POLICY AND PROCEDURES

OFFICE OF BUSINESS INFORMATICS

Maintaining CDER's Electronic Submissions Docket (Accepting submissions and records in electronic format)

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PURPOSE

This MAPP establishes internal procedures for accepting submissions and records in electronic format and for maintaining CDER's portion of the FDA Electronic Submissions Docket, FDA-1992-S-0039.

BACKGROUND

21 CFR Part 11, Electronic Records; Electronic Signatures permits FDA units to accept submissions and records required by law or regulation in electronic format only when the Agency has identified those records in Docket FDA-1992-S-0039.

POLICY

Only those submissions and records identified in the CDER portion of docket FDA-1992-S-0039 may be accepted by a CDER unit in electronic format, instead of paper.

Docket FDA-1992-S-0039 will be updated on a continual basis, in a timely manner.

RESPONSIBILITIES

The Office of Business Informatics (OBI) is responsible for:

1. Reviewing requests for additions, deletions, or changes to Docket FDA-1992-S-0039 submitted by requesting units.
2. Sending CDER docket updates to the Division of Dockets Management.
3. Ensuring that the acceptance criteria (method of transmission, file format, media, and attendant protocols for receiving the electronic submission) conform to applicable FDA policies and procedures.
4. Working with FDA's Office of Information Management (OIM) to ensure the FDA infrastructure can support the receipt, management, and archiving of the electronic records.
5. Ensuring OBI documents the process of receiving, processing and archiving of the electronic records specified in the docket.
6. Determining, in coordination with the requesting unit, the effective date CDER will begin accepting (or stop accepting) the applicable record or portion of a record.

Requesting units are responsible for:

1. Promptly submitting a request to OBI when they are prepared to accept or stop accepting or they intend to modify the acceptance criteria for all, or part of, an FDA mandated submission in electronic format.
2. Working with OBI to develop and maintain guidance for describing the acceptance criteria for the electronic submission as needed.

PROCEDURES

When a requesting unit is prepared to accept or stop accepting or intends to modify the acceptance criteria for all or part of a submission in electronic format, it will submit an email request to OBI using one of the following subject line:

1. RE: Accept submission in electronic format
2. RE: Stop Accepting submission in electronic format
3. RE: Modify Acceptance Criteria

The notification should be sent by the requesting unit Office Director or his or her authorized representative. The notification should be directed to the Director, Division of Data Management Services and Solutions at esub@fda.hhs.gov. The notification must include the following information:

1. The name of the applicable record, or portion of that record.
2. The applicable law, regulation, or guidance mandating or supporting the electronic submission.

3. The standard file format(s) the requesting unit is prepared to accept the record in, including .pdf, .xml, or .xpt format.
4. The messaging standard, if applicable, that will be used in the exchange of information including eCTD, SPL, or ICSR format.
5. The proposed media on which the electronic submissions will be accepted.
6. The proposed method of transmission for electronic submission.
7. The name and address of the requesting unit, along with the name, phone number and email of a contact person who can provide additional information.
8. Any technical protocols or processes attendant to receiving, managing, or archiving the electronic record.
9. A copy of any relevant guidance describing the submission procedures. Guidance documents should be provided to OBI electronically, to allow for review and editing, prior to their release.

When OBI receives a request, it will:

1. Promptly review the request to ensure that applicable CDER and FDA electronic submission standards are being met. This includes checking the file format, media, transmission method, and archiving requirements. If the request conflicts with applicable electronic submissions standards, OBI will notify and work with the requesting unit to bring the request into compliance with the standards.
2. Maintain a record of information that includes items 1 through 8 of the preceding section.
3. Promptly send, to Division of Dockets Management, a completed "Docket FDA-1992-S-0039 Form" with the following information:

    a. The name (and applicable form designation) of the record or part of the record describing what is going to be submitted in electronic format.
    b. The section of the Code of Federal Regulations or law mandating the submission.
    c. The names and contact information of both CDER's receiving units and a contact person who can provide additional information.
    d. Additional guidance describing the acceptance criteria, as listed in items 1 through 9 in the Procedures section, above.
    e. The effective date that CDER will begin accepting or stop accepting, a record or portion of a record.

4. Promptly advise the requesting unit when the docket has been updated. CDER may then begin accepting, or may stop accepting the electronic submission.

REFERENCES

1. 21 CFR Part 11 Electronic Records; Electronic Signatures
2. Docket FDA-1992-S-0039 – FORM FDA 3872
3. Specification for Transmitting Electronic Submissions using eCTD Specifications

DEFINITIONS

Requesting Unit - Any CDER Office requesting an addition, deletion, or modification of a CDER entry in Docket FDA-1992-S-0039.

Acceptance Criteria - The specifications, terms and conditions that must be met before CDER will accept submissions and records in electronic format only.

SUMMARY OF CHANGES

FDA Electronic Submissions Docket, 92S-0251 was changed to FDA-1992-S-0039.

EFFECTIVE DATE

This MAPP is effective upon date of publication. Requesting units may accept electronic submissions when the records to be accepted have been identified in Docket FDA-1992-S-0039.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/15/97	Initial	n/a
5/17/13	1	Changed docket name to FDA-1992-S-0039. Added FDA Transmission Specification.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Submission of Electronic Record
(in accordance with 21 CFR, Part 11)

1. Receiving Unit

2. Name of Record

3. Regulatory Citation	4. Effective Date

5. Contact Information

Name	Telephone Number

Fax Number	Email Address

Contact Address

Address 1		
Address 2 *(if applicable)*		
City	State	ZIP Code

6. Address to which Electronic Record is to be submitted

Address 1		
Address 2 *(if applicable)*		
City	State	ZIP Code

7. Electronic Formats

a.	b.	c.

8. Media

a.	b.	c.

9. Transmission Methods

a.	b.	c.

10. An electronic copy of additional guidance describing the acceptance criteria for this electronic record may be found in

11. Comments

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