INFORMATION TECHNOLOGY

MAINTAINING CDER'S ELECTRONIC SUBMISSIONS DOCKET

CONTENTS

PURPOSE

- This MAPP establishes internal procedures for maintaining CDER's portion of the FDA Electronic Submissions Docket, 92S-0251.

BACKGROUND

- 21 CFR Part 11, Electronic Records; Electronic Signatures (effective on August 20, 1997) permits FDA units to accept submissions and records required by law or regulation in electronic form only when the Agency has identified those records in Docket 92S-0251.

REFERENCES

- 21 CFR Part ll, Electronic Records; Electronic Signatures

DEFINITIONS

- **Requesting Unit** - Any CDER Office requesting an addition, deletion or modification of a CDER entry in Docket 92S-0251. Requests for additions to the docket indicate the Center's readiness to accept a submission or record in electronic form only.

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

POLICY

- Only those submissions and records identified in the CDER portion of docket 92S-0251, may be accepted by a CDER unit in electronic form instead of paper.

- Docket 92S-0251 will be updated on a continuous basis, in a timely manner.

- CDER will develop and maintain mechanisms for making the docket information readily available to the public.

RESPONSIBILITIES

- The Office of Information Technology (OIT) is responsible for:

  1. Reviewing requests for additions, deletions, or changes to Docket 92S-0251.

  2. Maintaining a database of the CDER portion of the docket.

  3. Maintaining the docket information on the CDER Internet web site.

  4. Sending CDER docket updates to the Dockets Management Branch.

  5. Ensuring that the acceptance criteria (method of transmission, file format, media, and attendant protocols for receiving the electronic submission) conform to applicable CDER policies and procedures.

  6. Ensuring that the CDER infrastructure can support the receipt, management and archiving of the electronic records.

7. 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 OIT when they are prepared to accept, stop accepting, or intend to modify the acceptance criteria for all or part of an FDA mandated submission in electronic form.

2. Working with OIT 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, stop accepting, or intends to modify the acceptance criteria for all or part of a submission in electronic form, it will submit a request to OIT. The notification may be by electronic mail. The notification should be directed to the OIT Electronic Submissions Coordinator and must be issued by the requesting unit Office Director or his/her authorized representative. The notification must include the following information:

1. The name of the applicable record, or portion of that record.

2. The applicable FDA law or regulation mandating submission of the record.

3. The file format(s) the requesting unit is prepared to accept.

4. The proposed media on which the electronic submissions will be accepted.

5. The proposed method of transmission for electronic submission.

6. The name and address of the requesting unit, along with the name and phone number (and, optionally, the E-mail address) of a contact person who can provide additional information.

7. Any technical protocols/processes attendant to receiving, managing, and archiving the electronic record.

8. A copy of any relevant guidance describing the submission procedures. Guidance documents should be provided to OIT electronically to allow for review and editing prior to their release.

- When OIT receives a request, it will:

1. Promptly review the request to ensure that applicable CDER electronic submission standards are being met (e.g., with respect to file format, media, transmission method, and archiving requirements). If the request conflicts with CDER's electronic submissions standards, OIT will notify and work with the requesting unit to bring the request into compliance with the standards.

2. Maintain a database of information that includes items 1 through 7 of the preceding section.

3. Promptly send to Dockets Management Branch, a completed "Docket 92S-0251 Form" (see Attachment A) with the following information:

   a. The name (and applicable form designation) of the record or part of the record that is being (or is no longer being) accepted in electronic form.

   b. The section of the law or the regulation mandating the submission.

   c. The name and address of CDER's receiving unit which will receive the submission, and the name, address, and phone number of a contact person who can provide additional information.

   d. Additional guidance describing the acceptance criteria, as listed in items 1 through 8 above.

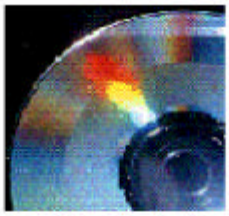
   e. The effective date that CDER will begin accepting (or stop accepting) a record or portion of a record.

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

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 92S-0251.

Attachment A



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1. Receiving Unit .....:
2. Record Name .....:
3. Regulatory Citation.....:
4. Effective Date .....:

5. For information …

Contact: Phone:
Fax: Email:
Address:

6. Submit Electronic Records to…

Address:

Attachment A

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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…