Center of Excellence Safety Reporting Portal (SRP) Registration and Adverse Event Reporting Process for 503B Registered Outsourcing Facilities

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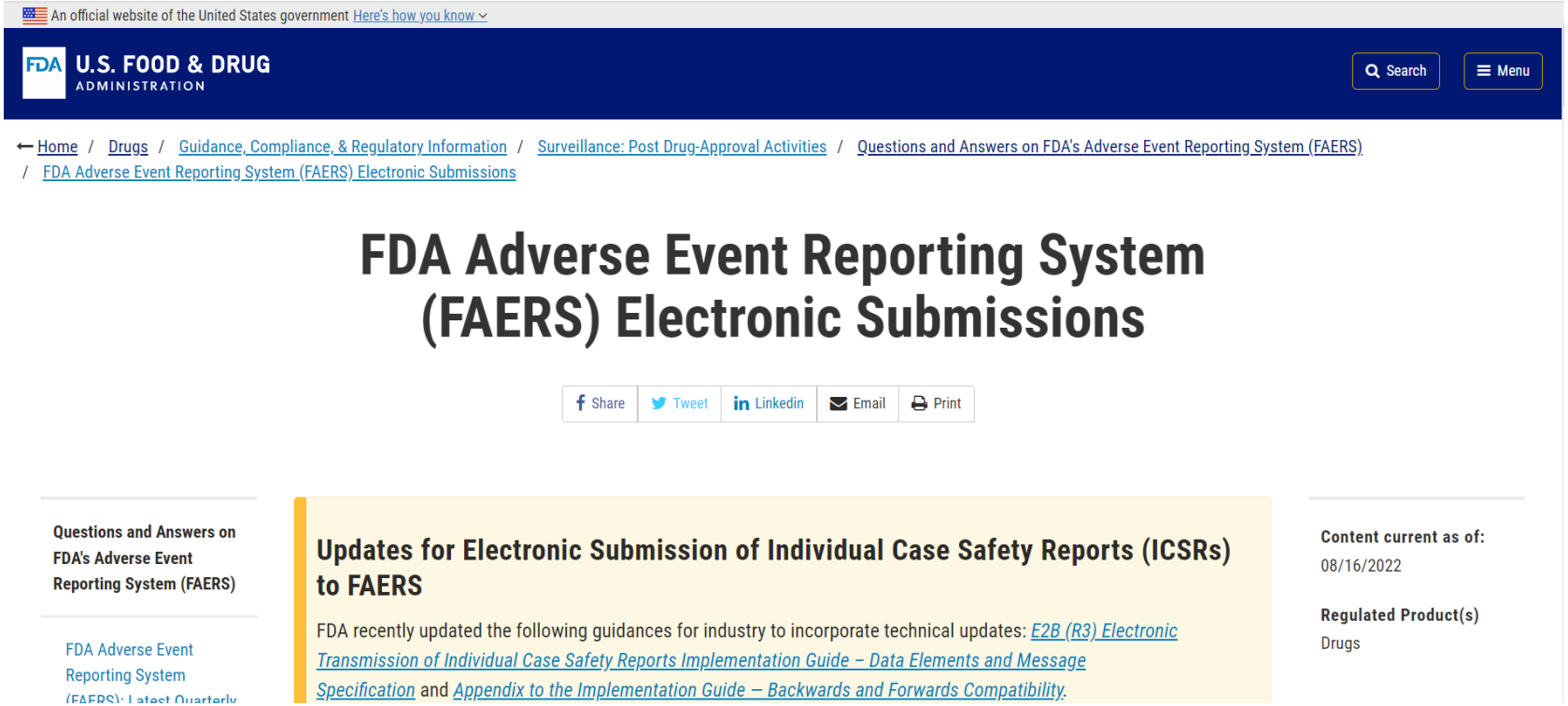
Objectives

- Recognize the two options for submitting adverse event reports to the FDA
- Be familiar with the registration process for SRP
- Know how to log in to SRP account and submit a report
- Know how to submit an attachment to a report
- Know how to contact the FDA if there are any questions regarding reporting or registration

