Field Alert Reporting

Margaret Sands
Supervisory CSO/Drug Program Monitor
New England District Office
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).
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:
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.''

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.

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

Initial Follow-Up Final

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

1. PRODUCT
2. PRESCRIPTION
3. GENERIC NAME OF DRUG PRODUCT
4. TRADE NAME OF DRUG PRODUCT
5. MANUFACTURER AND ADDRESS OF MANUFACTURER
6. MANUFACTURER
7. REPORT SAMPLE STRENGTH AND EXPIRATION DATE
8. GROSS WEIGHT
9. STRENGTH
10. EXPEDITED DATE FOR NEW PRODUCTS

1. DATE & DATE BY WHICH RECIPIENT WAS INFORMED
2. DATE & DATE BY WHICH RECIPIENT WAS INFORMED
3. HOW WAS INFORMATION SUPPLIED TO APPLICANT (i.e., PHONE, FAX, E-MAIL, CERTIFIED MAIL)
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FOURTH FEDERAL ADMINISTRATION
PREVIOUS FEDERAL ADMINISTRATION

FORM FDA 3331 (5/08)
PREVIOUS PAGE IS BOUND
Add Continuation Page
## Part A
### Administrative and Identification Information

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### Marketing Authorization Holder - MAH (A.2)

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

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**FORM FDA 1932 (1/10)**

Page 1
## Biological Product Deviation Report (BPDR)

### Biotherapy Act of 1997

#### A. Facility Information

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<th>Requirement</th>
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#### B. Biological Product Deviation (BPD) Information

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<td>Description of Contributing Factors or Root Cause (use Page 3 for additional space)</td>
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<td>Follow-Up (use Page 4 for additional space)</td>
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#### C. Unit/Product Information

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Please check the type of product:

- Blood
- Non-Blood
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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