

Postmarketing Drug Safety and Inspection Readiness

June 19, 2018

**Center for Drug Evaluation and Research (CDER)
Small Business and Industry Assistance (SBIA) Webinar**

United States Food and Drug Administration (FDA)
CDER / Office of Compliance
Office of Scientific Investigations (OSI)
Division of Enforcement and Postmarketing Safety (DEPS)
Postmarket Safety Branch (PSB)



This one file contains all the slides used in the
MORNING sessions for the webinar.



Agenda

Session 1:

Postmarketing Adverse Drug Experience (PADE)
Inspections

Session 2:

Risk Evaluation and Mitigation Strategies (REMS)
Inspections

Session 3:

Inspection Readiness

Session 1: PADE Inspections

Outline

- Objectives
- PADE Laws and Regulations
- Written Procedures
- Business Relationships and Agreements
- Electronic Reporting



Objectives

1. Gain an understanding of PADE laws and regulations for products regulated by CDER
 - New Drug Applications (NDA) products
 - Abbreviated New Drug Applications (ANDA) products
 - Biologic License Applications (BLA) products
 - Unapproved, prescription products
 - Unapproved, non-prescription products (e.g. over-the-counter (OTC) monograph products)

2. Recognize best practices for a PADE program

PADE Inspections: Overview of Laws and Regulations

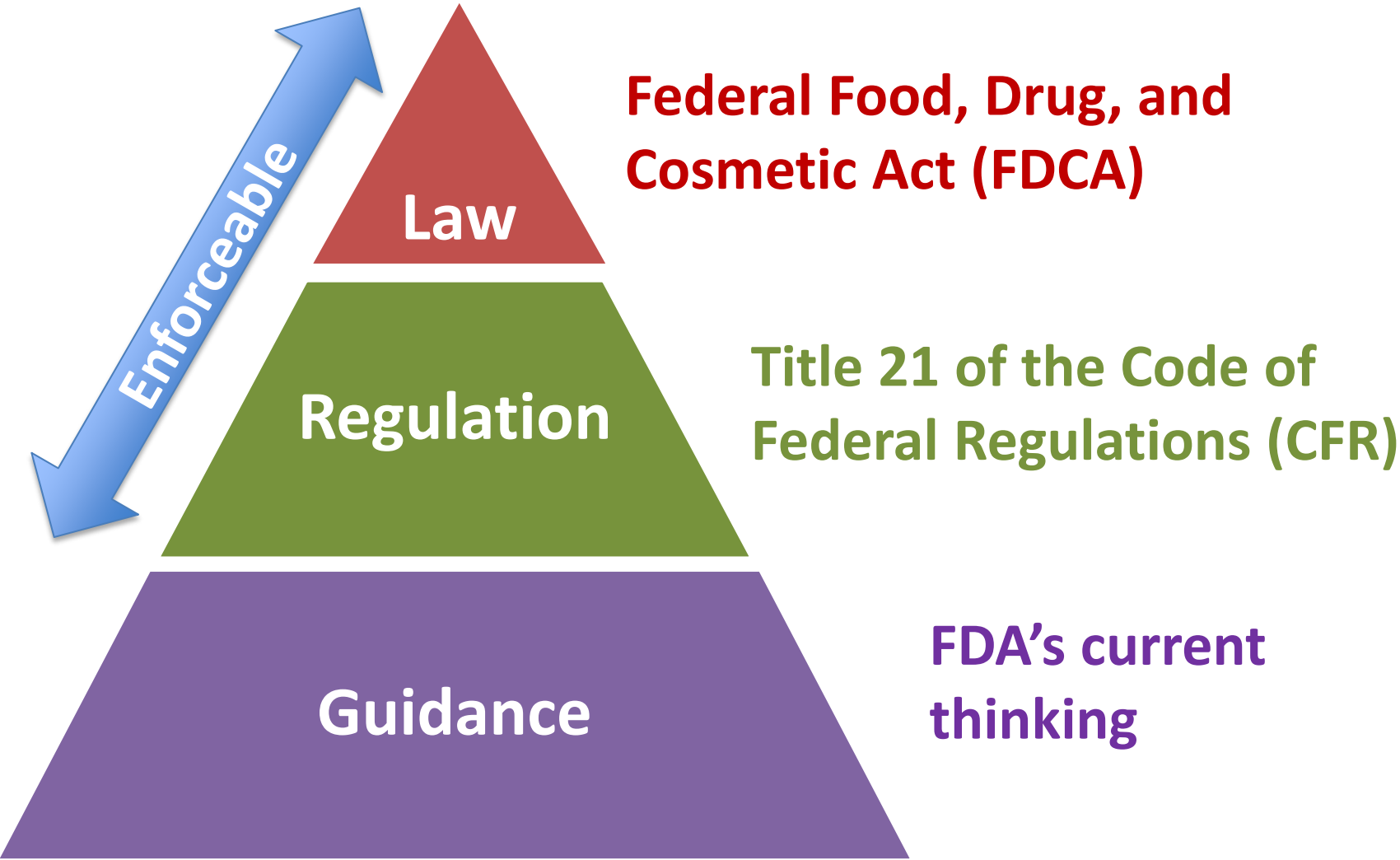
Kelley Simms, PharmD, MS

Commander, US Public Health Service

Consumer Safety Officer

PADE Compliance Team

PADE Legal Framework



PADE Statutory Provisions / Regulations: Prescription Drug Products for Human Use



