U.S. Food Drug Administration - Electronic Submission Gateway - Center Submission Types

Legend:

(A) denotes AS2 only.

(W) denotes WebTrader only.

(P) denotes Production environment only.

(T) denotes Test environment only.

(NGP) denotes Not for General Public NGP.

(*) CDRH's only eligible submission categories via the FDA ESG CDRH "Electronic_Submissions" submission type are "Recall Reports of Corrections and Removals" and "Radiological Health Reports and Correspondence". Further, CDRH Premarket submissions should be sent via the CDRH Customer Collaboration Portal.

Note: If a WebTrader Display Name or an AS2 Submission Type does not have either the (P) or (T) annotation, then it is allowed in both Production and Test.

Note: If an item does not have the (W) or (A) annotation, then it is allowed in both WebTrader and AS2.

Center	WebTrader Display Name	AS2 Submission Type	AS2 Routing ID	Notes
CBER	510K	510K	CBER_510K	Medical Device Premarket Notification
	AERS	AERS	FDA_AERS	Adverse Event Reports (AERS)
	AERS Attachments	AERS_ATTACHMENTS	FDA_AERS_ATTACHMENTS	AERS Attachments
	AERS_PREMKT_CBER	AERS_PREMKT_CBER	FDA_AERS_PREMKT_CBER	AERS Pre-Market CBER
	AERS_ATTACHMENTS_PREMKT_CBER	AERS_ATTACHMENTS_PREMKT_CBER	FDA_AERS_ATTACHMENTS_PREMKT_CBER	AERS Attachments for Pre-Market CBER
	BEST	BEST	CBER_BEST	Medical Device Premarket Notification
	CDISC	CDISC	CBER_CDISC	Clinical Data Interchange Standards Consortium (CDISC)
	EBLA	EBLA	CBER_EBLA	BLA – Biologics License Application (eBLA format)
	eDMF	eDMF	CBER_EDMF	DMF – Drug Master File (eDMF format)
	EIDE	EIDE	CBER_EIDE	IDE – Investigational Device Exemption (eIDE format)
	EIND	EIND	CBER_EIND	IND – Investigational New Drug Application (eIND format)
	EUA	EUA	CBER_EUA	Emergency Use Authorization (EUA)
		H1N1_Lot_Release **(A)**	CBER_H1N1_LOT_RELEASE	Influenza A (H1N1) 2009 Monovalent Vaccines Lot Release
	Lot_Release_Protocol	Lot_Release_Protocol	CBER_LOT_RELEASE_PROTOCOL	CBER Lot Release Protocol for Biological Products
	NDA	NDA	CBER_NDA	New Drug Application
	PMA	PMA	CBER_PMA	Premarket Approval Application (PMA)
	Pre_IND	PRE_IND	CBER_PRE_IND	Pre Investigational New Drug Application
	Promotional_Materials	Promotional_Materials	CBER_PROMOTIONAL_MATERIAL	Promotional Materials
	QSUBS	QSUBS	CBER_QSUBS	Q-Submissions
	SEND_PILOT **(T)**	SEND_PILOT **(T)**	CBER_SEND_PILOT	
	SPL_LDD	SPL_LDD	CBER_SPLLD	Structured Product Labeling (SPL) Lot Distribution Database (LDD)
	VAERS	VAERS	CBER_VAERS	Vaccine Adverse Event Reporting System (VAERS)

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Center	WebTrader Display Name	AS2 Submission Type	AS2 Routing ID	Notes
CDER	ACA6004_Drug_Samples	ACA6004_Drug_Samples	CDER_ACA6004	Affordable Care Act (ACA) Section 6004 Certain Drug Sample Information
	AERS	AERS	FDA_AERS	Adverse Event Reports (AERS)
	AERS Attachments	AERS_ATTACHMENTS	FDA_AERS_ATTACHMENTS	AERS Attachments
	AERS IND **(T)**	AERS_IND **(T)**	AERS_IND	AERS for Investigational New Drug Application
	AERS Attachment IND **(T)**	AERS_ATTACHMENTS_IND **(T)**	AERS_ATTACHMENTS_IND	AERS Attachments for Investigational New Drug Application
	AERS_PREMKT **(T)**	AERS_PREMKT **(T)**	FDA_AERS_PREMKT	AERS Pre-Market
	AERS_Attachments_PREMKT **(T)**	AERS_Attachments_PREMKT **(T)**	FDA_AERS_ATTACHMENTS_PREMKT	AERS Pre-Market Attachment
	AERS_PREMKT_CDER	AERS_PREMKT_CDER	FDA_AERS_PREMKT_CDER	AERS Pre-Market for CDER
	AERS_ATTACHMENTS_PREMKT_CDER	AERS_ATTACHMENTS_PREMKT_CDER	FDA_AERS_ATTACHMENTS_PREMKT_CDER	AERS Pre-Market Attachment for CDER
	ECTD	ECTD	CDER_ECTD	Filing Options: ▪ eCTD – Electronic Common Technical Document (includes DMF - Drug Master File and EUA – Emergency Use Authorization) ▪ BLA – Biologics License Application (eCTD and eBLA format) ▪ ANDA – Abbreviated New Drug Application (eANDA format) ▪ NDA – New Drug Application (eCTD and eNDA format)
	ECTD WAIVED	ECTD_WAIVED	CDER_ECTD_WAIVED	Electronic Common Technical Document (eCTD) Waived
	EDMF TYPEIII	EDMF_TYPEIII	CDER_EDMF_TYPEIII	Electronic Drug Master Files (eDMF) Type III Packaging Material
	EIND	EIND	CDER_EIND	Electronic Investigational New Drug Application (eIND format)
	FFU-PILOT **(T)**	FFU-PILOT **(T)**	CDER_FFU-PILOT	Focus-Forming Units (FFU) pilot submissions
	GDUFA_Facility_Registration	GDUFA_Facility_Registration	CDER_GDUFA_FACILITY_REGISTRATION	Generic Drug User Fee Amendments (GDUFA) Facility Registration
	PFC	PFC	CDER_PFC	Pre-Submission Facility Correspondence (PFC)
	Voluntary_Direct_AEs **(W)**			Voluntary Direct Adverse Events
CDRH	Adverse Events	Adverse_Events	CDRH_AERS	CDRH Adverse Events
	Electronic_Submissions **(*)**	Electronic_Submissions **(*)**	CDRH_ESUBS	Electronic Submissions
	GUDID	GUDID	CDRH_GUDID	Global Unique Device Identification Database (GUDID)