Overview

- https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions



Overview

- Two options for submitting Individual Case Safety Reports (ICSRs) electronically:
  - Option A: Database-to-Database Transmission via Electronic Submissions Gateway (ESG)
  - Option B: The Safety Reporting Portal (SRP) by manually entering the data via our SRP portal

Technical Requirements to Submit via Database-to-Database Transmission

- Individual Case Safety Reports (ICSRs) must be in Extensible Markup Language (XML) format
- Attachments must be in PDF format
- XML files and Attachments must adhere to the "Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments" document and be submitted to the FDA via the Electronic Submission Gateway (ESG)
- Additional instructions on how to prepare and submit ICSRs in XML format can be found in "Steps to Submitting ICSRs Electronically in the XML Format" document.

Safety Reporting Portal (SRP)

- For use by OFs that do not have database-to-database capability
  - Companies that submit ICSRs electronically via the ESG cannot use the SRP
- Must have an account to access and use SRP
- Steps for getting SRP account
  - Contact FAERSESUB@fda.hhs.gov to advise FDA of intent to begin submitting via the SRP
  - Complete registration form
  - Allow 7 to 10 business days for account request review and activation
  - FDA will email a notification with the subject line “SRP Account Activation” that will include the web link to the SRP portal along with account information

Tips for Registration Form

- Detailed instructions are sent with the registration form
- Required Fields are designated with an "*"
  - Encouraged to fill out forms completely as possible
- Select "Yes" to indicate that the organization is a 503B outsourcing facility under "Type of Registration"
- Drug Authorization Number for compounded products is "COMP99"

- Email FAERSESUB@fda.hhs.gov if there are any questions

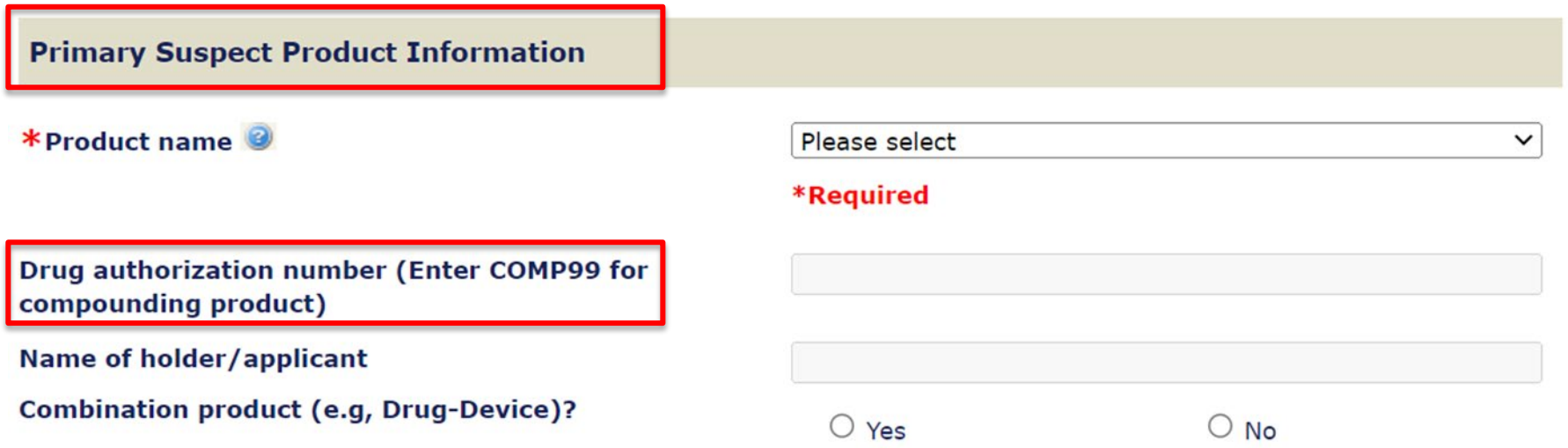
Submitting ICSRs in SRP

- https://www.safetyreporting.hhs.gov/

Submitting ICSRs in SRP

- Easy to follow questionnaire
  - Manual Entry of Adverse Event Report Data
  - "*" Required Fields
- Edit checks
  - Ensure data quality
    - i.e. Age without unit
  - Conformance to E2b standards
- Email FAERSESUB@fda.hhs.gov if there are any questions