FDCA, Subchapter V, Part A, Section 505 (21 USC §355)	New drugs
21 CFR 310.305	New drugs: Records and reports concerning ADEs on marketed prescription drugs for human use without approved new drug applications
21 CFR 314.80	New drug applications: Postmarketing reporting of ADEs
21 CFR 314.81(b)(2)	New drug applications: Annual reports
21 CFR 314.90	New drug applications: Waivers
21 CFR 314.98	Abbreviated applications: Postmarketing reports
21 CFR 314.540	Accelerated approval of new drugs for serious of life-threatening illnesses: Postmarketing safety reporting
21 CFR 314.630	Approval of new drugs when human efficacy studies are not ethical or feasible: Postmarketing safety reporting
21 CFR Part 4, Subpart B	Postmarketing safety reporting for combination products

PADE Statutory Provisions / Regulations: Licensed Biological Products for Human Use



PHS Act, Subchapter II, Part F, Subpart 1 (21 USC §262)	Regulation of biological products
21 CFR 600.80	Biological products: Postmarketing reporting of adverse experiences
21 CFR 601.28	Biologics licensing: Annual reports of postmarketing pediatric studies
21 CFR 601.44	Accelerated approval of biological products for serious of life-threatening illnesses: Postmarketing safety reporting
21 CFR 601.70	Postmarketing studies: Annual progress reports of postmarketing studies
21 CFR 601.93	Approval of biological products when human efficacy studies are not ethical or feasible: Postmarketing safety reporting
21 CFR Part 4, Subpart B	Postmarketing safety reporting for combination products

PADE Statutory Provisions / Regulations: Unapproved, Non-prescription Products (e.g. OTC monograph)



FDCA, Subchapter VII, Part H, Section 760 (21 USC §379aa)	Serious adverse event reporting for nonprescription drugs
21 CFR 329.100	Postmarketing reporting of ADEs under section 760 of the FDCA
21 CFR Part 4, Subpart B	Postmarketing safety reporting for combination products

PADE Inspections: Written Procedures

Diane Bruce, PharmD

Namita Kothary, PharmD, RAC (US)

Consumer Safety Officers

PADE Compliance Team

Written Procedures

- Required in PADE Regulations
 - 21 CFR 310.305: Unapproved prescription products
 - 21 CFR 314.80: Approved application drug products
 - 21 CFR 600.80: Approved application or licensed biologic products
- Not required for unapproved, non-prescription (OTC monograph) products covered under FD&C Act (Section 760)



Approval vs. Marketing

Once a drug is approved, applicant holders **MUST** receive, evaluate, and report all adverse drug experiences (ADEs) to FDA, even if the drug is not marketed.



✓ Marketed
Or
✓ NOT marketed



Written Procedures Must Address...



Surveillance

- Account for all sources
- Spontaneous
- Solicited
- Internet sources (firm-sponsored)
- Literature

...and more!

Receipt

- ADE info
 - Initial
 - Follow-up
- Receipt from any source

Evaluation

- Seriousness
- Expectedness
- Relatedness
- ADEs from any source
- Follow-up procedures

Reporting

- 15-day Alert Reports
- Non-expedited individual case safety reports (ICSRs)
- Aggregate Reports
- All info must be submitted electronically

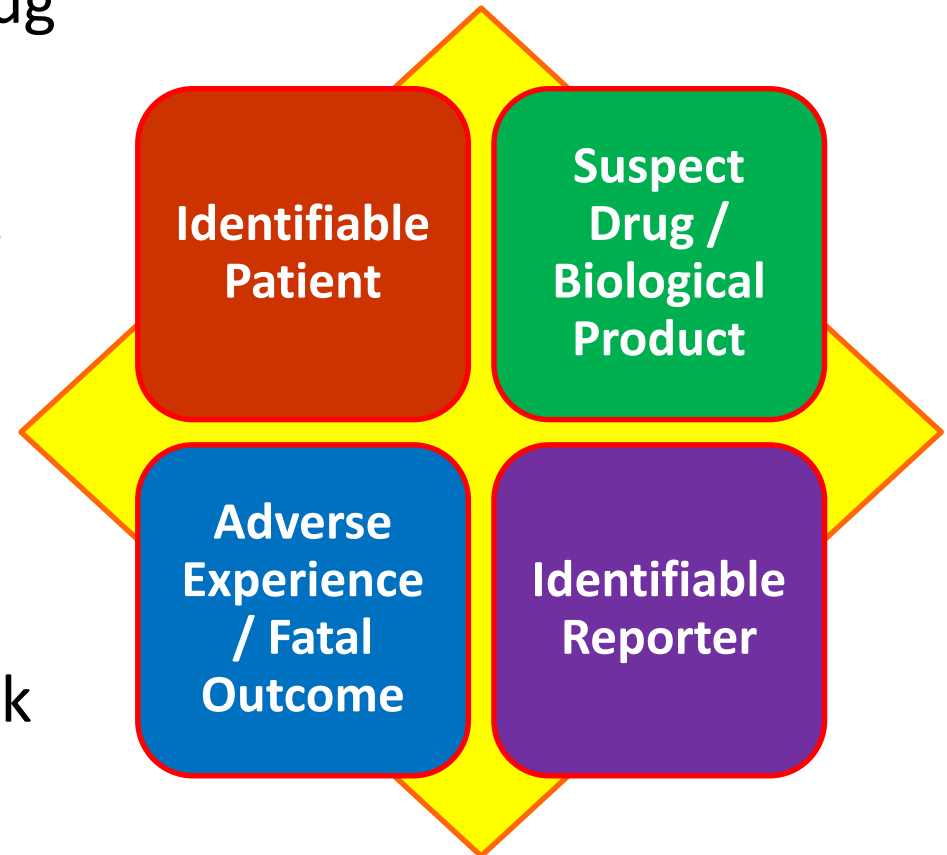
Surveillance

What is an ADE?

Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including:

- Use in professional practice
- Overdose (intentional and accidental)
- Abuse
- Withdrawal
- Failure of expected pharmacological action (lack of effect)

Data Elements for Reportable ADEs





Spontaneous ADEs: Examples of Sources

... and many more!

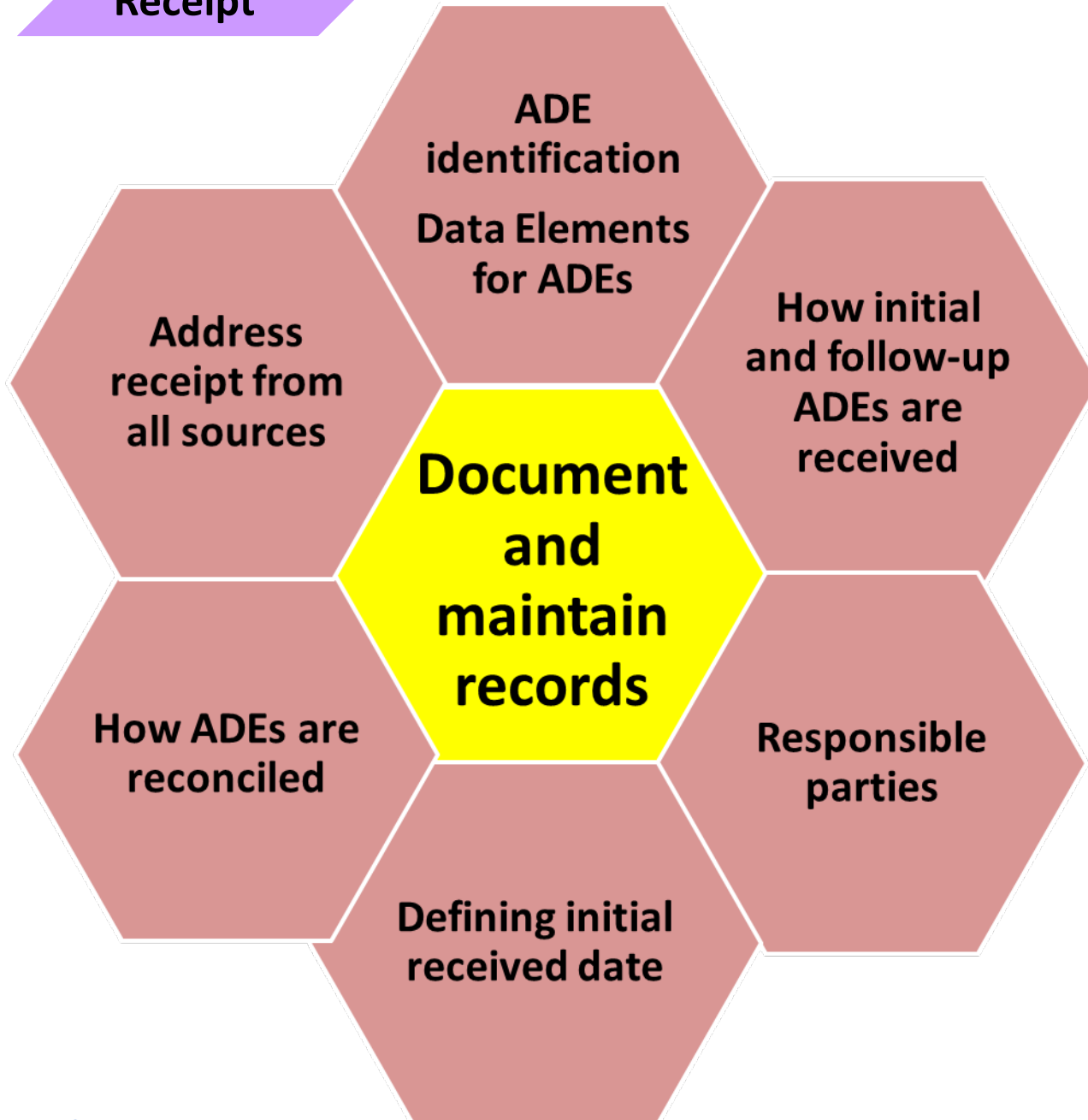
Solicited ADE: Examples of Sources



Systematic collection of data involving solicitation of ADE information



Receipt



Receipt of ADE information

Evaluation

Evaluating ADEs

Seriousness	Serious if ≥ 1 of the following outcomes:
	<ul style="list-style-type: none"> Death Life-threatening Hospitalization Persistent or significant disability Congenital anomaly / birth defect Other serious / important medical event
Expectedness	Unexpected if one of the following:
	<ul style="list-style-type: none"> Not listed in current labeling Greater severity or specificity than ADE listed in label
Relatedness	Impacts reporting of solicited ADEs
	Related if there is a reasonable possibility that the drug caused ADE

