Electronic Submission
FDA Safety Report Type Flag Requirement

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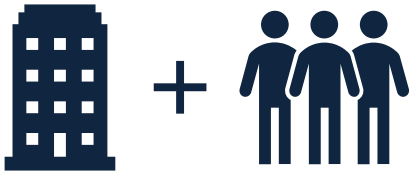
New FDA Safety Report Type Flag Requirement for FAERS Submissions
February 19, 2021

Learning Objectives

- Discuss and define the FDA Safety Report Type Flag requirement
- Highlight benefits associated with the requirement
- Locate the revised technical specification Guide
- Communicate implementation considerations
- Connect with FDA for assistance/feedback

FAERS Submission Requirements + Benefits

What is FAERS?



Industry and public stakeholders submit individual case safety reports (ICSR) for human drug and nonvaccine biologic products

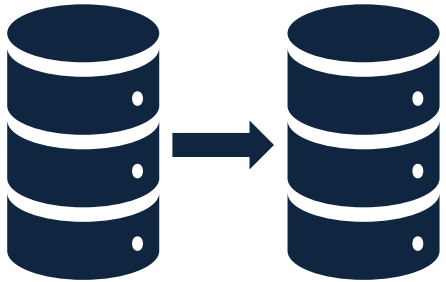
FDA stores ICSRs in a safety surveillance database

Staff monitor database for safety signal and further evaluate if FDA action is warranted

Submitting ICSRs – Option 1

Database to Database Transmission (E2B)

- Submissions must use standardized International Conference on Harmonisation (ICH) E2B standards
- ICSRs must be submitted in the eXtensible Markup Language (XML) format
- Attachments must be in PDF format



Submitting ICSRs – Option 2

Safety Reporting Portal

- Must have an account to access the portal
- Must not be a Gateway partner
- Attachments must be in PDF Format

Great for those who do not have database to database capability!

New Reporting Requirement

ICSRs currently do not include safety report type in submissions

New Regional R2 Elements	Benefits
Element Name: FDA Safety Report Type **Element ID:** A.1.FDA.16 **Element Tag:** <fdasafetyreporttype> **Element Length:** 1 **Element Data Type:** N **Conformance:** Required **Element Allowed Values:** • 1 = IND Safety Report • 2 = IND Exempt BA/BE Safety Report • 3 = Postmarketing Safety Report	• Distinguish premarket (IND and IND-Exempt BA/BE) safety reports from postmarketing safety reports • Determine which reports are posted publicly easily

ICSRs from postmarketing studies required under 314.80 (e) must be marked as "3" regardless of whether the study was conducted under an IND

Updated DTD 2.1 & 2.2

```
<!-- A.1.FDA.16 FDA Safety Report Type -->
<!--
Field ref: A.1.FDA.16
Field title: FDA Safety Report Type
Field name: fdasafetyreporttype
Field length:    1N
Field values:
1=IND Safety Report
2=IND Exempt BA/BE Safety Report
3=Postmarketing Safety Report
Comment: The FDA Safety Report Type data element distinguishes
premarket (IND and IND-Exempt BA/BE) safety reports from
postmarketing safety reports and is used to determine which reports
are posted publicly.
Note: This is a mandatory data element
-->
<!ELEMENT fdasafetyreporttype (#PCDATA)>
<!ATTLIST fdasafetyreporttype
      %lang.att;
>
```

Implementation Considerations

Routing Mechanism Method 1

AS2 Header Attributes

Current State: Post market reports (does not apply to pre-market)

- Destination: "CDER"
- Attribute values: "**AERS**" for XML's and "**AERS_ATTACHMENTS**" for PDF's

Proposed Future State: For IND reports, new header attributes need to be setup/configured to route the files into the new folders (does apply to pre market ICSRs)

- Destination remains the same ("CDER")
- Attribute values: "**AERS_PREMKT**" for XML's and "**AERS_ATTACHMENTS_PREMKT**" for PDF's

Attribute value for PDF's is applicable only for E2B (R2) submissions

Routing Mechanism Method 2

AS2 Routing IDs

Current State: Post market reports (does not apply to pre-market)

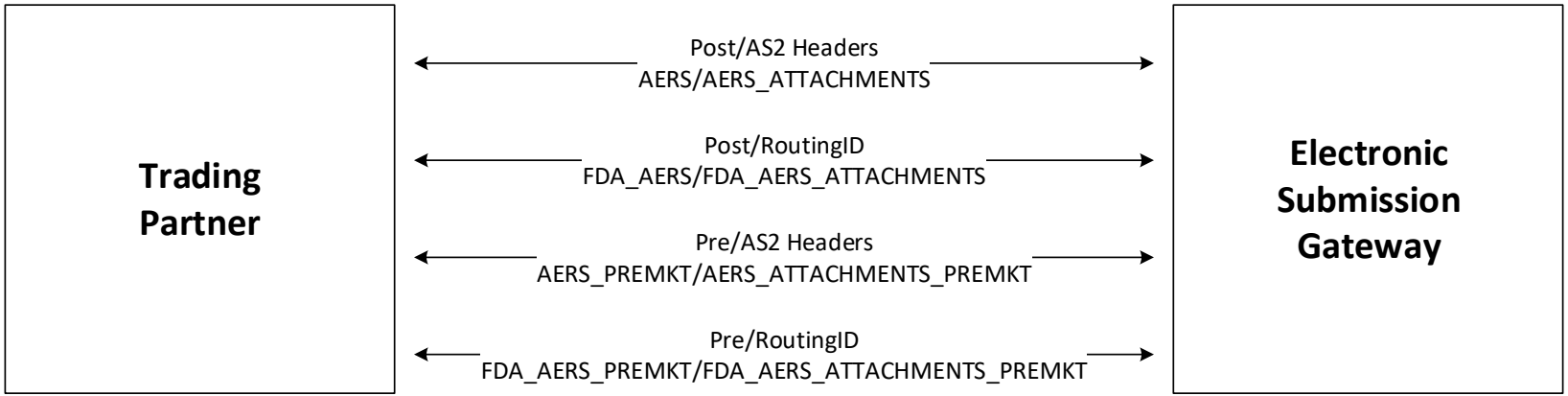
- Routing ID's: "**FDA_AERS**" for XML's and "**FDA_AERS_ATTACHMENTS**" for PDF's

Proposed Future State: For IND reports, new Routing ID's would need to be setup and corresponding configuration changes required (would apply to pre market ICSRs).