Considerations for 503B Entities



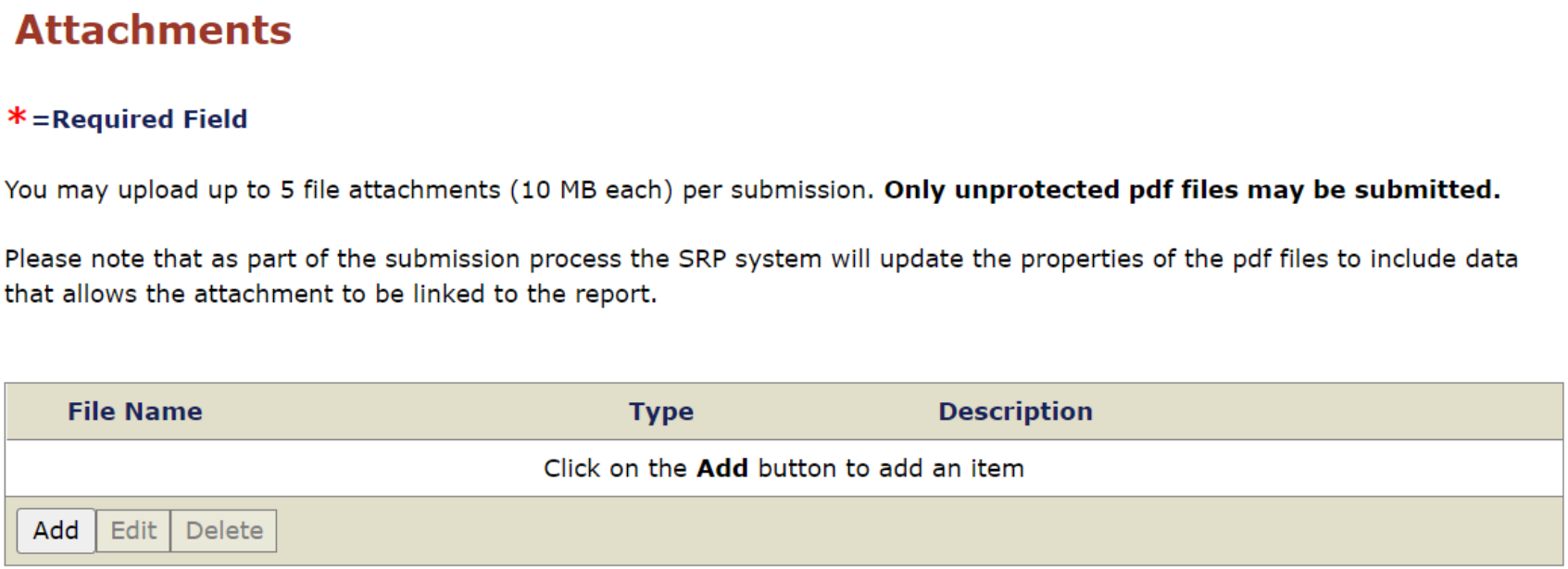
- Primary Suspect Product is the product that is compounded by the 503B Entity
- “COMP99” is the Authorization Number for a compounded product

Submitting ICSR Attachments

- Supporting information for ICSRs, e.g.:
  - Current labeling for the compounded drug product
  - Hospital discharge summaries, autopsy reports/ death certificates, relevant laboratory data and other critical data
- SRP portal features allows for browsing, selecting, and attaching documents to an ICSR
  - Follow instructions in SRP to submit attachments

Submitting ICSR Attachments

- May upload 5 attachments (10MB each) per submission
- Only unprotected PDF files are accepted



Attachments

*=Required Field

You may upload up to 5 file attachments (10 MB each) per submission. **Only unprotected pdf files may be submitted.**

Please note that as part of the submission process the SRP system will update the properties of the pdf files to include data that allows the attachment to be linked to the report.

File Name	Type	Description
Click on the **Add** button to add an item		

Add | Edit | Delete

QUESTIONS?

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