Determine Reportability

Expedited (15-day Alert Reports)

NDA, ANDA, BLA, and unapproved prescription drugs: Submit within 15 calendar days of information receipt

- Spontaneous: serious, unexpected ADEs
- Solicited: serious, unexpected, possibly related ADEs

OTC Monograph products: Submit serious, domestic ADEs within 15 business days of information receipt

Non- expedited (Periodic ICSRs)

NDA, ANDA, BLA: Submit with periodic safety report

- Spontaneous: serious, expected ADEs
- Spontaneous: non-serious ADEs
- Not applicable for literature, study, or foreign ADEs

Not applicable for unapproved prescription and OTC monograph products

Review and Investigate ADEs

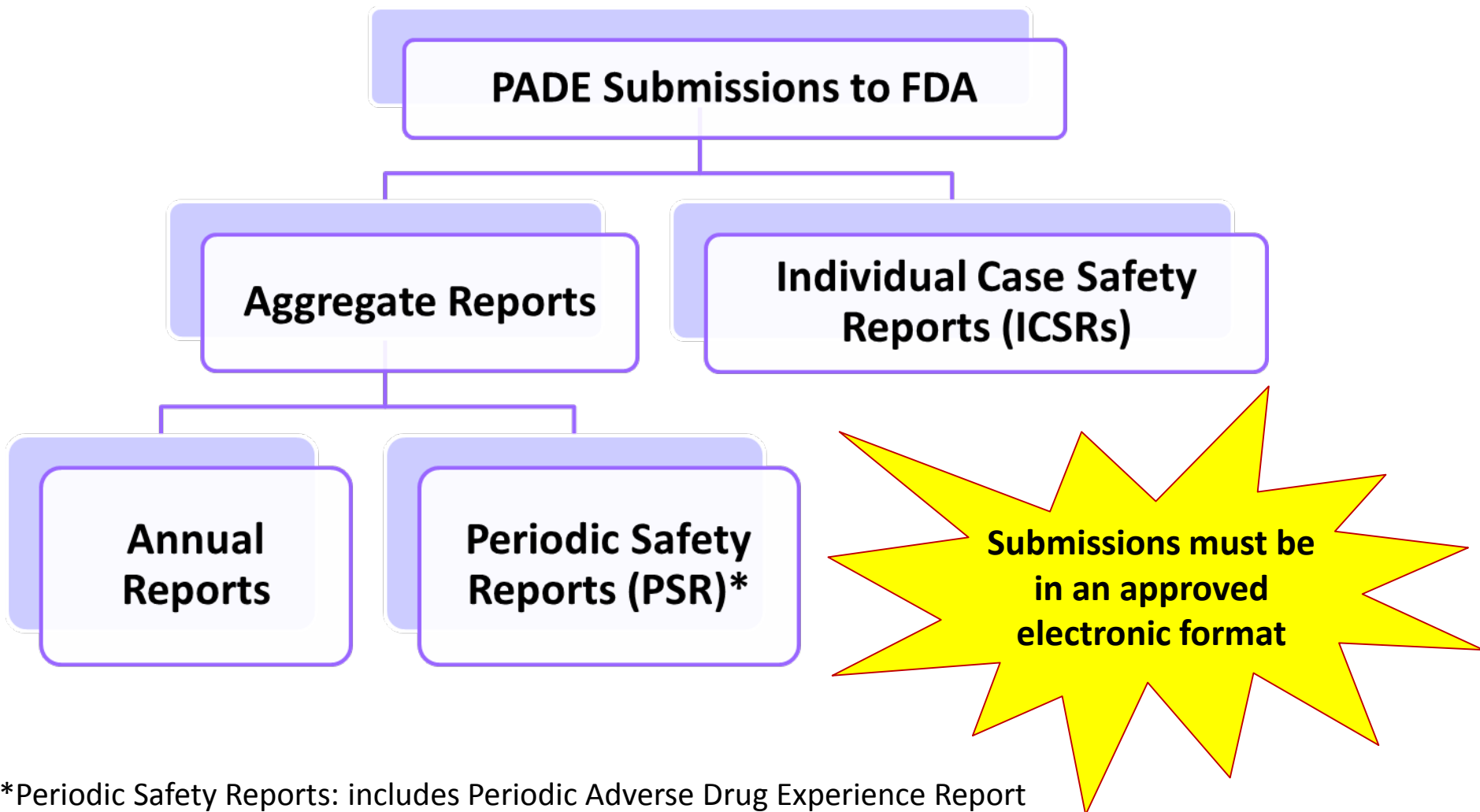
- Promptly review ADE information
- Determine if follow-up is needed, especially if missing data elements
 - Must investigate 15-day Alert Report ADEs
 - Maintain records of follow-up attempts
- Evaluate information for reportability

Reporting

Who is responsible for PADE reporting?

