



Surveillance Program Team FAR and DQRS programs

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Agenda

- Overview of SPT
- Drug Quality Reporting System (DQRS)
- Field Alert Reports (FARs)
- Impact of DQRS and FAR programs
- Questions

Surveillance Programs Team (SPT)

SPT is part of the Center for Drug Evaluation and Research (CDER), Office of Compliance (OC), Division of Compliance Risk Management and Surveillance (DCRMS)

Goals and Objectives of SPT

- Protect public health by assuring that safe and effective drugs are available
- Monitor drug industry compliance with regulations
- Prioritize risk
- Reduce consumer exposure to poor quality drugs
- Identify trends
- Provide a centralized system for voluntary and mandatory reporting of marketed drug quality problems

Four Programs of SPT

- 1) Drug Quality Reporting System (DQRS)
 - Identifies potential drug quality issues associated with the manufacturing, labeling and packaging of pharmaceuticals.
- 2) Field Alert Reporting (FARS) – Enforces mandatory reporting to the Agency of safety and drug quality issues by industry.

Four Programs Continued

- 3) Biologic Product Deviation Reports— Enforces mandatory reporting to the Agency of safety and CDER biologic quality issues by industry.
- 4) Drug Quality Sampling and Testing Program – Identifies quality issues of pharmaceuticals through collecting and testing.

DQRS Program

- Since the early 1970s, the FDA has operated the Drug Quality Reporting System (DQRS), which encourages health care professionals and consumers to voluntarily report observed or suspected defects or quality problems with marketed drug products. The agency receives reports through the [MedWatch Program](#).
- SPT evaluates and prioritizes drug quality reports in order to identify and follow-up on significant health hazards through assignment and review of investigative reports.

DQRS Key Points

- **Voluntary Program**
 - Reports are received by mail, phone, fax or internet from consumers and health care professionals
- **Protection of public health by allowing for**
 - Rapid identification of Significant Health Hazards
- **Detection of industry problems/trends which may require corrective action**
 - Quality issues may result in assignment of sample collection or GMP inspection by investigators

SPT Responsibilities

- Review and evaluate for health hazard significance and patterns.
- Prioritize:
 - Priority 1 – Imminent or serious health hazard – Immediate Follow-Up
 - Priority 2 – Potentially significant cGMP Problems – Expedited Follow-Up
 - Priority 3 – Routine Follow-Up
- Forward to district offices, other CDER offices, and manufacturers for appropriate follow-up.



Form FDA 3500

U.S. Department of Health and Human Services
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Form Approved: OMB No. 0910-0291. Expires: 10/31/05
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #

General Instructions Page ___ of ___

A. PATIENT INFORMATION Section A - Help

1. Patient Identifier _____ 2. Age at Time of Event, or Date of Birth: _____ 3. Sex Female or Male _____ 4. Weight _____ lb or _____ kg

In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Section B - Help

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: (mm/dd/yyyy) _____ Disability or Permanent Damage
 Life-threatening _____ Congenital Anomaly/Birth Defect
 Hospitalization - initial or prolonged _____ Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) _____ 4. Date of this Report (mm/dd/yyyy) 09/14/2007

5. Describe Event, Problem or Product Use Error

(Continue on page 2)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 2)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

(Continue on page 2)

C. PRODUCT AVAILABILITY Section C - Help

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: (mm/dd/yyyy) _____

D. SUSPECT PRODUCT(S) Section D - Help

1. Name, Strength, Manufacturer (from product label)

#1 _____
#2 _____

2. Dose or Amount _____ Frequency _____ Route _____

#1 _____
#2 _____

3. Dates of Use (If unknown, give duration from/to (or best estimate))

#1 _____
#2 _____

4. Diagnosis or Reason for Use (Indication)

#1 _____
#2 _____

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Lot # _____ 7. Expiration Date _____

#1 _____
#2 _____

8. Event Reappeared After Reintroduction?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

9. NDC # or Unique ID _____

E. SUSPECT MEDICAL DEVICE Section E - Help

1. Brand Name _____

2. Common Device Name _____

3. Manufacturer Name, City and State _____

4. Model # _____ Lot # _____

Catalog # _____ Expiration Date (mm/dd/yyyy) _____

Serial # _____ Other # _____

5. Operator of Device
 Health Professional
 Lay User/Patient
 Other: _____

6. If Implanted, Give Date (mm/dd/yyyy) _____ 7. If Explanted, Give Date (mm/dd/yyyy) _____

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Section F - Help

Product names and therapy dates (exclude treatment of event)

