before submitting the FAR by email.

**At the top of page 1:**

- Verify that the name and address of the district office selected on page ii appears at the top of the page in the "To" section.
- **Manufacturer Control #** – Enter your firm's internal report control number, please use the same control number for all subsequent Follow Up and Final report submissions as that will be used to match subsequent reports to the Initial report.
- Check the box that applies to the "Type of Report" to indicate whether the report is an initial, follow-up, or final report. Initial FAR refers to the FAR that you first submit to comply with the requirements of § 314.81(b)(1). Follow-up FAR refers to any subsequent FARs you submit to provide additional information about the issues identified in the initial FAR. Examples of additional information reported in a follow-up FAR include significant findings of the ongoing investigation; additional facilities or lots identified within scope; and sample analyses, laboratory test results, or potential root causes identified. Final FAR refers to the FAR you submit to close out the Initial FAR with the root cause and corrective actions identified. Although Follow-up and Final FARs are not required, they are strongly recommended. For Initial reports, provide the estimated submission date of the Final report in the "Remarks" section (#16). For reports that are both Initial and Final (i.e., no further submission to FDA is contemplated), check both boxes. For Follow-up or Final reports, provide the submission date of the Initial report in the "Remarks" section (#16).

**Enter the appropriate information in the following fields of the form:**

**Field 1: Firm Name and Address Where Problem Occurred**

List the name and address of the finished drug product manufacturing facility for the NDA or ANDA if that is where the problem occurred. For a problem related to the active pharmaceutical ingredient (API) or any raw material, list the supplier's facility information. If the problem involves a facility other than the finished drug product manufacturing facility, (e.g., labeling or packaging facility), list that facility's information. If any facility other than the finished drug product manufacturing facility is listed in Field 1, include the name and address of the finished drug product manufacturing facility in the "Remarks" section (#16) as well as any additional facilities implicated but not already included in Field 1.

*(continued on next page)*

**Field 2: DUNS and FEI number of the facility listed in #1**

DUNS=Data Universal Numbering System; FEI=Facility Establishment Identifier. These fields are limited to 15 characters. If the DUNS/FEI is unknown, enter N/A or check the N/A box.

**Field 3: NDA/ANDA number of the drug product**

Select whether the problem involves an NDA or ANDA drug product and provide the NDA or ANDA number. When submitting a FAR for a CBER-regulated drug product, include the preceding alpha characters "BN" before entering the numeric portion for an NDA, or "BA" before entering the numeric portion for an ANDA that is approved by CBER. This field is limited to eight characters. Select "other" if you wish to report a product without an NDA or ANDA number. If multiple NDAs or ANDAs are involved, submit one Form FDA 3331a per NDA/ANDA.

**Field 4: NDC number of the drug product**

Enter the National Drug Code (NDC) number. The NDC includes the labeler code (4 or 5 digits), product code (3 or 4 digits), and, if appropriate, the package code (1 or 2 digits), and is acceptable in the following formats 4-4-2, 5-4-1, or 5-3-2 for a total of 12 characters, including dashes. Separate NDC numbers with semicolons (e.g., 01234-456-89; 01234-456-10). (For prescription drugs, valid NDC numbers may be found on the National Drug Code Directory's Web site.) If the product does not have an NDC number, enter "None" and explain why in the "Remarks" section (#16).

**Field 5: Generic name of the drug product**

Enter the nonproprietary name of the drug product.

**Field 6: Trade/Brand name of the drug product**

Enter the brand/proprietary name of the drug product.

**Field 7a: Dosage form**

Enter the dosage form(s) associated with the drug product that is the subject of the FAR as indicated in the approved drug product label

**Field 7b: Dosage strength and package size**

Enter the dosage strength associated with the drug product that is the subject of the FAR. Use appropriate units and package size as indicated in the drug product's approved labeling.

**Field 8: Lot Number, Expiration Date, Batch Size, # of Consumer Complaints**

Enter the lot number, expiration date, batch and # of consumer complaints separating each value with a coma. If listing more than one lot, separate each set of lot, date, size, complaint values with semicolons (e.g., 123ABC, 12/2017, 15000, 4; RBDS-1234, 09/2017, 30000, 15). If the lot number to report is for anything other than the finished drug product please include those lots numbers in the "Remarks" section (#16).

**Field 9: Date when notified about problem(s) or when problem(s) first became known to applicant holder (mm/dd/yyyy)**

Note that the applicant may not wait to confirm or invalidate a problem if this means failure to comply with the 3-working-day reporting requirement per 21 CFR 314.81(b)(1).