- Application holders for approved products
 - NDA
 - ANDA (“generics”)
 - BLA (including biosimilars)
- Non-application holders (manufacturers, packers, and distributors) named on the label of:
 - Approved products
 - Unapproved products (prescription and OTC monographs)
- Non-applicants must report serious ADEs to applicant within 5-days or submit 15-day alerts directly to FDA

Reporting to FDA



*Periodic Safety Reports: includes Periodic Adverse Drug Experience Report (PADER) and Periodic Benefit-Risk Evaluation Report (PBRER) formats

Submitting ICSRs

- Must submit electronically via Electronic Submission Gateway (ESG) or Safety Reporting Portal (SRP)
- Reportable when 4 basic data elements are known

	Expedited ICSRs	Periodic ICSRs	Follow-up ICSRs <i>(submit separately from initial ICSR)</i>
NDA, ANDA, BLA	Submit within 15 calendar days	Submit with PSR	Expedited ICSRs: Submit within 15 calendar days Non-expedited: Submit with next PSR
Unapproved prescription products	Submit within 15 calendar days	Not-applicable	Expedited ICSRs: Submit within 15 calendar days
OTC monograph products	Submit within 15 business days	Not-applicable	Submit information received within one year of the initial report within 15 business days

Aggregate Safety Reports

- Applies to approved NDAs, ANDAs, and BLAs
- Must submit electronically to eCTD
 - ICSRs must be submitted via ESG or SRP

	Post approval	Time period	Submission due
Annual Report	All years	Annually	within 60 days of US approval date
PADER*	First 3 years	Quarterly	within 30 days of close of quarter
	>3 years	Annually	within 60 days of US approval date

**Firm may apply for waivers for PADER requirements (e.g., use of International Birth Date, PBRER format)*

Waivers

- Firms may request waivers for certain PADE requirements
- Waivers stay with the application, even if the application transfers firms
- Examples of PADE waivers
 - Submit PBRER instead of PADER
 - To not submit non-serious, expected ADEs
 - High volume of ADEs associated with legal cases
 - Submit periodic reports on a date other than the US approval date (e.g. international birth date)
 - Paper submissions

PADE Inspections: Business Relationships and Agreements

Richard Abate, RPh, MS

Team Lead

PADE Compliance Team

Using Contractors for Pharmacovigilance Activities



Oversight of PV contractors

- Any PADE activities can be outsourced to a third party (e.g. vendor, contractor, consultant, or other pharmacovigilance provider)
- However, the applicant or non-applicant named on the label remains responsible for compliance



Business Partners – A Source of Safety Data





Business Partners



- Joint development & marketing of drugs
- Contract manufacturers
- Drug safety data generated needs to be collected and exchanged between partnering firms (any source of ADEs)
- Laws and regulations govern the exchange, review, & reporting of safety data
 - 21 CFR 314.80(c)(1)(iii)
 - 21 CFR 310.305(c)(3)
 - 21 CFR 600.80(c)(1)(iii)
 - FDCA, Subchapter VII, Sec 760



Business Partners as a Source of ADE Data



- Business partners are potential “sources” of ADE data
 - Firms must establish written procedures (agreements) regarding any business partner that might get safety data
- Written agreements with business partners
 - Safety Data Exchange Agreements or SDEAs
 - Pharmacovigilance (PV) Agreements
 - Contracts / Work orders



Written Agreements with Business Partners



There is no “one size fits all”

Written Agreements with Business Partners should explain:

1. What data get exchanged?

- ✓ *Serious ADEs or all ADEs [21 CFR 314.80(c)(1)(iii)]*
- ✓ *Ensures ADEs sent to a business partner are actually received (and vice versa)*



There is no “one size fits all”



2. When does the exchange take place?

- ✓ *Timelines for non-applicants sending serious ADEs to applicants is no more than 5 calendar days [21 CFR 314.80 (c)(1)(iii)]*
- ✓ *Do exchange timelines facilitate compliance with reporting requirements*

3. What provisions ensure that terms of the agreement are met?

- ✓ *Reconciliation of data, meetings, or audits of business partners*



There is no “one size fits all”



4. **Who prepares aggregate reports (PADERS/PBRERs) for FDA?**
 - ✓ *When activity for safety reports is contracted to affiliates, the applicant holder remains responsible for compliance*

5. **How are ICSRs and aggregate reports submitted to FDA?**
 - ✓ *Who is responsible*
 - ✓ *Timelines, method and format for submission, submission confirmations*

Electronic Reporting of Individual Case Safety Reports

Suranjan De, Deputy Director

Regulatory Science Staff

Office of Surveillance and Epidemiology, CDER

Objective

- Understand electronic reporting of Individual Case Safety Report (ICSR)

Outline

- Introduction to FAERS
- Why an electronic ICSR submission requirement
- Submission Methods
- Submission of Periodic Safety Reports
- Future state of electronic submission
- References