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Center	WebTrader Display Name	AS2 Submission Type	AS2 Routing ID	Notes
CFSAN		DSR_Adverse_Events **(A)**	CFSAN_DSR_ADVERSE_EVENTS	CFSAN DSR Adverse Events
	EON-Payload-Files **(P)**	EON-Payload-Files **(P)**	CFSAN_EON_PAYLOAD_FILES	CFSAN Emergency Operations Network (EON) Payload Files
	Food_Pilot_Listing **(P)**	Food_Pilot_Listing **(P)**	CFSAN_FOOD_PILOT_LISTING	CFSAN Voluntary Food Pilot Program
	Form3479	Form3479	CFSAN_Form3479	Food Contact Substance Formulation Notification (Form 3479)
	Form3480	Form3480	CFSAN_FORM3480	Filing Options: ▪ Food Contact Notification (Form 3480) ▪ Food Master File for FCS (Form 3480) ▪ Pre-notification Consultation (Form 3480)
	Form3480A	Form3480A	CFSAN_FORM3480A	Food Contact Notification Amendment (Form 3480A)
	Form3503	Form3503	CFSAN_FORM3503	Filing Options: ▪ Color Additive Petition (Form 3503) ▪ Color Master File (Form 3503) ▪ Food Master File (Form 3503) ▪ Food Additive Petition (Form 3503)
	Form3665	Form3665	CFSAN_FORM3665	Biotechnology Final Consultation (Form 3665)
	Form3666	Form3666	CFSAN_FORM3666	New Protein Consultation (Form 3666)
	Form3667	Form3667	CFSAN_FORM3667	Generally Recognized As Safe Notice (Form 3667)
	NDI **(P)**	NDI **(P)**	CFSAN_NDI	New Dietary Ingredients (NDI)
	Threshold_of_Regulation	Threshold_of_Regulation	CFSAN_TRESHOLD_OF_REGULATION	
CTP		Adverse_Events **(A)**	CTP_AE	CTP's Adverse Events
	Electronic_Submission	Electronic_Submission	CTP_ESUB	Electronic Submission
CVM	Adverse_Events_Reports	Adverse_Events_Reports	CVM_AERS	CVM's Adverse Events
	eSubmitter	eSubmitter	CVM_ESUBMITTER	
	Manage Form	Electronic_Submissions	CVM_ESUBS	Electronic Submissions
CVM-VDD	eSubmitter **(T)**	eSubmitter **(T)**	CVMVDD_eSubmitter	CVM VDD's Electronic Submissions
GWTEST	ConnectTest **(T)**	ConnectTest **(T)**	GWTEST_CONNECTION	To test the connectivity for submissions and receipts / notifications. Not more than 1GB to 50GB submissions.
	SizeTest **(T)**	SizeTest **(T)**	GWTEST_7GB	To test the size of submissions.
HC	Transaction	Transaction	HC_Transaction	FAQ Language Options: ▪ Frequently Asked Questions - Common Electronic Submissions Gateway ▪ Foires aux questions - Portail commun de demandes électroniques

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Center	WebTrader Display Name	AS2 Submission Type	AS2 Routing ID	Notes
MWP		MWP_Report **(A, NGP)**	MWP_REPORT	Microwell Plate Report
OC	SPL	SPL	OC_REGLIST_SPL	Structured Product Labeling (SPL) includes NDC Labeler Code Request, Establishment Registration, and Drug Listing
OOPD	HUD_Designation_Requests **(T)**	HUD_Designation_Requests **(T)**	OOPD_HUD_DESIGNATIONS	
	Orphan_drug_Designation_Requests **(T)**	Orphan_drug_Designation_Requests **(T)**	OOPD_ORPHAN_DRUG_DESIGNATIONS	
OPQ	704a4_Pharma_Inspection_Records **(W)**			
ORA	Document_Requests **(W)**			