Field Alert Reporting

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Field Alert Program

- Quickly identify drug products that could pose a potential health hazard to the public.
- Regulatory reporting requirement (effective 5/1985) that all holders/applicants with approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) are required to submit Field Alert Reports (FARs) to the jurisdictional FDA district office, as specified in 21 CFR 314.81(b).

21 CFR 314.81

Other postmarketing reports.

(a) Applicability. Each applicant shall make the reports for each of its approved applications required under this section and section 505(k) of the act.

(b) Reporting requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

NDA Field Alert Report

- The applicant shall submit information of the following kinds about distributed drug products
  - (i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.
  - (ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application.

Field Alert Program

- FARs must be submitted to the FDA district office that is responsible for the facility where problem occurred within 3 working days by the applicant. The facility where problem occurred may not be in the same district as the applicant (i.e. contract manufacturer, contract labeler/repacker, etc).
- The 3 working days begins when the applicant becomes aware of a reported problem (complaint or internal testing) ; not the day the applicant confirms or invalidates a problem. If the problem is appropriately invalidated within 3 working days, then no FAR.
- The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: ``NDA--Alert Report."

Regulatory Guidance

- 7356.021 Drug Quality Reporting System NDA Field Alert Reporting

District Role

- Form FDA 3331 submitted to the District Office within three (3) working days containing the aforementioned information for distributed product
- District must forward an electronic copy of all Field Alert reports to CDER Division of Compliance Risk Management & Surveillance (DCRMS) within 5 working days of receipt from firm. ORA/DFFI is notified for reports concerning foreign manufacturers.

District Role

- NDA Field Alerts in NWE-DO are acknowledged and evaluated by Investigations Branch. The FAR coordinator is the primary contact with the firm, CDER, and Compliance Branch.
- Evaluate by reviewing firm history, consult with Recall Coordinator, Compliance staff.
- After initial evaluation may need to obtain further information from the firm.
- Assignment of directed inspection or follow-up at next scheduled inspection determined.

Role of DCRMS

- Conduct their own review to determine whether drug firms are complying with the NDA Field Alert Report requirements by:

  - evaluating the reports and any investigational information that is sent to the division by the district offices,

  - coordinating investigational and regulatory actions with FDA headquarters and the district offices,

  - issuing assignments to investigate NDA Field Alert reports, and

  - providing guidance on enforcement issues, and recommending regulatory action

How to Report

- Via Form 3331 for NDA and ANDAs

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094853.pdf

- Via telephone or other rapid communication means and then with prompt written follow-up.
- Email is the preferred method to submit FARS
  - New England FAR Mailbox is:

    ORANWEFAR@fda.hhs.gov

How to Report

- BLA reports are to be made electronically using BPDR Form 3486 - For use by biological product manufacturers to report biological product deviations (BPD) that may affect the safety, purity, or potency of a distributed product in accordance with 21 CFR, Part 600.14 or 606.171.

