Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Technical Specifications Document

Associated Guidance Documents:

Draft Guidance for Industry: ***Providing Submissions in Electronic Format – Postmarketing Safety Reports*** **(June 2014)**

Draft Guidance for Industry: ***Postmarketing Safety Reporting for Combination Products*** **(February 2018)**

For questions regarding this technical specifications document, contact (CDER) Suranjan De at 240-402-0498, or (CBER) Office of Communication, Outreach and Development at 301-827-1800 or 800-835-4709.

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)

February 2018

Specifications for Preparing and Electronically Submitting ICSRs and ICSR Attachments to FAERS

Revision History Table

Date	Version	Summary of Changes
2008-06-11	1.0	Original version.
2008-08-06	1.1	Added Filename format information.
2008-10-10	1.2	Updated UTF-8 to ISO-8859-1 encoding; indicated simultaneous acceptance of ICSR and ICSR attachments; provided another acceptable file extension for SGML files; and clarified use of abbreviations (NDA, ANDA, and STN).
2008-10-22	1.3	Provided clarification in Section II; updated footnote 3; and added new paragraph to Section V.C.
2013-07-05	1.4	Updated AERS to FAERS migration changes, removed references to SGML file formatting, incorporated updates from CBER.
2018-02-06	1.5	Added a new section to highlight data fields for reporting ICSRs on Combination Products.

Specifications for Preparing and Electronically Submitting ICSRs and ICSR Attachments to FAERS

Table of Contents

I. THE ELECTRONIC SUBMISSION 1

II. FILENAME 2

III. ELECTRONIC TRANSPORT FORMAT: XML FILES 2

IV. DATA ELEMENTS FOR ELECTRONIC SUBMISSIONS 3

V. ELECTRONIC FORMAT FOR ICSR ATTACHMENTS 17

APPENDIX I. EXAMPLES OF CORRECT AND INCORRECT APPLICATION NUMBER AND DRUG ELEMENT FORMAT 19

Specifications for Preparing and Electronically Submitting ICSRs and ICSR Attachments to FAERS

This document provides current specifications for submitting individual case safety reports (ICSRs) and ICSR attachments in electronic form for marketed drug and biological products, including therapeutic vaccines to the FDA Adverse Event Reporting System (FAERS). This document does not apply to Investigational New Drug (IND) Safety Reports or the following biological products: prophylactic vaccines, whole blood, components of whole blood, or human cells, tissues, and cellular and tissue-based products (HCT/Ps), which are regulated under section 361 of the Public Health Service Act.

ICSRs and ICSR attachments are to be submitted through the FDA Electronic Submission Gateway (ESG).[1] ICSRs are to be prepared in accordance with the International Council for Harmonisation (ICH) E2B(R2) data elements in XML file format for compatibility with the FAERS database. ICSRs are not be submitted to the electronic Common Technical Document (eCTD) in a portable document file (PDF) format.[2]

If you have not previously submitted an ICSR in electronic format to the FDA, you should notify the FAERS electronic submission coordinator of your intent at faersesub@fda.hhs.gov. The FAERS coordinator will assist you with submission of a test file.

I. THE ELECTRONIC SUBMISSION

Each initial ICSR or follow-up ICSR may consist of several parts, including structured information and nonstructured information, such as ICSR attachments.

In order for FDA to process, review, and archive the ICSRs, prepare your ICSR for electronic submission as follows:

A. Provide a unique filename for the submission; see section II of this document.

B. Add a file header and file extension; see section III of this document.

C. Populate the elements of the ICSR file; see section IV of this document.

D. If applicable, add ICSR attachments to ICSR files; see section V of this document.

[1] For information on providing submissions using the ESG, refer to http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

[2] See FAERS Electronic Submissions at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm

II. FILENAME

A. Each electronic submission of ICSRs or attachments to ICSRs must have a unique filename (e.g., your named file + date time stamp to the second: filenameYYYYMMDDHHMMSS). You may choose your own format to maintain uniqueness.

B. If you do not receive a FAERS acknowledgement within 2 hours of the ESG message delivery notice of acknowledgement, resubmit the original submission without changing the filename.