**Field 10: How was the problem discovered**

Describe how the problem was discovered, (i.e., through routine product testing, consumer complaint, etc.)

*(continued on next page)*

**Field 11: State Problem(s)**

Describe the nature of the problem identified in the FAR. For multiple unrelated problems separate FARs should be submitted.

**Field 12: Coded Quality Issue/Defect**

Provide quality defects term(s) that most accurately characterize the quality defect described in narrative format in Field 11-State Problem(s). We encourage the use of Medical Dictionary for Regulatory Activities (MedDRA – the international standard medical terminology used by regulatory authorities and the regulated biopharmaceutical industry developed by ICH), provide the most specific quality issue/defect. e.g. Out of specification test results assay. Terms should be listed with the most important term(s) first.

**Field 13: Reported Quality Issue/Defect**

Include additional structured information about the quality issue/defect described in narrative format in *Field 11-State Problem(s)*. Include a list of specific quality defects that most accurately characterize the described quality issue for which there is no MedDRA term available. The list may utilize a terminology that is another accepted standard, a verbatim term, or the manufacturer's own terminology. Terms should be listed with the most important term(s) first

**Field 14: Describe Root causes of Problem(s)**

Provide the root cause(s) of the problem(s). If root cause(s) is/are not determined provide a brief summary of the investigations conducted or ongoing.

**Field 15: Describe Corrective Action(s) Taken (if any) to Prevent the Recurrence of Problem(s)**

Describe all corrective actions taken (to date) to prevent the recurrence of the problem.

**Field 16: Remarks**

Provide additional information pertinent to the FAR or the underlying problem. If this is an initial report, indicate the estimated date that the follow-up or final report will be submitted. If this is a follow-up or final report, indicate the date that the initial report was submitted. You may also use this section to indicate whether the product was recalled. If the field for the "Firm name and address where problem occurred" (#1) does not include the name and address of the finished drug product manufacturing facility, include it here, along with its FEI/DUNS number.

**"Reporting Establishment":**

In the "Reporting Establishment" section, provide the firm name and mailing address, DUNS/FEI number, name and title of the authorized representative, telephone number, email address, and date submitted in a mm/dd/yyyy format. The firm name and address should be either the application holder or its authorized U.S. agent when the application holder is located overseas. If the reporting establishment does not have an FEI or DUNS number, enter N/A or check the N/A box.

## Section II: Saving the Completed Form

**IMPORTANT: Save the completed form to your computer before clicking the "Submit by Email" button.**

You can use the File/Save option to save an editable copy of the form for your own needs, but please submit a read-only version of the form to FDA. Make sure you use different filenames for the read-only and editable versions.

*(continued on next page)*

**Creating a Read-Only Version**

- Using Adobe Reader: Print the completed form and scan the document to a PDF file, or use a third-party utility to print the form directly to a PDF file.
- Using Adobe Acrobat: Use the File/Print option to print the completed form as an Adobe PDF to create a read-only version of the form.

## Section III: Submitting the Form

1. Once all fields are filled out and you have saved the completed form to your computer, click the "Submit by Email" button on the last page of the form.
   a. Upon clicking "Submit by Email," your e-mail client will open a new email addressed to the ORA district office you selected on page ii of the form. The CDER-XML-FAR mailbox will be listed as a "Cc" recipient and an XML file generated by the form will be attached. CDER will process the XML data for both CDER and CBER FARs.
   b. You may add other district offices to the "To" and "Cc" lines as needed (e.g., to send a courtesy copy to the district office at which your headquarters is located).
   c. Do not change the subject line, which will be automatically filled out with information from fields 3 and 5 on the form and the submission date and time stamp. If you need to add additional information, please do so in the body of the email.
2. Attach the saved, read-only PDF copy of the form and any other pertinent documents to the e-mail.
3. Send the email with both the XML and PDF attachments. Only once you have sent this email will the FAR be submitted. Reminder: The FAR must be submitted within 3 days in order to be compliant with the time frame established in 21 CFR 314.81.

## Section IV: Technical Notes

1. You should use Adobe Reader version 9 or higher.
2. The Adobe "Submit by Email" feature is compatible with MS Outlook and Web-based e-mail services such as Hotmail, Gmail, and Yahoo mail.
3. Additional information can be found on the Web page Field Alert Report Form: Questions and Answers.
4. For additional help, contact your ORA district office. (Contact information is found on page ii of the form.)
5. FDA encourages all application holders of approved drug products to use this form to submit FARs.