What is a Field Alert Report (FAR), Biological Product Deviation Report (BPDR) and Consumer Complaint? And How Do These Differ?

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SBIA - CDER Post-market Reports - A Primer on Field Alert Reports and Biological Product Deviation Reports - May 24, 2023

Learning Objectives

A. Consumer Complaints and Med Watch Reporting

B. Overview of FAR and BPDR reporting requirements as outlined in 21 CFR Parts 314 and 600:

   1. What are the FARs and BPDRs reporting requirements?
   2. Who is responsible for reporting?
   3. How does a firm report?
   4. Questions and Answers

Med Watch Reporting

- A majority of serious reaction reports are received from health care professionals by completing a Med Watch Form 3500
- However, consumers can self-report a serious reaction to a medical product by completing a Med Watch Form 3500 or 3500b (consumer friendly version of the form)
- These self-reported serious reaction(s) are often referred to as consumer complaints
- Both forms can be found at https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
- The reporting of product quality related reactions by consumers is voluntary via the MedWatch Program

21 CFR 211.198 Outlines Records and Retention Requirements for Product Quality Related Consumer Complaints

- 21 CFR 211.198 requires among other things that:
  1. Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed.
  2. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility.
  3. A written record of each complaint shall be maintained in a file designated for drug product complaints.

Challenge Question #1

If you want to self-report a Serious Adverse Event what form do you need to fill out?

A. Med Watch Form 3500

B. Med Watch Form 3500b

C. Either A or B

Overview of Field Alert Report (FAR) reporting requirements as outlined in 21 CFR 314.81

- FDA **requires** reporting of certain deviations and unexpected events that occur in drug product manufacturing.
- Any incident or defect concerning one or more of the following must be reported:

1. Incidents that cause the drug product or its labeling to be mistaken for or applied to another article;
2. Bacterial contamination;
3. Any significant chemical, physical, or other change or deterioration in the distributed drug product;
4. Any failure of one or more distributed batches of the drug product to meet the specifications established in its application.

Overview of Field Alert Report (FAR) reporting requirements (continued)

- The purpose of field alert reports (FARs) is to quickly identify quality defects in distributed drug products that may present a potential safety threat.
- FDA's Field Alert Report (or FARs) reporting requirements are authorized under 505(k) of the Federal Food, Drug, and Cosmetic Act. The requirements have been in effect since the agency published the final rule in 1985 that implemented the FARs reporting requirements outlined in 21 CFR 314.81(b)(i).
- **Within 3 working days** of receiving information concerning significant quality problems with distributed drug product, applicants of approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs) must submit a FAR to FDA to comply with 21 CFR 314.81(b)(1).

Overview of Biological Product Deviation Report (BPDR) reporting requirements as outlined in 21 CFR 600.14

- The manufacturer of a CDER-regulated product that holds a biological product license and had control over the product when a deviation or unexpected event associated with manufacturing occurred, is **required** to submit a Biological Product Deviation Reports (BPDR) to FDA **as soon as possible, but not later than 45 calendar days** from the date of discovery of information that reasonably suggests a reportable event has occurred.

Overview of Biological Product Deviation Report (BPDR) reporting requirements (continued)

- FDA requires reporting of certain deviations and unexpected events that occur in biological product manufacturing.
- Per 21 CFR 600.14, the manufacturer must report such events associated with testing, processing, packing, labeling, storage, holding, or distribution if the safety, purity, or potency of a distributed product may be affected by the deviation or unexpected event.

Challenge Question #2

Are FARs and BPDRs required or voluntary?

A. Required

B. Voluntary

C. Depending on the Incident and Defect, Both A and B

How Do I Submit a Field Alert Report (FAR) as outlined in 21 CFR 314.81?

- FDA encourages all of industry to use the Form **FDA 3331a** to submit FARs electronically but we will accept paper submissions. Although submission of FARs solely in an electronic format is not required under 21 CFR 314.81(b)(1) at this time, we recommend using the automated (XML) version of Form FDA 3331a.
- Form FDA 3331a can also be saved as a PDF document, printed and submitted in paper format, if preferred or when necessary, to satisfy the reporting requirements under 21 CFR 314.81(b)(1).
- The Form FDA 3331a and the associated instructions can be found at https://www.fda.gov/about-fda/reports-manuals-forms/forms

How Do I Submit a Biological Product Deviation Report (BPDR) reporting requirements as outlined in 21 CFR 600.14?

- Reports should be submitted to CDERDQRSREPORTS@fda.hhs.gov using the FDA Form 3486.
- To facilitate prompt processing of all incoming BPDRs, CDER strongly recommends that all information relevant to the BPDR be submitted in the FDA Form 3486. This should include the initial submission and all subsequent follow up or final submissions.
- The Form FDA 3486 and the associated instructions can be found at https://www.fda.gov/about-fda/reports-manuals-forms/forms

Summary

- The reporting of product quality related consumer complaints is voluntary via the MedWatch Program
- Field Alert Reports (FARs) are required per 21 CFR 314.81 and must be submitted within 3 working days
- Biological Product Deviation Reports (BPDRs) are required per 21 CFR 600.14 and must be submitted within 45 days

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Questions?


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