  http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129716.htm

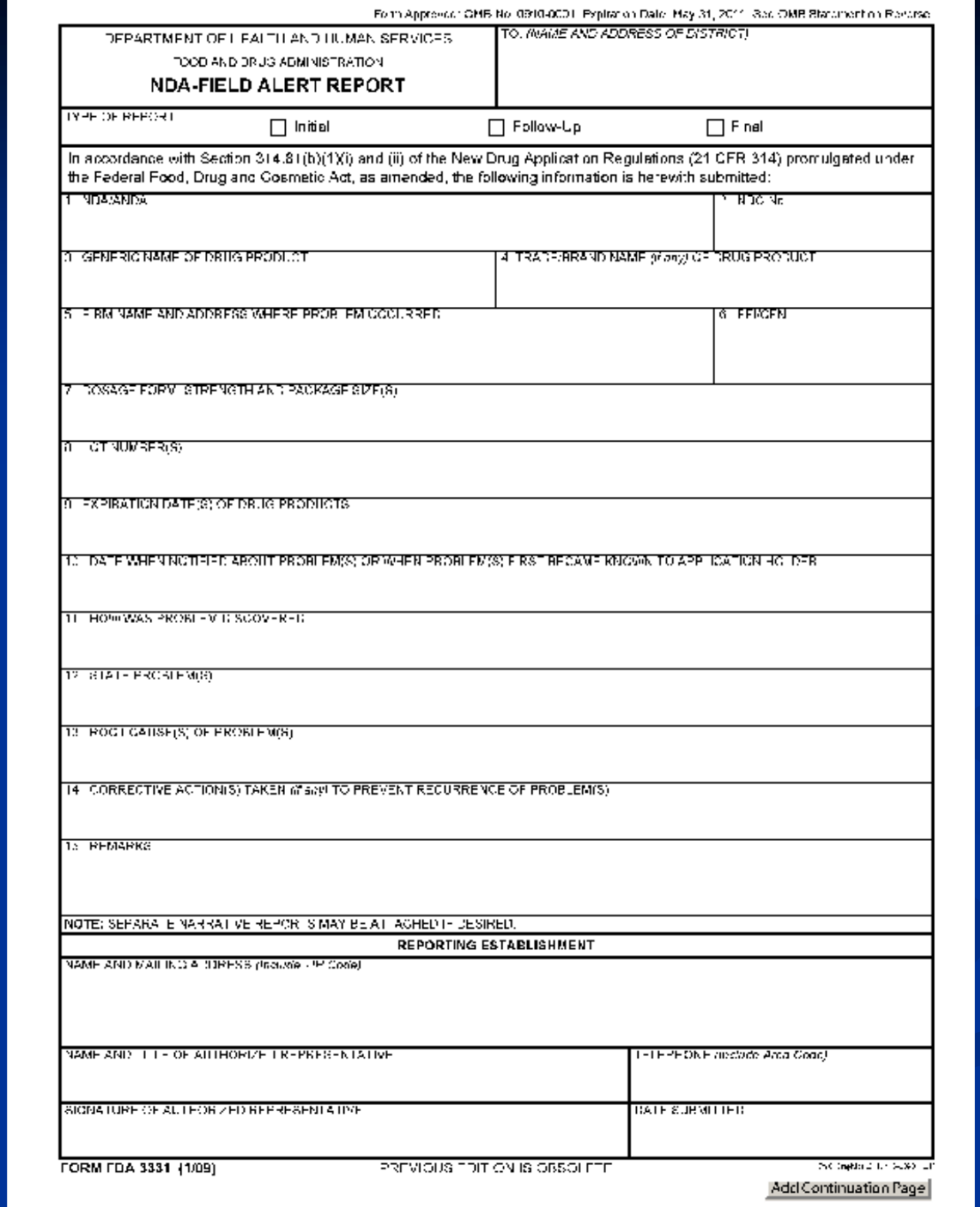
How to Report

- Vet Meds – use Form 1932 - requires applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report ADEs and product and manufacturing defects. – accepts paper or electronic submissions

  http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm212682.htm

FAR

FDA-3331



Form Approved: OMB No. 0910-0001 Expiration Date: May 31, 2011 See OMB Statement on Reverse

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*

TYPE OF REPORT ☐ Initial ☐ Follow-Up ☐ Final

In accordance with Section 314.81(b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1 NDA/ANDA | 2 NDC No.

3 GENERIC NAME OF DRUG PRODUCT | 4 TRADE/BRAND NAME *(if any)* OF DRUG PRODUCT

5 FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED | 6 FEI/CFN

7 DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)

8 LOT NUMBER(S)

9 EXPIRATION DATE(S) OF DRUG PRODUCTS

10 DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER

11 HOW WAS PROBLEM DISCOVERED

12 TOTAL PROBLEM(S)

13 ROOT CAUSE(S) OF PROBLEM(S)

14 CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)

15 REMARKS

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT

NAME AND MAILING ADDRESS *(Include ZIP Code)*

NAME AND TITLE OF AUTHORIZED REPRESENTATIVE | TELEPHONE *(Include Area Code)*

SIGNATURE OF AUTHORIZED REPRESENTATIVE | DATE SUBMITTED

FORM FDA 3331 (1/09) PREVIOUS EDITION IS OBSOLETE

Add Continuation Page

CVM

FDA-1932

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT

(Forward to address at right. Attach all correspondence that pertains to this reaction.)

Form Approved: OMB No. 0910-0645
Expiration Date: 9/30/2012
(See Burden Statement on page 8.)