(Continue on page 2)

G. REPORTER (Confidentiality statement) Section G - Help

1. Name and Address _____

Phone # _____ E-mail _____

2. Health Professional? Yes No 3. Occupation _____

4. Also Reported to:
 Manufacturer User Facility Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



NDA

Field Alert Reporting System

NDA Field Alert Reports (FARS)

- Mandatory reporting program
 - 21CFR 314.81 (b)(i) and (ii)
- New Drug Application/Abbreviated New Drug Applications (NDA/ANDA)
- Effective May 23, 1985

Required Reporting

21 CFR 314.81 (b) (1)(i)

- ..any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.
(adulterated or misbranded)

Required Reporting

21 CFR 314.81 (b) (1)(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.

Applicant Holder Obligations

- Applicant holders are required to submit NDA/ANDA Field Alert Reports on drug products manufactured and/or distributed domestically or in a foreign market.
- US Office/Agent (21 CFR 314.50(a)(5)) is responsible for reporting to the FDA District Office that is responsible for the facility involved (21 CFR 314.81 (b) (1)).
- Notify the District Office within 3 working days of receipt of the information.

Three Working Days

- Starts when the firm becomes aware of a reportable problem by means of a
 - Verbal or written complaint
 - Internal testing
 - Unconfirmed problem
 - Confirmed problem

Guidelines for FAR Reporting

- FAR Required
 - Further investigation required
 - Corrective action initiated
 - e.g., Formulation revision, labeling change
 - Product Recall
- FAR Not Required
 - If the product has not been distributed
 - Problem is invalidated within 3 working days
 - e.g., Analytical lab error

FAR Reporting (continued)

- Information may be provided by telephone or other means of rapid communication with prompt written follow-up
- Form FDA 3331 highly recommended
 - Internet Availability of Form FDA 3331
 - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3331_508.pdf



FDA Form 3331

Form Approved: OMB No. 0910-0201. Expiration Date: May 31, 2011. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION NDA-FIELD ALERT REPORT		<small>TO: (NAME AND ADDRESS OF DISTRICT)</small>
<small>TYPE OF REPORT</small> <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up <input type="checkbox"/> Final		
<small>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:</small>		
<small>1. NDA/ANDA</small>		<small>2. NDC No.</small>
<small>3. GENERIC NAME OF DRUG PRODUCT</small>		<small>4. TRADE/BRAND NAME (if any) OF DRUG PRODUCT</small>
<small>5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED</small>		<small>6. FEICPN</small>
<small>7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)</small>		
<small>8. LOT NUMBER(S)</small>		
<small>9. EXPIRATION DATE(S) OF DRUG PRODUCTS</small>		
<small>10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER</small>		
<small>11. HOW WAS PROBLEM DISCOVERED</small>		
<small>12. STATE PROBLEM(S)</small>		
<small>13. ROOT CAUSE(S) OF PROBLEM(S)</small>		
<small>14. CORRECTIVE ACTION(S) TAKEN (if any) TO PREVENT RECURRENCE OF PROBLEM(S)</small>		
<small>15. REMARKS</small>		
<small>NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.</small>		
<small>REPORTING ESTABLISHMENT</small>		
<small>NAME AND MAILING ADDRESS (include ZIP Code)</small>		
<small>NAME AND TITLE OF AUTHORIZED REPRESENTATIVE</small>		<small>TELEPHONE (include Area Code)</small>
<small>SIGNATURE OF AUTHORIZED REPRESENTATIVE</small>		<small>DATE SUBMITTED</small>

FORM FDA 3331 (1/09)
PREVIOUS EDITION IS OBSOLETE
FD-3331 (01-01-09) 3P

[Add Continuation Page](#)

District Office (DO) FAR Handling

- Receives FAR - Initial, Follow-up, Final and submits copies to SPT
- Submits initial assessment of the FAR in a District Action Plan (DAP) to SPT along with FAR
- Conducts appropriate follow-up at district level, from requesting further information to conducting a “for-cause” inspection
 - also the DO
- Determines compliance with regulations during routine inspections and pre-approval inspections and makes recommendations to SPT regarding FAR reporting.