- Routing ID's: "**FDA_AERS_PREMKT**" for XML's and "**FDA_AERS_ATTACHMENTS_PREMKT**" for PDF's

Routing ID's for PDF's is applicable only for E2B (R2) submissions

Routing Mechanism



Submission Rules

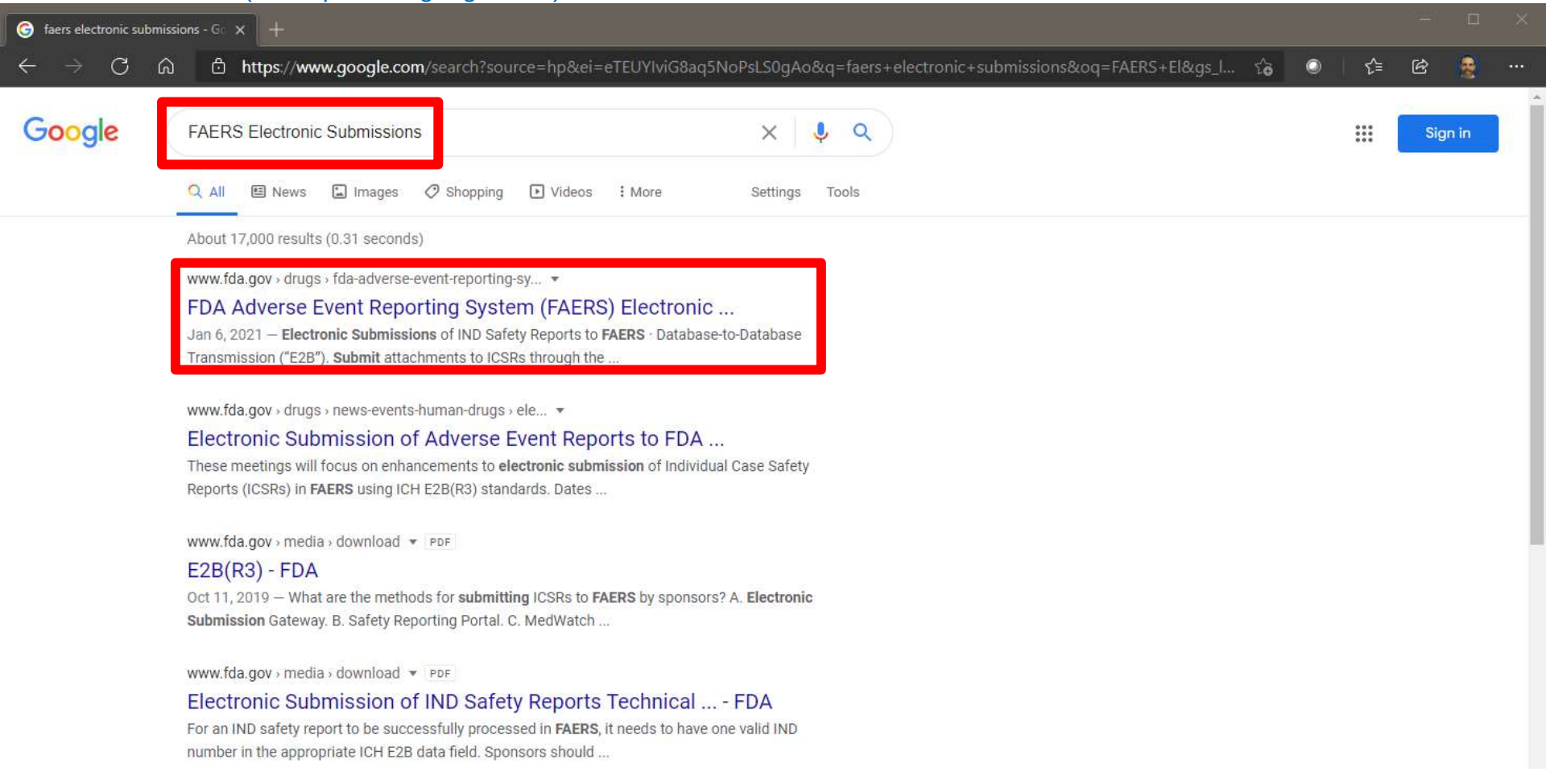
The submission rules define the condition that shall result in a negative acknowledgement and not be accepted by FAERS

Table 11. Submission Rules and Acknowledgement Status

Data Element	DTD Descriptor 2.1/2.2	Rejection Rule Description	Acknowledgement
A.1.FDA.16	<fdasafetyreporttype>	Data value 1 or 2 submitted using AS2 Header where XML file: AERS or Routing ID where XML file: FDA_AERS	reportacknowledgment code (B.1.8) = 02
A.1.FDA.16	<fdasafetyreporttype>	Data value 3 submitted using AS2 Header where XML file: AERS_PREMKT or Routing ID where XML file: FDA_AERS_PREMKT	reportacknowledgment code (B.1.8) = 02

New Technical Specification Document

Navigate to your favorite search engine
(ex. http://www.google.com) & Search for "*FAERS Electronic Submissions*"



FDA Adverse Event Reporting System (FAERS) Electronic Submissions

Updates for Electronic Submission of Individual Case Safety Reports (ICSRs) to FAERS

Premarketing Safety Reporting

Starting **June 28, 2021**, FDA will begin accepting electronic submissions for **IND Safety Reports** to FAERS. In preparation for the upcoming receipt of IND Safety Reports, FDA has posted the following documents regarding the electronic submission of certain investigational new drug applications (INDs) safety reports for drugs and biological products to FAERS. These documents are posted to help prepare systems for electronic submissions of IND safety reports.

1. *Providing Regulatory Submissions in Electronic Format: IND Safety Reports - Draft Guidance for Industry (October 2019)*
2. *Electronic Submission of IND Safety Reports - Technical Conformance Guide (October 2019)*
3. *The revised technical specifications document Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments (December 2020)*. FDA has revised this document to include data elements, descriptors, and descriptor values for reporting certain IND safety reports as individual case safety reports (ICSRs).