Electronic Reporting of ICSRs

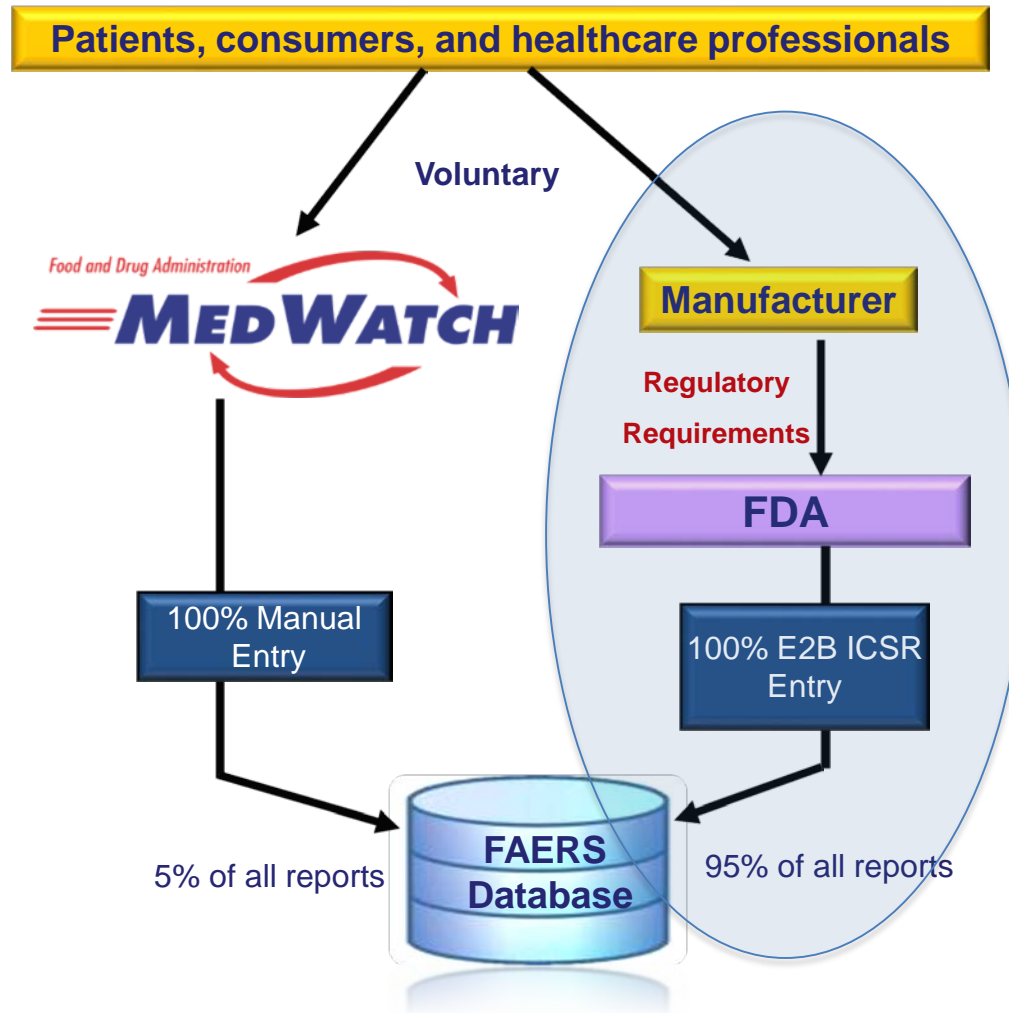
FDA Adverse Event Reporting System (FAERS)

- FDA's postmarketing safety surveillance database for drugs and therapeutic biologics
- FDA uses FAERS data to monitor, identify and analyze adverse event and medication errors
- FDA staff in CDER and CBER regularly examine the FAERS database as part of routine safety monitoring
- When a safety signal is identified from FAERS data, it is further evaluated



Electronic Reporting of ICSR

How post-marketing adverse event reports get to FDA



Electronic Reporting of ICSR

What Reports are in the FAERS Database?



For

Drugs and therapeutic biologics (Rx + OTC) - **CDER**

Tissue products, therapeutic blood products - **CDER**





Electronic Reporting of ICSRs

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements

- **Submit safety reports in an electronic format** that FDA can process, review, and archive
- **Improve** the Agency's systems for **collecting and analyzing** postmarketing safety reports
- **Enable** Agency to **more rapidly review** postmarketing safety reports, **identify and evaluate** emerging safety problems, and **disseminate** safety information in support of FDA's public health mission
- Electronic submission of ICSRs **enhances** global pharmacovigilance by **facilitating electronic transmission and exchange of appropriate information** from ICSRs among regulatory bodies and regulated entities through use of **common data elements and transmission standards**



Electronic Reporting of ICSRs

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements

Document Information

Date Posted:

May 27, 2015

RIN:

0910-AF96

CFR:

21 CFR Parts 310, 314, 329, and 600

Federal Register Number:

2015-12753

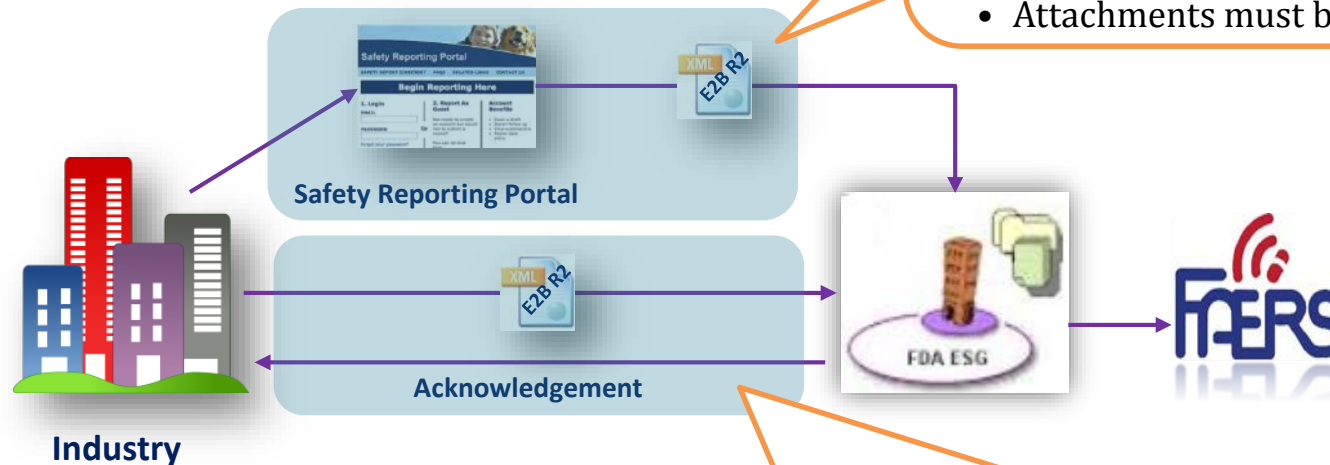
<https://www.regulations.gov/#!/documentDetail;D=FDA-2008-N-0334-0009>