C. If you receive a FAERS acknowledgement with a response of an unsuccessful (failed) acknowledgment:

1. For a single ICSR submission, resubmit the corrected ICSR with a new unique filename.

2. For a submission consisting of multiple ICSRs, and one or more ICSRs in the submission failed to process, separate the failed ICSRs from the successfully submitted ICSRs, correct the failed ICSRs, and resubmit only the corrected ICSRs as a new submission with a unique filename. For example, if there were 50 ICSRs in an original submission and 15 of them failed to process successfully, then only the failed 15 ICSRs must be separated, corrected appropriately, and resubmitted with a new unique filename. The resubmission must not contain any of the successfully processed ICSRs.

III. ELECTRONIC TRANSPORT FORMAT: XML FILES

FDA accepts the data elements defined in the guidance for industry E2B(M) Data Elements for Transmission of Individual Case Safety Reports (April 2002)[3]. The ICH E2B(R2) guidance provides additional information and clarification of the previously issued guidances.[4]

The electronic transport format also known as the Document Type Definition (DTD) for XML files is described in the associated document "XML Formatted DTD" (DTD Version 2.1 and DTD Version 2.2).

[3] For information on Guidance for Industry on E2BM Data Element for Transmission Of Individual Case Safety Reports https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073092.pdf

[4] See the guidance for industry entitled *E2B Data Elements for Transmission of Individual Case Safety Reports* (January 1998) (E2B). FDA currently supports use of E2B data elements in addition to the E2B(M) data elements. However, it is preferred that ICSRs be submitted with E2B(M) data elements to allow for the most efficient processing of the submissions. For those who wish to use E2B data elements and the corresponding electronic transport format (ICH M2 Electronic Transmission of Individual Case Safety Report Message Specification Final Version 2.3 Document Revision February 1, 2001 (ICH ICSR DTD Version 2.1)), please refer to documentation provided at http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf

A. XML Header

1. The addition of an XML header enables FDA to process ICSRs in an XML format successfully. For this reason, add the following XML header to the ICSR file:

<?xml version="1.0" encoding="ISO-8859-1"?>
<!DOCTYPE ichicsr SYSTEM "https://www.accessdata.fda.gov/xml/icsr-xml-v2.1.dtd">

For submission of combination product reports use the following XML header to the ICSR file:

<?xml version="1.0" encoding="ISO-8859-1"?>
<!DOCTYPE ichicsr SYSTEM "https://www.accessdata.fda.gov/xml/icsr-xml-v2.2.dtd">

2. FDA supports only the ISO-8859-1 character set for encoding the submission.

B. ICSR Message Header Information

For submission of combination product reports use the value “2.2” for the DTD Descriptor <messageformatversion>

<messageformatversion>2.2</messageformatversion>

C. File Extension

Use “xml” as the file extension for submissions in XML format. The name of the file should be 200 characters or less, excluding the three-digit extension. We do not support file names with multiple periods “.” or the use of any special or foreign characters except underscore “_” and dash “-“.

IV. DATA ELEMENTS FOR ELECTRONIC SUBMISSIONS

A. Minimum Data Elements

An electronic ICSR should contain the four minimum data elements listed in Table 1.

Table 1: Minimum Data Elements

Element	Data
B.1	Identifiable patient
A.2	Identifiable reporter
B.2	Reaction or event
B.4	Suspect drug product

B. Administrative and Identification Elements

So that FDA can successfully process your electronic ICSR submission, populate the administrative and identification elements as indicated in Table 2.

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 (expedited); 2=no (non-expedited); 4=5-Day; 5=30-Day
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

*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)). This is the company's unique case report number, which is used for the life of the case.

C. Authorization/Application Number Format (B.4.k.4.1)

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

1. For human drug products, 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 Application), use "999999".

2. For human biological products, include the appropriate acronym "BLA" "STN" or "PLA" followed by a space and the primary six-digit number (e.g., STN 123456).

Table 3: Detailed Description of Application Number Formats

Type of Application	Recommended Format
NDA/ANDA	NDA or ANDA 012345
STN/BLA/PLA	STN or BLA or PLA 123456
Rx No Application	000000
Non-Rx No Application	999999
Compounded products	COMP99

D. Identification Numbers for Initial and Follow-Up ICSRs

1. Use the same <safetyreportid> for the E2B(M) elements in section A.1.0.1 for the initial ICSR and any of its follow-up ICSRs; this allows the follow-up report to be linked to the initial report in the FAERS database.