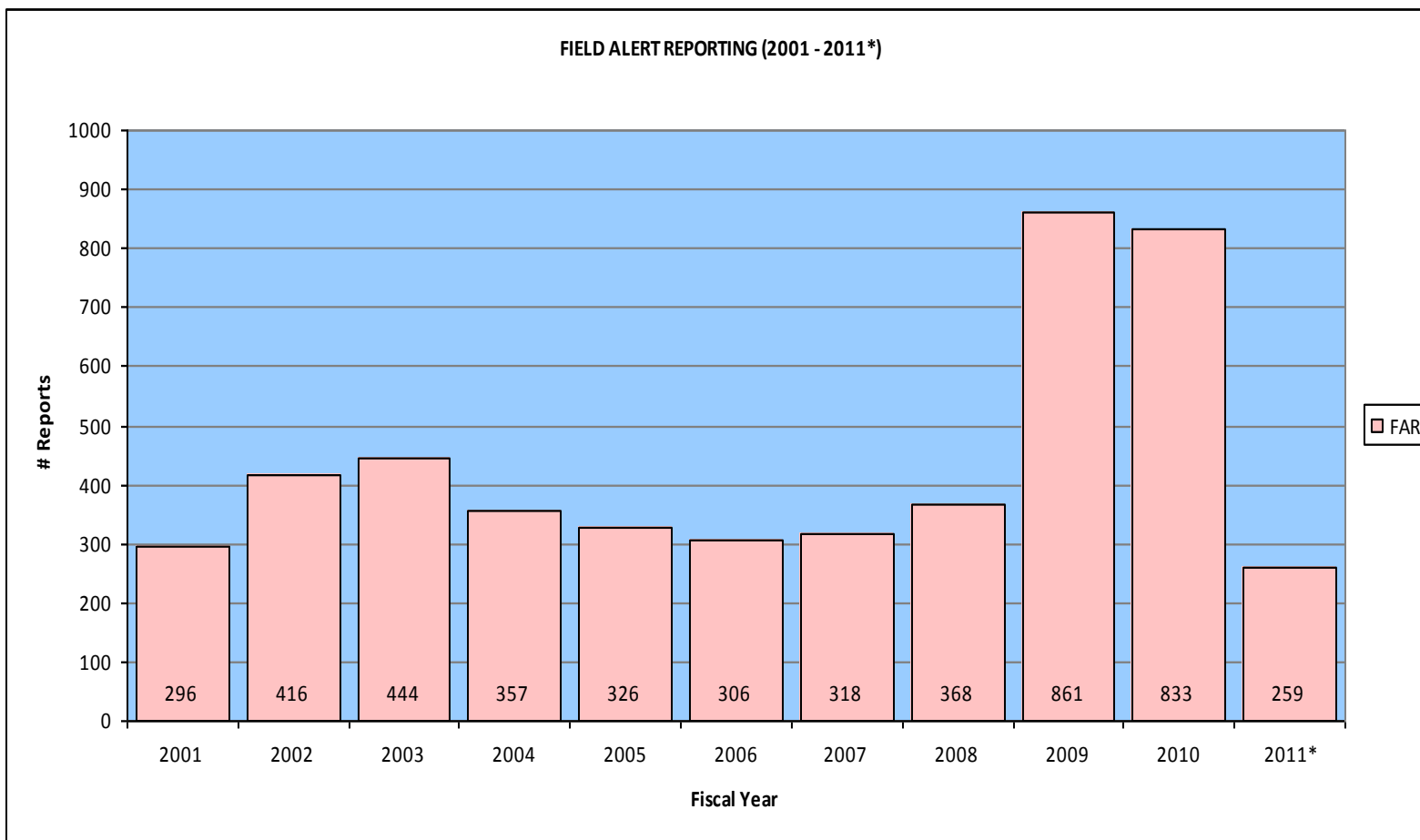
SPT FAR Handling

- Receives all FARs from all districts
- Reviews FAR and the district action plan
- Assesses if FAR complies with reporting requirement
- Forwards FAR to appropriate CDER offices/divisions for consultation/review
- Approves the regulatory action regarding FAR reporting recommended by DO
- Confers with Division of Manufacturing and Product Quality (DMPQ) for CGMP issues and recalls
- Liaisons between the district offices and CDER

Impact of DQRS and FAR programs

- Reported Drug Quality Issues may result in:
 - Recalls
 - Container/packaging changes
 - Labeling changes
 - FAR (following a DQRS report)
 - Corrective Actions
 - Market Withdrawal
 - Withdrawal of Approval - CFR 314.81(d)

Total Number of FARs Received





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Questions?