For investigational drugs and biological products without an established name (i.e. INN or USAN name), or if the established name exceeds established E2B character lengths, prior to submission of IND safety reports to FAERS, the sponsor should submit to the IND a general correspondence in eCTD format to inform FDA of how the product name will be submitted within the established E2B character lengths. Please refer to the *Electronic Submission of IND Safety Reports - Technical Conformance Guide (October 2019)* for further information.

Postmarketing Safety Reporting

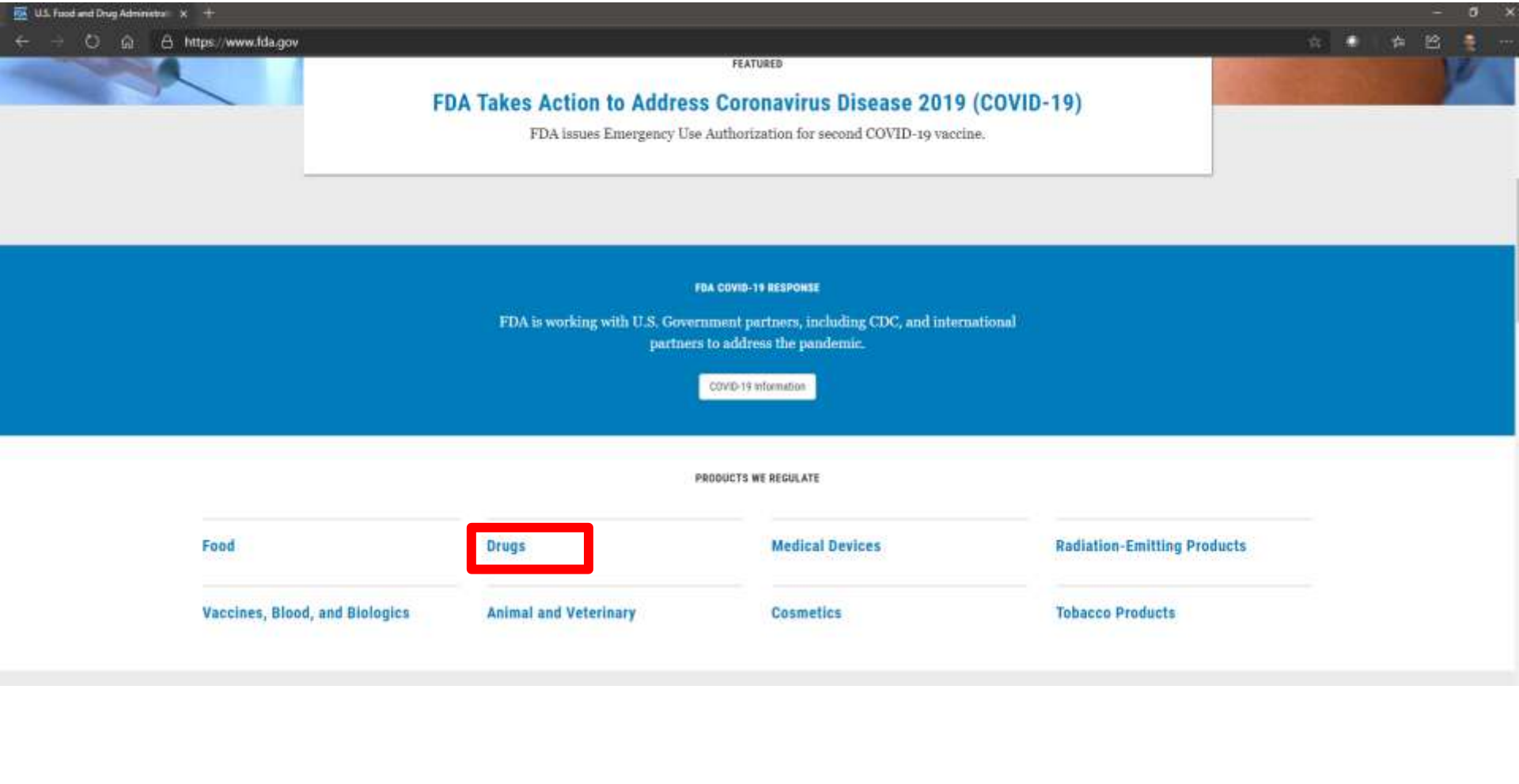
Starting **June 28, 2021**, FDA is implementing a new mandatory regional data element for the electronic submission of ICSRs. The new regional data element, A.1.FDA.16 (FDA Safety Report Type), will distinguish the safety report type as IND Safety Reports, IND Exempt