2. A common data element is essential to provide linkage between two reports. If the initial ICSR was submitted on paper but its follow-up ICSR is to be submitted electronically, include the MCN listed in Box G9 of the FDA Form 3500A from the initial report in both A.1.0.1 <safetyreportid> and in A.1.10.2 <companynumb> field in the follow-up electronic submission.

3. Always use the <safetyreportid> that was assigned to the initial ICSR when submitting follow-up reports. If you need to change the <safetyreportid> internally, note the internally reassigned <safetyreportid> in the narrative section of the follow-up report (i.e., element B.5.1) (e.g., "This ICSR has been reassigned the Company ID number COA12345"). Do not use the internally reassigned <safetyreportid> for any follow-up reports.

4. In the event that an incorrect <safetyreportid> has been used in a follow-up report, contact the FAERS electronic submission coordinator at faeresub@fda.hhs.gov so that the follow-up ICSR can be matched to the initial ICSR.

E. MedDRA Specific Elements

Use the Medical Dictionary for Regulatory Activities (MedDRA) to code medical terminology.[5] When possible, use the Lowest Level Term (LLT), and record the LLT as the MedDRA numeric code rather than the LLT name (e.g., the LLT name is Rash; the MedDRA numeric code for LLT Rash is 10378444).

1. Reaction/Event

a) Reaction/event as reported by the primary source field:
Record the original reporter's words verbatim and/or use short phrases to describe the reaction/event in element (B.2.i.0).

b) Reaction/event MedDRA term LLT numeric code or text field:
Record the MedDRA LLT that most closely corresponds to the term reported by the original reporter in element (B.2.i.1).

c) Reaction/event MedDRA Preferred Term (PT) numeric code or text field:
Record the MedDRA PT that most closely corresponds to the term reported by the original reporter in element (B.2.i.2).

[5] Companies can license MedDRA from an international maintenance and support services organization (MSSO) (toll free number 877-258-8280; Direct 571-313-2574; fax 571-313-2345; e-mail MSSOhelp@mssotools.com).

2. Other E2B Elements

   For the E2B elements listed in Table 4, use either MedDRA text or, preferably, the corresponding numeric code.

Table 4: Additional E2B Elements for Preferred MedDRA Coding

Element	DTD Descriptor 2.1	Length
B.1.7.1a.2	<patientepisodename>	250 AN
B.1.8f.2	<patientdrugindication>	250 AN
B.1.8g.2	<patientdrugreaction>	250 AN
B.1.9.2b	<patientdeathreport>	250 AN
B.1.9.4b	<patientdetermineautopsy>	250 AN
B.1.10.7.1a.2	<parentmedicalepisodename>	250 AN
B.1.10.8f.2	<parentdrugindication>	250 AN
B.1.10.8g.2	<parentdrugreaction>	250 AN
B.3.1c	<testname>	100 AN
B.4.k.11b	<drugindication>	250 AN
B.4.k.17.2b	<drugrecuraction>	250 AN
B.4.k.18.1b	<drugreactionasses>	250 AN
B.5.3b	<senderdiagnosis>	250 AN

F. Drugs(s) Description and Case Narrative Elements

In order for FAERS to successfully process your electronic ICSR submission, applicants are advised to populate the drug description and narrative elements as indicated in Table 5.

Table 5: Detailed Description of Drug(s) and Narrative Elements*†

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
B.4.k.1	<drugcharacterization>	1N	1=Suspect 2=Concomitant 3=Interacting
B.4.k.2.1	<medicinalproduct>	70AN	Proprietary medicinal product name
B.4.k.2.2	<activesubstancename>	100AN	Drug substance name
B.5.1	<narrativeincludeclinical>	20000AN	Case narrative

* Include <medicinalproduct> and/or <activesubstancename>. FDA cannot process the ICSR without at least one of these drug elements.

† APPENDIX I lists specific examples of correct drug element formats.

1. Record Multiple Drugs By:

   a) Listing the proprietary drug product name in element (B.4.k.2.1) and/or as the drug substance name in element (B.4.k.2.2).

b) Listing the characterization of each reported drug's role, such as suspect (primary, secondary), concomitant, or interacting in element (B.4.k.1).