Food and Drug Administration
7500 Standish Place (HFV-210), Rm N403
Rockville, MD 20855-9921

NOTE: This report is required by law (21 CFR 514.80 and 512 (l) of the Federal Food, Drug, and Cosmetic Act (FDCA)). Failure to report can result in withdrawal of approval of the application (21 CFR 514.80 (h) and 512 (e) of the FDCA).

The data elements marked with an asterisk [*] require a value or text to be entered. An asterisk at the section level applies to all fields within that section. An asterisk at the subsection level applies to all fields within that subsection. Otherwise, asterisks apply to individual fields.

Part A
Administrative and Identification Information

Regulatory Authority - RA (A.1)*

RA Name		Street Address	
City	State/County or Province	Mail/Zip Code	3-character country code

Marketing Authorization Holder - MAH (A.2)

*MAH Information (A.2.1)**

Business Name		Street Address	
City	State/County or Province	Mail/Zip Code	3-character country code

Person Acting on Behalf of the MAH (A.2.2)

Title *(e.g., Mr., Ms., Dr.)*	First Name	Last Name
Telephone Number	Fax Number	Email Address

Person(s) Involved in the AER (A.3)

Primary Reporter (A.3.1)

Title *(e.g., Mr., Ms., Dr.)*	First Name	Last Name*
Telephone Number	Fax Number	Email Address
Business Name		Street Address
City	State/County or Province	Mail/Zip Code	3-character country code*

Primary Reporter Category (A.3.1.1)*:

BPDR

FDA-3486

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOLOGICAL PRODUCT DEVIATION REPORT

FDA USE ONLY
Date Received:
Date Reviewed:
BPD ID:
BPD No.

* Indicates required information

A. FACILITY INFORMATION

1. Reporting Establishment Information

* Reporting Establishment Name

* Street Address Line 1

Street Address Line 2

* City | * State

Country | * Zip Code

* Point of Contact

* Telephone #

E-mail

2. * Reporting Establishment Identification Number

FDA Registration #

CLIA #

3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4; otherwise, continue on to Section B1.

* Establishment Name

Street Address Line 1

Street Address Line 2

* City | * State

* Country | Zip Code

4. Establishment Identification Number

FDA Registration #

CLIA #

B. BIOLOGICAL PRODUCT DEVIATION (BPD) INFORMATION

1. Establishment Tracking #
2. Date BPD Occurred
3. * Date BPD Discovered
4. * Date BPD Reported
5. * Description of BPD *(use Page 2 for additional space)*
6. * Description of Contributing Factors or Root Cause *(use Page 3 for additional space)*
7. * Follow-Up *(use Page 4 for additional space)*
8. * Please Enter the 6 Character BPD Code ☐☐ ☐☐ ☐☐

C. UNIT / PRODUCT INFORMATION

Please check the type of product: Blood ☐ (Continued on Page 5)
Non-Blood ☐ (Continued on Page 6)

Form Approved:
OMB No. 0910-0458
Expires: 1/31/2014

See OMB Statement on Page 8.

PSC Publishing Services (301) 443-6740 EF

What to Report

- Examples
  - Mislabeling, missing label, obscured label
  - Matters involving dissolution failures, impurity levels, sub/super potency
  - OOS results obtained during stability testing
    - If cannot appropriately invalidate within 3 days then need to report
    - If product is at expiry may still need to report as the stability sample is representative of all marketed product of that application
  - OOS results obtained from retains – appearance, particulates
  - Complaints for distributed product which are deemed significant

What to Report

- Deviations identified after product was distributed or during stability testing.
- Regulation speaks to “significant” chemical, physical, or other change or deterioration in the distributed product.

Inspections

- Some assignments are issued/directed to focus on the applicant's field alert process and procedures. Can also be covered as part of a firm's GMP inspection.
- Violations involving cGMPs and FAR reporting requirements can be issued.

Observations Related to Field Alert Reporting

- Turbo 483 citation for FARs - the failure to report a field alert within three working days of receipt of information that would require reporting
  - such as bacteriological contamination, significant chemical, physical, or other change or deterioration, in a distributed drug product; a failure of one or more distributed batches of a drug to meet the specifications established for it in the application; and information concerning an incident that caused a drug product or its labeling to be mistaken for or applied to another article.

Questions

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