Content current as of:
02/03/2021

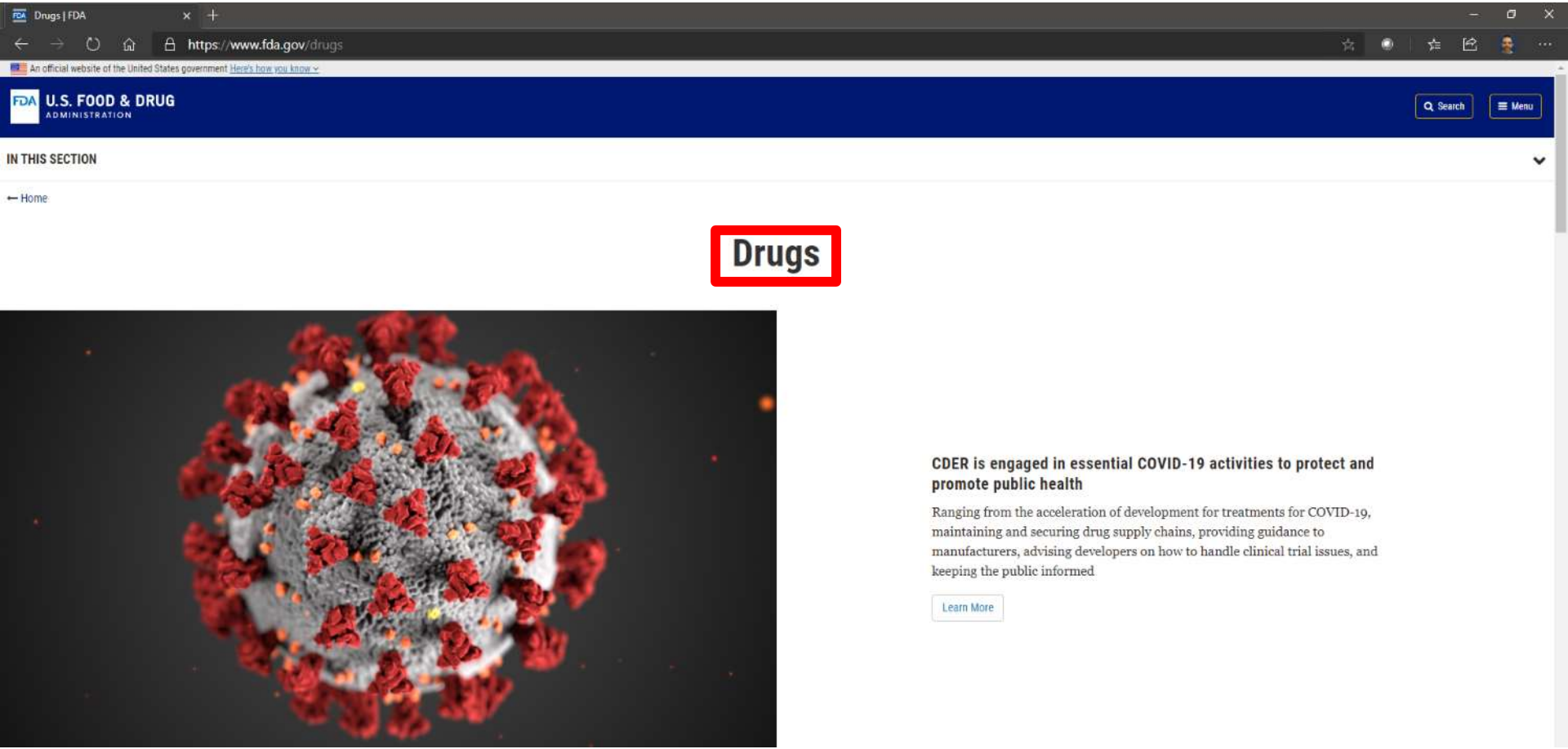
Regulated Product(s)
Drugs

Navigate to https://www.fda.gov

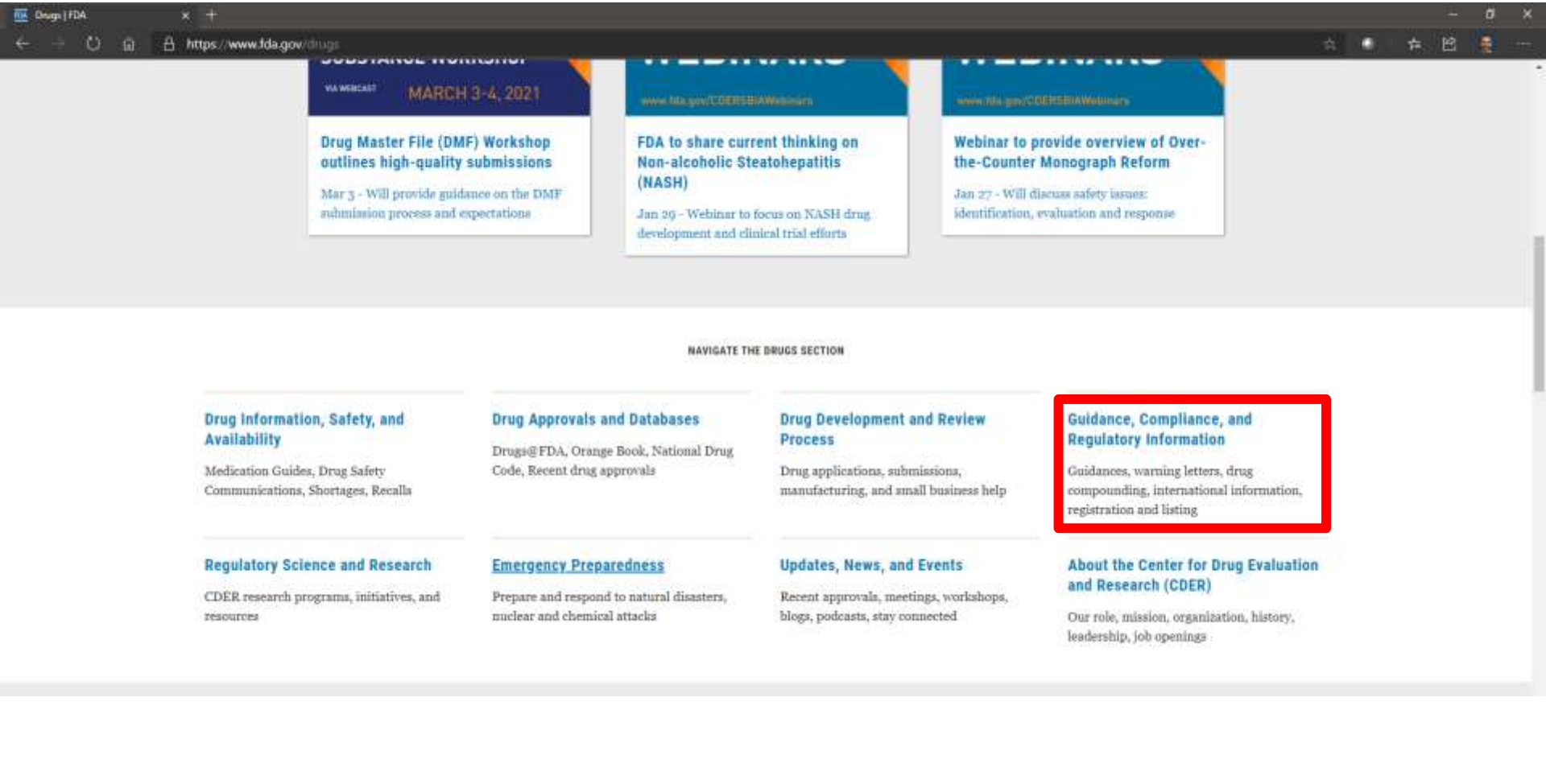
Select “Drugs”