2. Medicinal Product Names (B.4.k.2.1) and Active Substance Name (B.4.k.2.2)

   FDA validates medicinal product names to the available Structured Product Labeling (SPL),[6] the submitted label (as ICSR attachment), and the Substance Registration System (SRS).

   a) When the product has an SPL, use the same naming convention as it appears in the SPL when submitting the ICSR.
   b) When submitting a product label as an attachment to an ICSR, use the name as it appears on the submitted product label.
   c) If no medicinal product is named and only the active substance is named, use the name of the active substance as it appears in the SRS.[7]

3. Case Narrative

   a) Initial ICSR:
   Record all case narrative information including clinical course, therapeutic measures, outcome and all additional relevant information in element (B.5.1). If the information exceeds the field length, consider using abbreviations or describing the information using fewer words.

   b) Follow-up ICSR:
   Record both new information and corrections to previously submitted ICSRs in element (B.5.1).

G. Other Data Elements

1. Dosage information field
   Supplement the dosage information captured in the structured fields in element (B.4.k.6) <drugdosagetext>.

2. Pharmaceutical form field
   Record the pharmaceutical form in element (B.4.k.7) <drugdosageform>. FDA accepts the European Medicines Agency (EMA) dosage codes or text.[8]

3. Route of administration field
   Code the route of administration in element (B.4.k.8) <drugadministrationroute> as described in the ICH E2B(R2) Guidance.

---

[6] The SPL is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.
http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

[7] http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm

[8] For a complete list of dosage form codes and text:
http://eudravigilance.ema.europa.eu/human/PharmaceuticalDoseFormsUpdate.asp

4. Receiver field (A.3.2)
   Designate FDA as the receiver using the code or text listed in Table 6.

Table 6: Receiver Information

Element	DTD Descriptor 2.1	Code or Text
A.3.2.1	<receivertype>	2
A.3.2.2a	<receiverorganization>	FDA
A.3.2.2b	<receiverdepartment>	Office of Surveillance and Epidemiology
A.3.2.2d	<receivergivename>	FAERS
A.3.2.3a	<receiverstreetaddress>	10903 New Hampshire Avenue
A.3.2.3b	<receivercity>	Silver Spring
A.3.2.3c	<receiverstate>	MD
A.3.2.3d	<receiverpostcode>	20993
A.3.2.3e	<receivercountrycode>	US
A.3.2.3l	<receiveremailaddress>	faersesub@fda.hhs.gov

5. Message sender field (M.1.5)

   a) Test ICSRs:
   <messagereceiveridentifier>ZZFDATST</messagereceiveridentifier>

   b) Production ICSRs:
   <messagereceiveridentifier>ZZFDA</messagereceiveridentifier>

H. Combination Product Safety Report

In order for FAERS to successfully process your electronic ICSR submission for a marketed drug- or therapeutic biologic led- combination product, you are advised to populate the following data elements as indicated in Table 7.

Note: Some of the DTD descriptors listed in Table 7 are under existing E2B(R2) header elements, and some DTD descriptors are under new data elements. Those data element numbers that are new have the word "FDA" incorporated into the number and are U.S.-specific regional elements related to combination products.

Table 7: Combination Product Elements

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
M.1.2	<messageformatversion>	Message Format Version	Version number of Message Format	3AN	2.2	Use value 2.2 if using icsr-xml-v2.2.dtd Use value 2.1 if using icsr-xml-v2.1.dtd
A.1	<safetyreport>	Header/entity	Identification of the case safety report			
A.1.9	<fulfillexpeditecriteria>	Does this case fulfill the local criteria for an expedited report		1N	1=Yes 2=No 4=5-Day 5=30-Day	Use element values 1 for 15-Day Expedited[9] and 2 for Periodic Non-expedited[10]. Use element values 4 for remedial action to prevent an unreasonable risk of substantial harm to the public health. Use element values 5 for malfunction with no associated adverse event.

[9] 21 CFR 314.80(c) and 600.80(c) use the term "15-day Alert reports." In the combination product PMSR final rule (21 CFR 4.101), these reports are defined as "Fifteen-day reports".

[10] 21 CFR 314.80(c) and 600.80(c) use the term "Periodic adverse drug experience reports."