Electronic Reporting of ICSRs

Submission Methods

- There are two options for submitting ICSRs electronically

- **The Safety Reporting Portal (SRP) by manually entering data via web form**
 - Do not have database-to-database capability
 - Must have an account to access the portal site
 - Gateway partners cannot use the SRP
 - Attachments must be in the PDF format



- **Database-to-database transmission ("E2B")**
 - Use standardized ICH E2B(M) data elements
 - ICSRs must be submitted in the XML format
 - Attachments must be in the PDF format

Safety Reporting Portal (SRP)



Safety Reporting Portal

[ABOUT THE PORTAL](#) | [SAFETY REPORT DIRECTORY](#) | [FAQS](#) | [RELATED LINKS](#) | [CONTACT US](#)

Begin Reporting Here

1. Login

EMAIL

PASSWORD

[Forgot your password?](#)

Remember me

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- An applicant of an approved drug product or a manufacturer, distributor or packer listed on the label of any drug product
- Drug Manufacturers
- Dietary supplement manufacturers, packers, and distributors

Others, including health care providers, public health officials, and other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

[Learn more about mandatory and voluntary reporting.](#)

Reports You Can Submit Through this Portal

FDA safety issues involving:

- Marketed human drug and therapeutic biologics
- Human or animal reportable foods
- Animal drugs
- Animal foods
- Tobacco products
- Dietary supplements

NIH safety issues involving:

- NIH gene-transfer research

For other issues, [find out where to submit your report.](#)

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

Safety Reporting Portal

[Welcome Guest](#) | [HOME](#) | [FAQS](#) | [RELATED LINKS](#) | [CONTACT US](#) | [FEEDBACK](#) | [HELP](#)

New Guest Report

You have chosen to use this portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

***Select the option that best describes what you want to do:**

Start a new report

Follow-up on a report previously submitted as a guest portal user.

Follow-up on a report previously submitted as a logged in user.

None of the above

***Which of the following best describes you?**

Reportable Food Registry Report(mandatory): A food facility or responsible party that manufactures, processes, packs, or holds foods who is submitting a **reportable food** report.

Reportable Food Registry Report(voluntary): A federal, state, or local public health official who is submitting a **reportable food** report involving human and/or animal food.

Pet Food Report: A veterinarian or veterinary staff member who is submitting a product problem and/or adverse event report involving **pet food**.

Pet Food Report: A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving **pet food**.

Livestock Food Report: A veterinarian or other professional who is submitting a product problem and/or adverse event report involving **livestock food**.

Livestock Food Report: A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving **livestock food**.

Animal Drug Report: A marketing authorization holder (manufacturer) for an animal drug who is submitting a report on a product problem and/or an adverse event.

Tobacco Product Report: A healthcare professional submitting a product problem and/or health-related problem report involving a **tobacco product**.

Tobacco Product Report: A consumer or concerned citizen who is submitting a product problem and/or health-related problem report involving a **tobacco product**.

Dietary Supplement Report(mandatory): A dietary supplement manufacturer, packer, or distributor who is submitting a mandatory serious adverse event report.

Dietary Supplement Report(voluntary): A consumer, concerned citizen, or healthcare professional who is submitting a report about an illness, injury, or product problem associated with dietary supplement(s), or a manufacturer, packer, or distributor who is submitting a dietary supplement voluntary adverse event and/or product problem report.

Gene Research Study Report: A clinical trial primary investigator or researcher who needs to report an adverse event involving a **gene research study**.

Marketed Human Drug and Therapeutic Biologics Report (mandatory): An applicant, manufacturer, packager, and distributor of human drugs and biological products, other than vaccines who is submitting on a product problem and/or adverse event.

None of these describe me.

Please contact the [FDA coordinator](#) to request access.
Thank you for your interest.

|

Safety Reporting Portal (SRP)



SRP is based on the data elements from the MedWatch 3500A

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
FORM FDA 3500A (10/15)

Page 1 of 3

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See FRA statement on reverse.