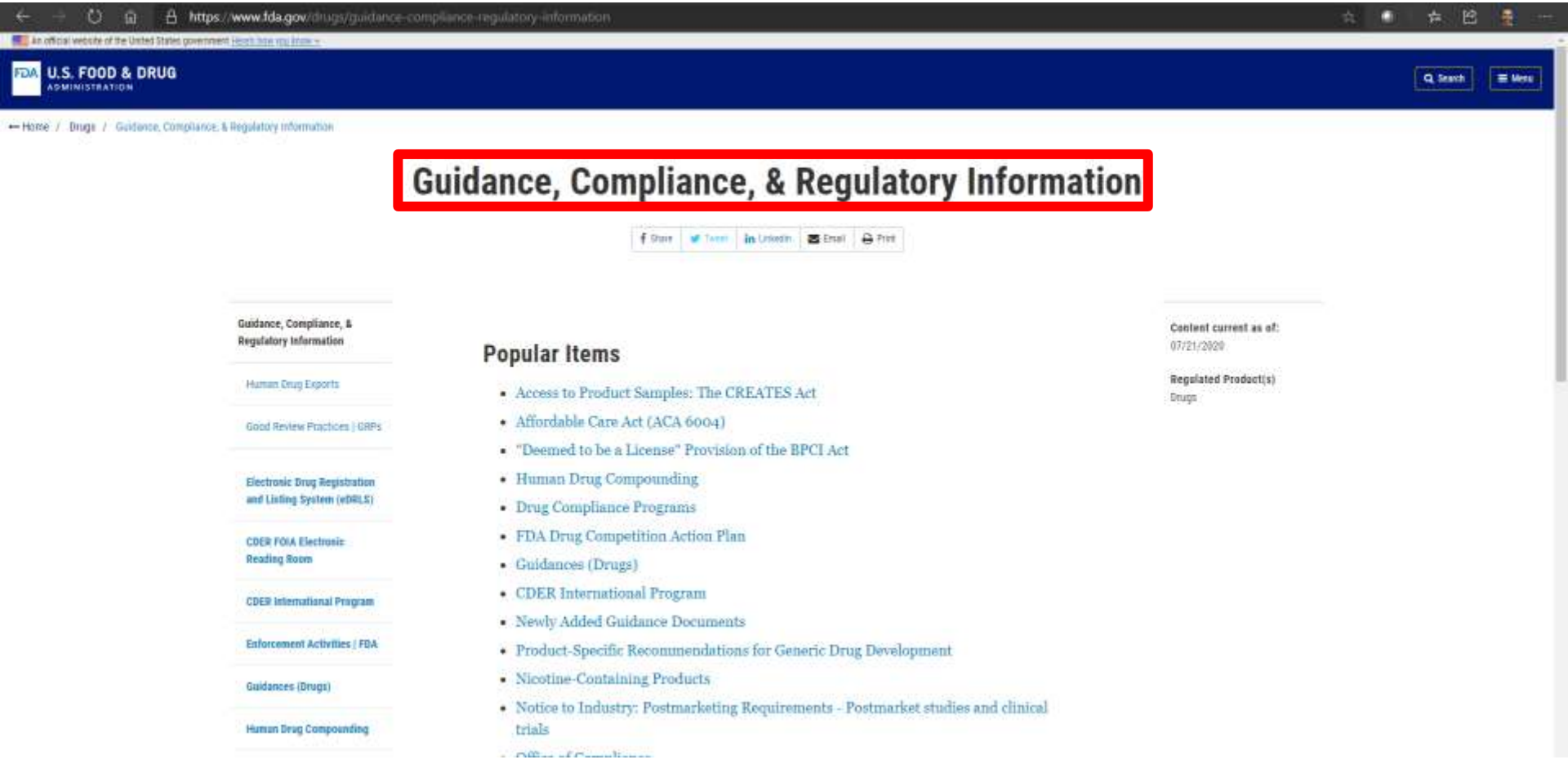
Navigate to https://www.fda.gov/drugs



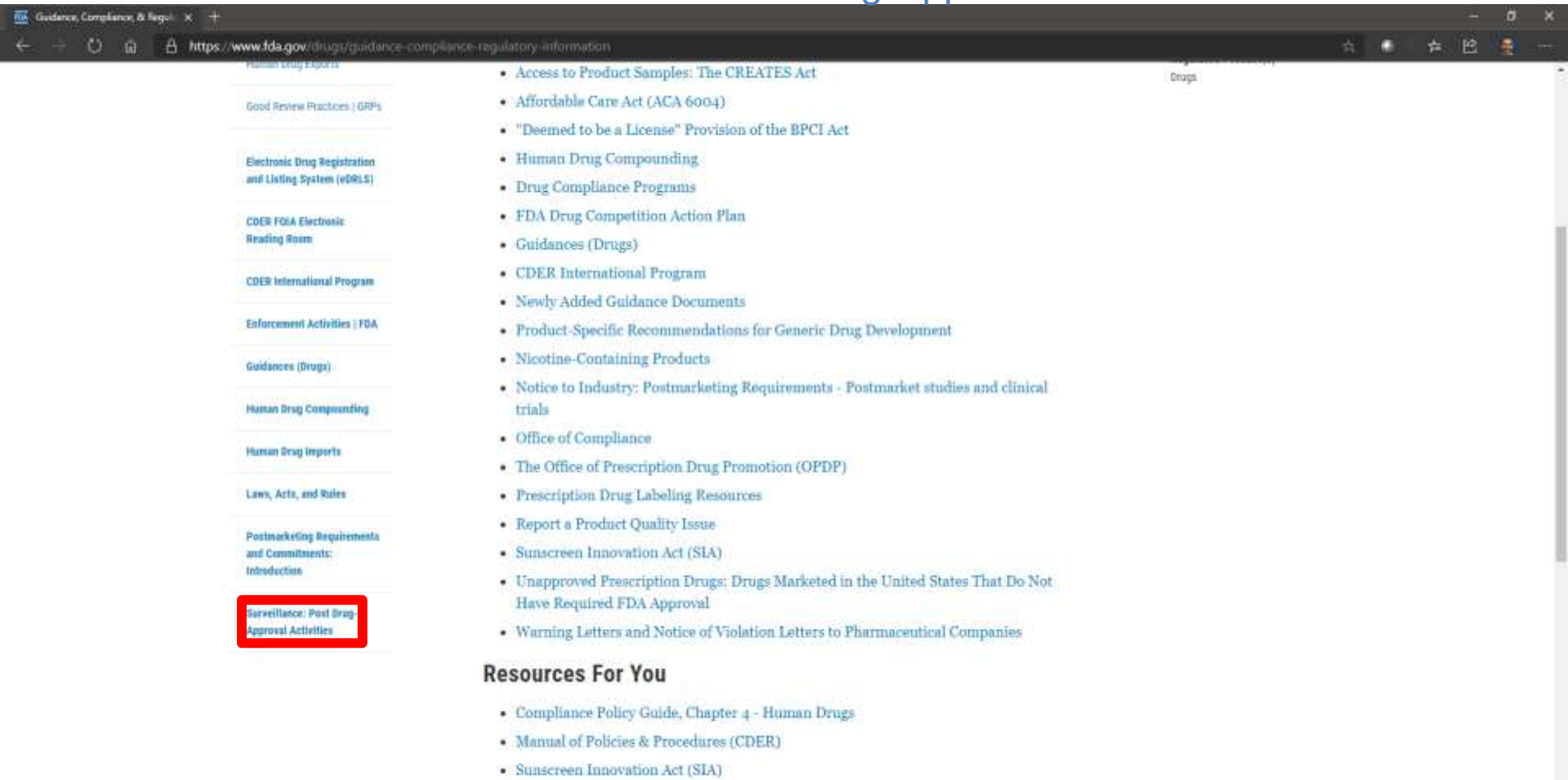
Select “Guidance, Compliance, and Regulatory Information”