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
						Do not use element value of 3.
A.1.FDA.15	<combinationproductreport>	Combination Product Report Flag	Combination Product Report Flag	1N	1=Yes 2=No	
A.2	<primarysource>	Primary source(s) of information	Header/entity		Area below should be a repeatable block	
A.2.1		Primary source(s)	Header			
A.2.1.3.FDA.4	<reporteremailaddress>	Reporter's Email Address		100AN		
B.1.1	<patientinitial>	Patient	Patient Identifier	10AN		If a single report is reported for a malfunction without an adverse event, the element value should be “NONE”. If there are multiple malfunction reports with no adverse event, then the element value should be “SUMMARY”.
B.4	<drug>	Drug(s) Information	Header/entity			
B.4.k.2		Drug identification	Header			
B.4.k.2.4.FDA.1a	<expirationdateformat>	Expiration date format	Product Expiration Date	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	
B.4.k.2.4.FDA.1b	<expirationdate>	Expiration date	Product Expiration Date	8N		
B.4.k.2.FDA.5	<productavailableforevaluation>	Product available for evaluation	Indicate whether product is available for evaluation	1N	1=Yes 2=No 3=Return	
B.4.k.2.6.FDA.1a	<productreturndateformat>	Product return date format	Date Format	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	
B.4.k.2.6.FDA.1b	<productreturndate>	Product return date	Date when Product was returned	8N		

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.1	<brandname>	Brand Name	The trade or proprietary name of the device constituent part of the suspect combination product as used in product labeling or in the catalog	80AN		At least one of the 3 must be reported <brandname> or <commondevicename> or <productcode> for the device constituent part
B.4.k.20.FDA.2	<commondevicename>	Common Device Name	Generic or common name of the device constituent part of the suspect combination product or a generally descriptive name	80AN		At least one of the 3 must be reported <brandname> or <commondevicename> or <productcode> for device constituent part
B.4.k.20.FDA.3	<productcode>	Product Code	Product Code assigned to the device constituent part based upon the medical device product classification	3AN	http://www.accessdata.fda.gov/premarket/ftparea/foiclass.zip	At least one of the 3 must be reported <brandname> or <commondevicename> or <productcode> for device constituent part
B.4.k.20.FDA.4	<manufacturer>	Manufacturer	Header/entity			
B.4.k.20.FDA.4a	<manufacturername>	Device Manufacturer Name	Manufacturer name of the device constituent part of the suspect combination product	100AN		
B.4.k.20.FDA.4b	<manufactureraddress>	Manufacturer Address	Manufacturer address of the device constituent part of the suspect combination product	100AN		
B.4.k.20.FDA.4c	<manufacturercity>	Manufacturer City	Manufacturer city of the device constituent part of the suspect combination product	35AN		

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.4d	<manufacturerstate>	Manufacturer State	Manufacturer state of the device constituent part of the suspect combination product	40AN		
B.4.k.20.FDA.4e	<manufacturercountry>	Manufacturer Country	Manufacturer country of the device constituent part of the suspect combination product	2AN	ISO3166	
B.4.k.20.FDA.5	<modelnumber>	Model Number	Model number of the device constituent part	30AN		
B.4.k.20.FDA.6	<catalognumber>	Catalog Number	Catalog number of the device constituent part	30AN		
B.4.k.20.FDA.7	<serialnumber>	Serial Number	Serial number of the device constituent part	30AN		
B.4.k.20.FDA.8	<udinumber>	Unique Identifier UDI#	Unique identifier of the device constituent part	50AN		
B.4.k.20.FDA.9a	<dateimplantedformat>	Implanted Date Format	Date format of implanted in the patient	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.
B.4.k.20.FDA.9b	<dateimplanted>	Implanted Date	Date implanted in the patient	8N		For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.10a	<dateexplantedformat>	Explanted Date Format	Date format of explanted from the patient	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.
B.4.k.20.FDA.10b	<dateexplanted>	Explanted Date	Date explanted from the patient	8N		If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.
B.4.k.20.FDA.11a	<deviceage>	Approximate age of device/product)	Age of device constituent part	5N		
B.4.k.20.FDA.11b	<deviceageunit>	Approximate age unit of device/product)	Age unit of device constituent part	3N	800=Decade 801=Year 802=Month 803=Week 804=Day 805=Hour	
B.4.k.20.FDA.12	<labeledsingleusedevice>	Single Use Device	Indicate whether the device constituent part was labeled for single use or not.	1N	1=Yes 2=No	
B.4.k.20.FDA.13a	<devicemanufacturedateformat>	Device Manufacture Date Format	Device Manufacture Date format	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	
B.4.k.20.FDA.13b	<devicemanufacturedate>	Device Manufacture Date	Device Manufacture Date	8N		
B.4.k.20.FDA.14		Remedial Action Initiated Remedial action taken for the product	Header			
B.4.k.20.FDA.14.1a	<remedialactionrecall>	Recall	Recall initiated	1N	1=Yes 2=No	