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # _____
UPI/importer Report # _____

FDA Use Only

Note: For date prompts of "dd-mm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier _____

2. Age Year(s) Month(s) Sex Male Female Weight _____ lb kg

3. Dose _____ Frequency _____ Route Used _____

4. Therapy Dates (if unknown, give duration) from/ to (or best estimate) (dd-mm-yyyy) #1 _____ #2 _____

5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't apply

5.a. Ethnicity (Check single best answer) Hispanic/Latino Not Hispanic/Latino

5.b. Race (Check all that apply) Asian American Indian or Alaskan Native Black or African American White Native Hawaiian or Other Pacific Islander

5. Diagnostics for Use (Indication) #1 _____ #2 _____

10. Event Reappeared After Reintroduction? #1 Yes No Doesn't apply

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)

2. Outcome Attributed to Adverse Event (Check all that apply) Death include date (dd-mm-yyyy) _____ Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mm-yyyy) _____ 4. Date of this Report (dd-mm-yyyy) _____

D. SUSPECT MEDICAL DEVICE

1. Brand Name _____

2. Common Device Name _____ 2b. Procode _____

3. Manufacturer Name, City and State _____

4. Model # _____ Lot # _____ 5. Operator of Device Health Professional Lay User/Patient Other

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

8. Is this a single-use device that was reprocessed and reused on a patient? Yes No

9. If Yes to Item 8, Enter Name and Address of Reprocessor _____

10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: _____

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) _____

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength #1 - Name and Strength _____ #1 - NDC # or Unique ID _____ #1 - Manufacturer/Compounder _____ #1 - Lot # _____ #2 - Name and Strength _____ #2 - NDC # or Unique ID _____ #2 - Manufacturer/Compounder _____ #2 - Lot # _____

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) _____

E. INITIAL REPORTER

1. Name and Address Last Name: _____ First Name: _____ Address: _____ City: _____ State/Province/Region: _____ Country: _____ ZIP/Postal Code: _____ Phone #: _____ Email: _____

2. Health Professional? Yes No 3. Occupation (Select from list) _____ 4. Initial Reporter Also Sent Report to FDA? Yes No Unk

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Safety Reporting Portal

HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP

My Reports

Draft Reports Click column header to sort the column

Date Saved (EST)	Report ID	Title	Report Type Description
09/13/2013 09:17:09 AM	4430 (I)	SPHR - Medicated Soap	SPHR Created by: Ann Goldberg
09/30/2013 07:17:09 AM	5540 (F)	Allergy Product X - Rash adverse event	SPHR-MCN: US-ABCPHARMA-1201808 Created by: Joe Smith

Start New Report Edit Delete

< <Page 1 of 1 >

Submitted Reports Available for Follow-Up

Submitted as of (mm/dd/yyyy): _____ ICSR Number (please enter the number only): _____ Search Reset

Submitted Reports. Click column header to sort the column

Date Submitted (EST)	Report ID	ICSR #	Title	Report Type Description
09/13/2013 09:17:09 AM	4431 (I)	120206 (I)	Prescription drug X - adverse event	SPHR - MCN: US-ABCPHARMA-1201808 Submitted by: Ann Goldberg
09/30/2013 11:30:22 AM	4432 (I)	1201806 (I)	Allergy Product X - Rash	SPHR - MCN: US-ABCPHARMA-1201808 Submitted by: Joe Smith

View View PDF

Electronic Reporting of ICSRs

Submitting Periodic Safety Reports (PSR)

Periodic safety reports are comprised of a **descriptive portion** and **non-expedited ICSRs** (21 CFR 314.80 and 600.80), regardless of the format.

- **Descriptive Portion:**
 - Use **Electronic Common Technical Document (eCTD)** specifications to submit the descriptive portion electronically.
 - **Indicate** in the descriptive portion that the **ICSRs have been submitted electronically** as XML files to the FDA Electronic Submissions Gateway (ESG) or via the Safety Reporting Portal (SRP).
- **Non-expedited ICSRs:** must be submitted as described in the options **on or before** the periodic safety report due date. Do NOT submit expedited ICSRs previously submitted.

Electronic Reporting of ICSRs



Future state of electronic submission

- “FDA Regional Implementation Specifications for ICH E2B(R3) Implementation: Postmarket Submission of Individual Case Safety Reports (ICSRs) for Drugs and Biologics, Excluding Vaccines” posted on June 23, 2016
- Follow core ICH E2B R3 with a few regional requirements
- Regional Elements
 - Ethnicity
 - Race
 - Drug descriptor
 - Combination
 - Compounding

Challenge Question #1

1. Methods to submit ICSR.

- a. Database-to-database
- b. Safety Reporting Portal
- c. Paper MedWatch
- d. a and b

Answer: D

Challenge Question #2

True or False?

Periodic reports are comprised of two parts: the Descriptive portion and the Non-expedited ICSRS

Answer: True

Electronic Reporting of ICSRs



References

- FDA Adverse Event Reporting System (FAERS) - Electronic Submission
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm>
- FDA issues final rule on postmarketing safety report in electronic format
<http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0334-0009>
- Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments
<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/UCM601820.pdf>
- Steps to Submitting E2B(R2) ICSRs Electronically in the XML Format
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115914.htm>
- Electronic Common technical Document (eCTD)
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>

Questions for the Panel

Click for resources:

- [Guidance for Industry: Compliance Policy for Combination Product Postmarketing Safety Reporting](#)
- [Guidance for Industry: Providing Regulatory Submissions In Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](#)
- [Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without An Approved Application](#)



Open Q&A begins shortly – type in your questions now.

Please send any questions we do not have time for to:

CDERSBIA@fda.hhs.gov

Learn about other resources from CDER Small Business & Industry Assistance:

[Visit Our Website!](#)