Navigate to
https://www.fda.gov/drugs/guidance-compliance-regulatory-information

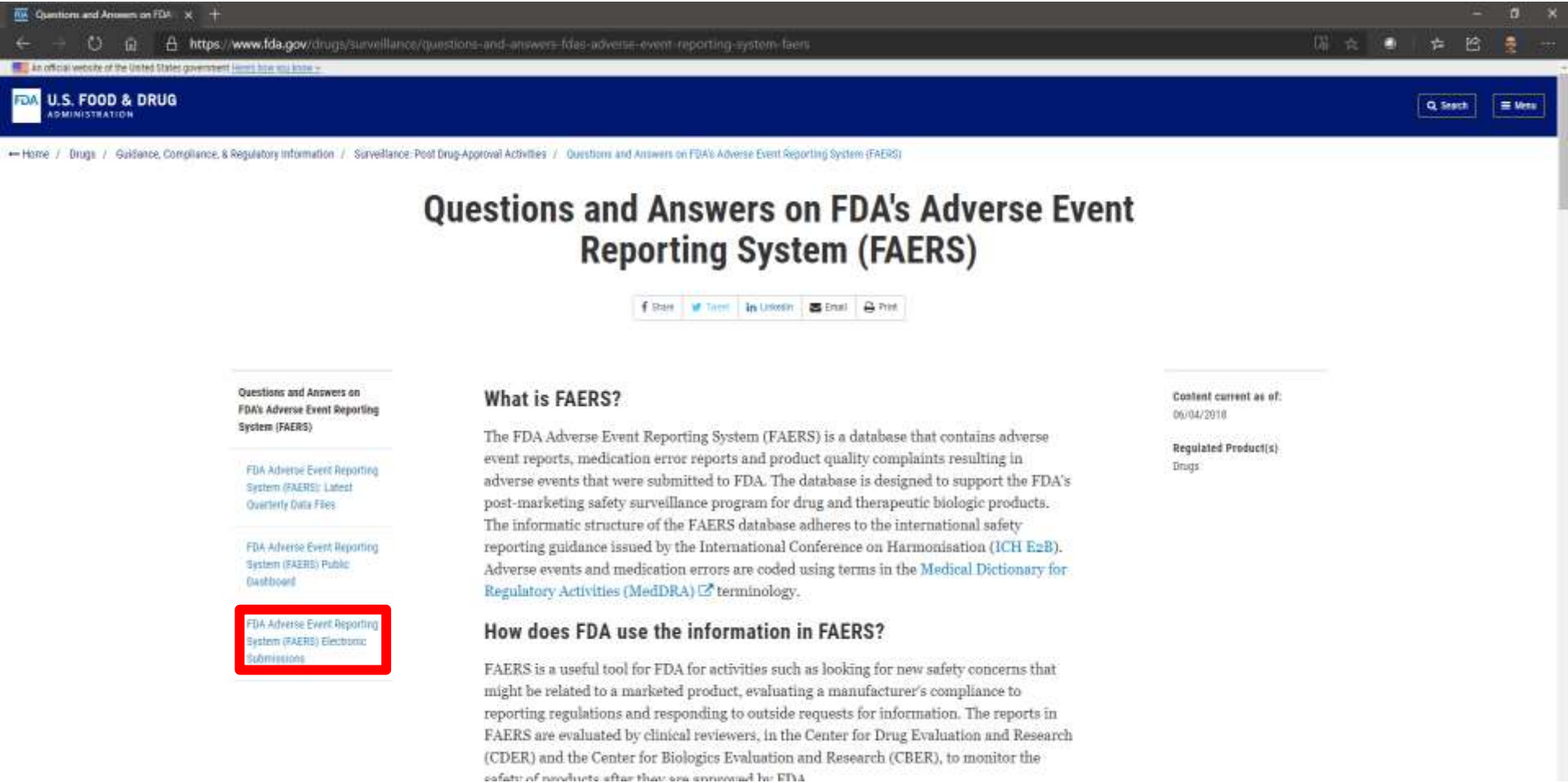


Select “Surveillance: Post Drug-Approval Activities”