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.14.1b	<remedialactionrepair>	Repair	Repair initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1c	<remedialactionreplace>	Replace	Replace initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1d	<remedialactionrelabel>	Relabeling	Relabeling initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1e	<remedialactionnotify>	Notification	Notification initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1f	<remedialactioninspection>	Inspection	Inspection initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1g	<remedialactionpatientmonitor>	Patient monitoring	Patient monitoring	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1h	<remedialactionmodifyadjust>	Modification/ Adjustment	Modification/ Adjustment initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1i	<remedialactionother>	Other	Other Remedial Action initiated	75AN		
B.4.k.20.FDA.15	<deviceusage>	Device Usage	Indicate the use of the device constituent part of the suspect combination product	1N	1=Initial Use of Device 2=Reuse 3=Unknown	
B.4.k.20.FDA.16	<devicelotnumber>	Device Lot Number	Lot number of the device constituent part of the suspect combination product	35AN		
B.4.k.20.FDA.17	<malfunction>	Malfunction	Malfunction of product	1N	1=Yes 2=No	
B.4.k.20.FDA.18		Follow-up type	Header			
B.4.k.20.FDA.18.1a	<followupcorrection>	Correction	Correction	1N	1=Yes 2=No	
B.4.k.20.FDA.18.1b	<followupadditionalinfo>	Additional Information	Additional Information	1N	1=Yes 2=No	
B.4.k.20.FDA.18.1c	<followupresponsetoFDA>	Response to FDA request	Response to FDA request	1N	1=Yes 2=No	
B.4.k.20.FDA.18.1d	<followupdeviceevaluation>	Device Evaluation	Device Evaluation	1N	1=Yes 2=No	
B.4.k.20.FDA.19	<deviceproblemandevaluation>	Device Problem and evaluation codes	Header/entity		Area below should be a repeatable block	

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.19.1a	<evaluationtype>	Evaluation Type	Type of problem and/or the evaluation	2N	01=Device Problem 02=Method 03=Result 04=Conclusion	
B.4.k.20.FDA.19.1b	<evaluationvalue>	Evaluation Value	The FDA code value based on the respective evaluation type	6N		The value depends on the respective <evaluationtype> If <evaluationtype> = 01 --> https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/MDRAdverseEventCodes/UCM584240.xlsx If <evaluationtype> = 02 --> https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/MDRAdverseEventCodes/UCM584242.xlsx If <evaluationtype> = 03 --> https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/MDRAdverseEventCodes/UCM584243.xlsx If <evaluationtype> = 04 --> https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/MDRAdverseEventCodes/UCM584245.xlsx

Data Element	DTD Descriptor	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.20	<operatorofdevice>	Operator of the Device	Operator of the Device	100AN		Use the value “Health Professional” or “Lay User/Patient”. If none applicable, then specify the other value.

V. ELECTRONIC FORMAT FOR ICSR ATTACHMENTS

FDA is able to accept and archive ICSR attachments in PDF format. Currently approved formats for the nonstructured component (attachments) of an ICSR are PDF version 1.4 (current ICH standard) or 1.6 (current version in use at FDA). An ICSR attachment may be electronically submitted to FAERS either at the same time or after its ICSR is submitted to FAERS. An ICSR must be successfully received in order to link the ICSR to its attachment(s).

A. Converting the ICSR Attachment to PDF

Applicants are to provide an individual PDF file for each attachment to an ICSR. If there is more than one piece of information in an ICSR attachment, include each piece of information in the same PDF file and provide a PDF bookmark to each piece of information. For example, if there is a hospital discharge summary and an autopsy report for a single ICSR, include both in a single PDF file with a bookmark to the hospital discharge summary and a bookmark to the autopsy report.