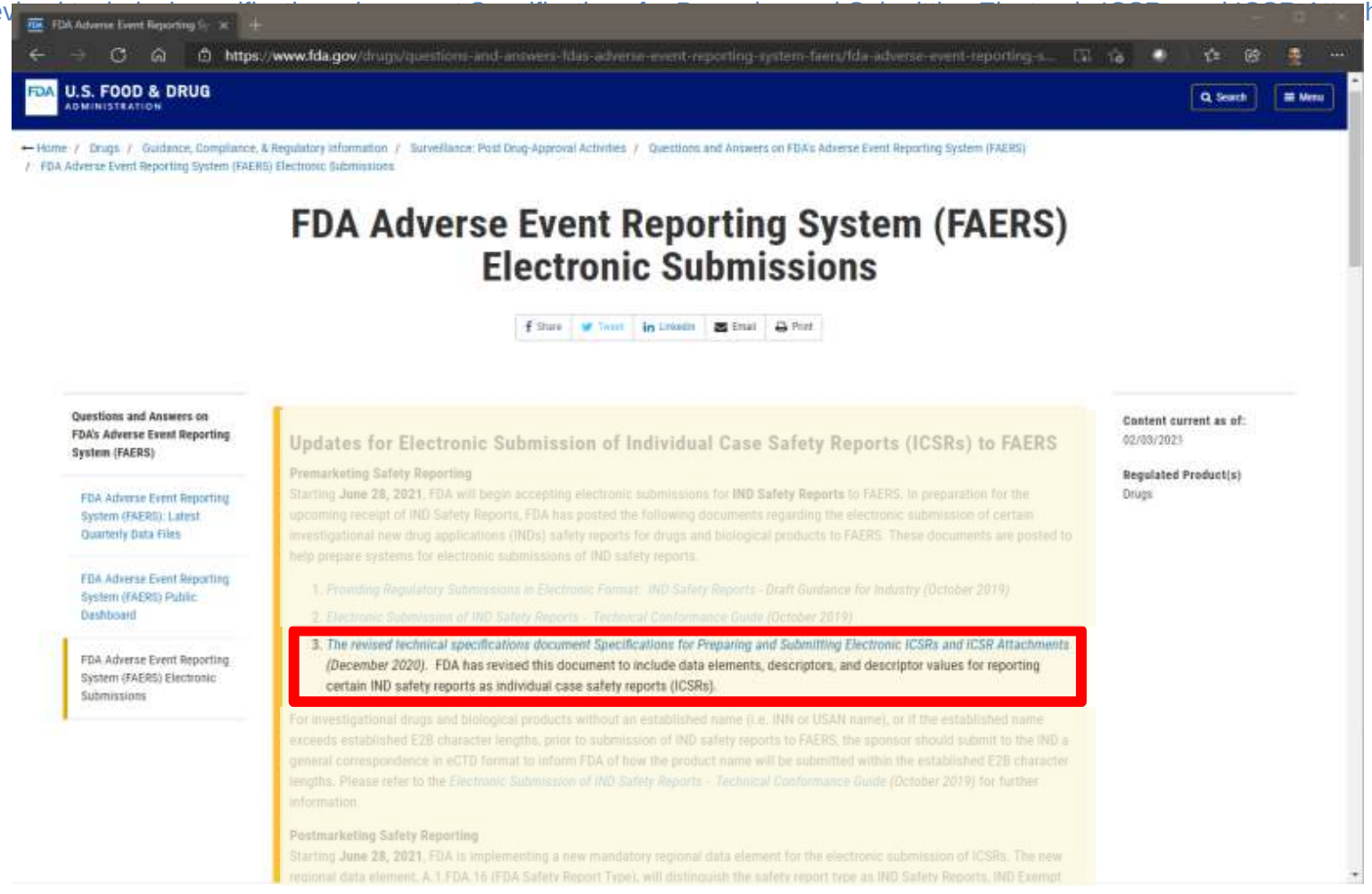
Select “Questions and Answers on FDA's Adverse Event Reporting System (FAERS)”

Select “FDA Adverse Event Reporting System (FAERS) Electronic Submissions”



Select

“3. The rev[illegible]hments”



Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Technical Specifications Document

Associated Guidance Documents and Conformance Guide:

Draft Guidance for Industry: Providing Submissions in Electronic Format – Postmarketing Safety Reports (June 2014)

Guidance for Industry and FDA Staff: Postmarketing Safety Reporting for Combination Products (July 2019)

Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format: IND Safety Reports (September 2019)

Electronic Submissions of IND Safety Reports Technical Conformance Guide (September 2019)

For questions regarding this technical specifications document, contact the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, at FAERSESUB@fda.hhs.gov; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, at CBERICSRSubmissions@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2020

2020-02-11	1.7	Added a new value to the data element B.4.k.1 for drug characterization to accommodate a similar device. Updated the data element B.4.k.18.2 to specify values. Updated the data element B.4.k.18.3 to use default
2020-12-18	1.8	Added a new regional data element A.1.FDA.16 (FDA Safety Report Type) in Table 2 Detailed Description of Administrative Tags Added section Submission Rules Added a new value to the data element B.4.k.1 and B.4.k.19 in section J Bioavailability/ Bioequivalence (BA/BE) Studies Not Conducted Under an IND

Table 2. Detailed Description of Administrative Tags[*]

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
A.1.9	<fulfillexpeditecriteria>	1N	1= Yes (15-Day expedited) 2= No (non-expedited) 4= 5-Day 5= 30-Day 6= 7-Day expedited
A.1.0.1	<safetyreportid>	100AN	Sender's (Case) Safety Report Unique Identifier[†]
A.1.10.1	<authoritynumb>	100AN	Regulatory authority's case report number
A.1.10.2	<companynumb>	100AN	Other sender's case report number
A.3.1.2	<senderorganization>	60AN	Sender identifier
A.2.3.2[‡]	<sponsorstudynumb>	35AN	IND or Pre-ANDA number under which the clinical trial where the event occurred is conducted
A.1.FDA.16[††]	<fdasafetyreporttype>	1N	1=IND Safety Report 2=IND Exempt BA/BE Safety Report 3=Postmarketing Safety Report

Include either <companynumb> or <authoritynumb> values. FDA cannot process the ICSR without one of these element values.

[†] The Sender's Safety Report Unique Identifier is comparable to the Manufacturer Report Number (also referred to as the Manufacturer Control Number (MCN)) provided on paper in FDA Form 3500A. This number is the company's unique case identification number, which is used for the life of the case.