B. Identification Information in the PDF Document Information Fields

Each PDF file contains fields to be filled in by the author of the document. FAERS uses these fields in its system to locate and retrieve the attachments to specific ICSRs. To help match the attachment(s) to the ICSR, applicants should fill in the PDF document information fields with the appropriate E2B(R2) data elements for the ICSR as indicated in Table 8.

Table 8: Document Information Fields in ICSR Attachments

PDF Document Information Field	Include/ Optiona	Use the Following Information* To Fill In the PDF Document	Length
Title	Include	A.1.0.1 <safetyreportid> Sender's (Case) Safety Report Unique Identifier	100AN
Subject	Include	A.1.10.1 <authoritynumb> Regulatory Authority's Case Report Number OR A.1.10.2 <companynumb> Other Sender's Case Report Number	100AN
Author	Optional	A.1.11.2 <duplicatenumb> Other identification number	100AN
Keywords	Optional	A.1.7b <receiptdate> Date of receipt of the most recent information for this ICSR	8N

* The information refers to the data elements in E2B(R2).

In addition:

- Use the ISO-8859-1 character set for the information fields.
- Do not exceed the character length indicated above for each information field.
- Avoid creating any custom fields with names identical to the information fields listed in Table 8.

If you need assistance, you can contact the FAERS electronic submission coordinator at faersesub@fda.hhs.gov.

APPENDIX I. EXAMPLES OF CORRECT AND INCORRECT APPLICATION NUMBER AND DRUG ELEMENT FORMAT

Examples of Application Number Format		Comment
Correct	<drugauthorizationnumb>NDA 012345</drugauthorizationnumb>	
Correct	<drugauthorizationnumb>BLA 123456</drugauthorizationnumb>	
Correct	<drugauthorizationnumb>NDA 012345</drugauthorizationnumb> <drugauthorizationholder>COMPANYX</drugauthorizationholder>	
Incorrect	<drugauthorizationnumb>123456**/10300**</drugauthorizationnumb>	Use the appropriate prefix for the NDA/ANDA/STN/BLA/PLA; do not include additional data after the application number
Incorrect	<drugauthorizationnumb>NDA **12-345;IND12,345** </drugauthorizationnumb>	Omit hyphens and commas in the application number. Do not populate the tag with two application numbers; the IND report needs to be submitted separately to the Office of New Drugs
Incorrect	<drugauthorizationnumb>**OTC Product**</drugauthorizationnumb>	For a non-prescription drug product marketed without an approved application (Non-Rx No Application), use “999999"
Incorrect	<drugauthorizationnumb>NDA 012345**(COMPANYX)**</drugauthorizationnumb> <drugauthorizationholder></drugauthorizationholder>	Do not populate the company name in the <drugauthorizationnumb> tag

Examples of Drug Element Format		**Comment**
Correct	<medicinalproduct>TYLENOL</medicinalproduct> <activesubstancename>ACETAMINOPHEN</activesubstancename>	The stated proprietary name in the <medicinalproduct> tag is the same as provided for structured product labeling (SPL) listing
Correct	<medicinalproduct>MIRACLE WONDER DRUG</medicinalproduct> <activesubstancename>ACETAMINOPHEN</activesubstancename>	The stated proprietary name is the same as provided in the product label
Incorrect	<medicinalproduct>AMAZING DRUG **OTC®**</medicinalproduct> <activesubstancename>ACETAMINOPHEN **500 mg**</activesubstancename>	Only the brand name and active substance should be listed in the <medicinalproduct> and <activesubstance> tags Any additional information should be captured in the relevant structured fields and not included as prefixes and suffixes in the drug name tags.
Incorrect	<medicinalproduct>NEW DRUG **40 mcg/mL**</medicinalproduct> <activesubstancename>NEWSUBSTANCE **Inj** </activesubstancename>	Only the brand name and active substance should be listed in the <medicinalproduct> and <activesubstance> tags Any additional information should be captured in the relevant structured fields and not included as prefixes and suffixes in the drug name tags.
Incorrect	<medicinalproduct>**MWD**</medicinalproduct> <activesubstancename>**APAP**</activesubstancename>	Do not use abbreviations for the brand name or active ingredients in the <medicinalproduct> and <activesubstance> tags