[‡] For IND and IND-exempt BA/BE study safety reports only. An IND-exempt BA/BE study refers to a BA/BE study not conducted under IND.

[††] The FDA Safety Report Type data element distinguishes premarket (IND and IND-Exempt BA/BE) safety reports from postmarketing safety reports and is used to determine which reports are posted publicly.

C. Authorization/ Application Number Format

In the section designated for drug and biological products information, use the following format for the "Authorization/ Application Number" element (B.4.k.4.1) <drugauthorizationnumb> as indicated in Table 3 and described below.

- For approved drug and biological products marketed under an approved application, include the acronym "NDA" or "ANDA," followed by a space and then the number for the application (e.g., NDA 012345, ANDA 012345). For prescription drug products marketed without an approved application (Rx No Application), use "000000." For a nonprescription drug product marketed without an approved application (Non-Rx No

Contact Information

For assistance contact the FAERS electronic submission coordinator at FAERSESUB@FDA.HHS.GOV

FDA Adverse Event Reporting System (FAERS) Electronic Submissions

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For assistance contact the FAERS electronic submission coordinator at faersesub@fda.hhs.gov

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2020

Resources

Technical Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

https://www.fda.gov/media/132096/download

FAERS Electronic Submissions

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

How to Request Safety Reporting Portal Account

1. Navigate to: https://www.safetyreporting.hhs.gov
2. Click “Create Account”
3. Select “A manufacturer, investigator, sponsor or applicant of a drug or biologic product”
4. Select “Human Drug/Therapeutic Biologic (given to a human) https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=9140736b-f914-4d10-8ee3-1ab02671f049

FDA tool to test new requirements – Coming soon!

Resources

Date	Version	Summary of Changes
2020-12-18	1.8	• Added a new regional data element A.1.FDA.16 (FDA Safety Report Type) in Table 2 Detailed Description of Administrative Tags • Added section Submission Rules

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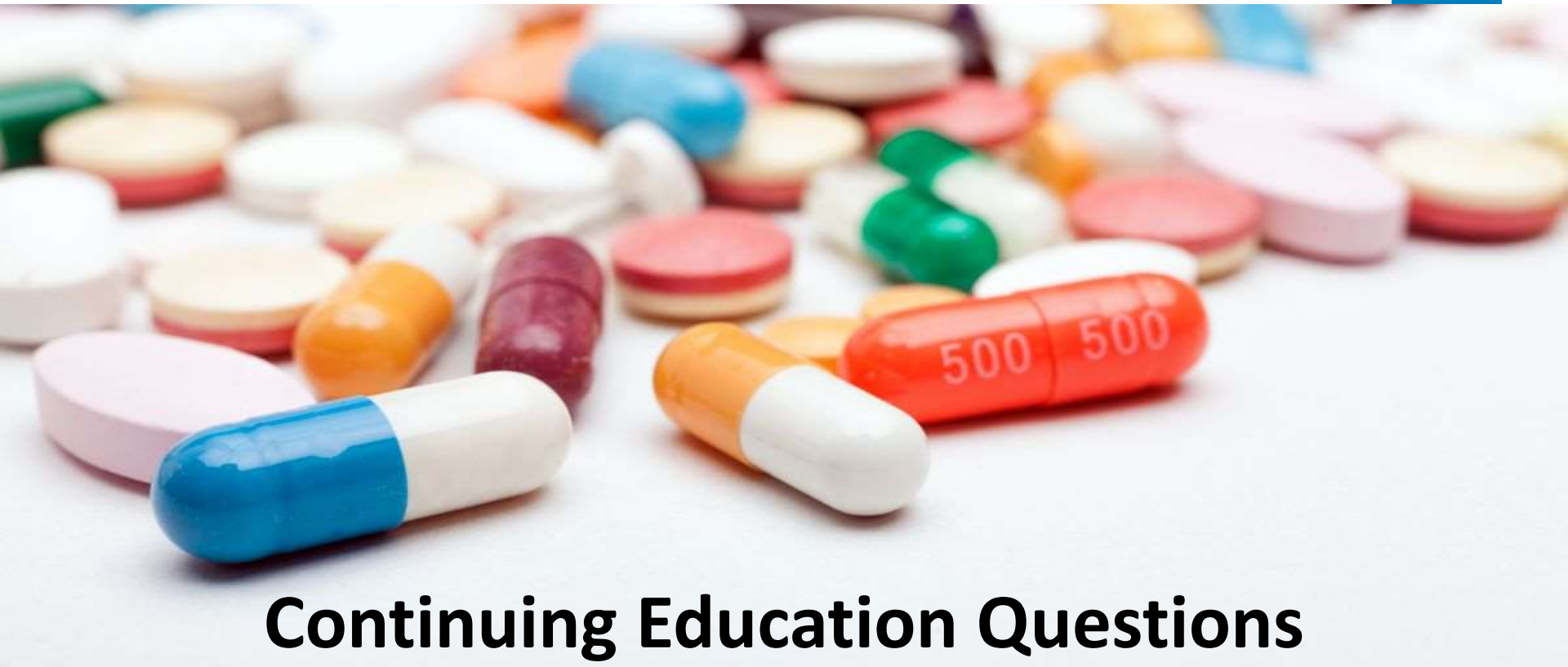

Continuing Education Questions

Challenge Question #1

What is the allowable value for the new data element FDA Safety Report Type for postmarket report?

A. 1: IND Safety Report

B. 2: IND Exempt BA/BE Safety Report

C. 3: Postmarketing Safety Report

D. None of the above

Challenge Question #2

Which condition will result in a negative acknowledgement of a FDA safety report?

A. <fdasafetyreporttype>3</fdasafetyreporttype>

AS2 Header where XML file: AERS or

Routing ID where XML file: FDA_AERS

B. <fdasafetyreporttype>3</fdasafetyreporttype>

AS2 Header where XML file: AERS_PREMKT or

Routing ID where XML file: FDA_AERS_PREMKT

Key Takeaways

Create an account to use the Safety Reporting Portal (if applicable)

Select the most appropriate routing mechanism

Comply with new flag type requirement by June 28, 2021

Questions?

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