Information Technology

Requesting and Accepting Non-Archivable Electronic Records for New Drug Applications

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PURPOSE

This MAPP clarifies the policy and procedures in the Center for requesting and accepting non-archivable electronic records for new drug applications (NDAs).

BACKGROUND

21 CFR Part 11, Electronic Records; Electronic Signatures, permits us to accept submissions and records required by law or regulation in electronic format when we have identified the records in Docket 92S- 0251. The rule went into effect on March 20, 1997.

On February 1, 1999, we announced in Docket 92S-0251 that the Center is ready to accept NDAs in electronic format in lieu of paper. We published the guidance for industry, *Providing Regulatory Submissions in Electronic Format - NDA*, which lays out in detail the Agency's policy and recommendations on how sponsors should provide electronic submissions that we can efficiently archive and review.

This MAPP clarifies the policy and procedures in the Center for requesting and accepting non-archivable electronic records for new drug applications (NDAs).

REFERENCES

- 21 CFR Part 11, Electronic Records; Electronic Signatures
- Guidance for industry: *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999)
- OIT Services MAPP 7600.5

DEFINITIONS

Records in electronic format or electronic records include any combination of text, graphics, data, or other information represented in digital form.

In an electronic NDA, the document and dataset records that make up the application are in electronic format. An NDA submission can be the original NDA, NDA supplements and all amendments.

POLICY

- Center policy is to encourage the submission and review of electronic NDAs as described in the guidance for industry, *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999*).*
- It is Center policy to discourage the submission of records in electronic formats that are not archivable. The only electronic records that are archivable are those provided as described in the guidance.
- In the case when some records are submitted in an electronic format that are not archivable, the submission must still be accompanied by an electronic archivable version containing the same information.
- Requests from Center staff for word processing files for the purpose of copying and pasting text, figures, or tables on individual pages or portions of pages are not consistent with Agency policy. In most instances when such functions are needed, they can be adequately performed with archival files.
- If a word processing file is submitted, it cannot be accepted by the Agency ***in lieu of*** the archival electronic record as described in the guidance; in other

words, the Agency cannot accept a record in a word processing file format unless the record is also provided as recommended by the guidance.

- Requests from Center staff for datasets in formats other than that described in the guidance also are not consistent with Agency policy. In most instances, staff can use the archival dataset to convert data to desired alternative formats.

- If datasets are requested or accepted in a format that is different from that recommended in the guidance, it cannot be accepted ***in lieu of*** the archivable electronic record as outlined in the guidance. The Agency cannot accept dataset records in a file format not described in the guidance unless the record is also provided as recommended in the guidance.

- For a transition period beginning in February 1999, the Agency has been making exceptions to its electronic submissions acceptance policy on a case-by-case basis in situations when a sponsor is unable to provide electronic submissions as described in the guidance. This transition period will end January 31, 2000,

- If a sponsor is asked or offers to provide electronic records that will require the installation of hardware or executable software on any component of the CDER maintained information technology infrastructure, or if the use of the records requires OIT staff support beyond that needed for the electronic submission described in the guidance, advance approval from the Office of Information Technology (OIT) will be needed.

RESPONSIBILITIES

1. The Office of Review Management (ORM) or the Office of Pharmaceutical Science (OPS) division reviewing the NDA is responsible for (1) ensuring that any agreements made between reviewers and sponsors for electronic records is consistent with CDER policy, (2) determining if OIT support is needed, and (3) providing a description of the agreed to electronic records to the appropriate electronic submission coordinator.

    - In ORM, the electronic submission coordinator is the Associate Director for Electronic Review.

    - In OPS, the electronic submission coordinator is the Associate Director for Information Technology.

    If OIT support is needed, the review division should request the support as described in the OIT Services Manual no later than 20 days prior to the

proposed installation date of the electronic records. The review division should send the request to OIT through the appropriate electronic submission coordinator.

2. The electronic submission coordinator is responsible for monitoring agreements made between the division and sponsors and forwarding requests for OIT support to OIT.

3. OIT is responsible for (1) reviewing any proposal forwarded by the electronic submission coordinator, (2) determining if resources are available to support the electronic records, and (3) negotiating with ORM and/or OPS to determine what level of support should be provided as described in the OIT Services MAPP. OIT will also provide ORM and OPS with technical advice on modifying an unsupportable proposed electronic record to make it more compatible with the CDER IT infrastructure. The response to ORM and/or OPS should be at least 10 days prior to the proposed installation of the review aid.

PROCEDURES

1. The review division should send a copy of correspondence, meeting minutes, or other documentation describing agreements made with the sponsor in regard to requests for and acceptance of electronic records to the appropriate electronic submission coordinator.

2. If it is determined that OIT support is needed, the review division should request support using the process defined in the OIT Service Manual. This request should be sent through the appropriate electronic submission coordinator and received by OIT no later than 20 days prior to the target submission date. OIT help desk will log the service request, contact the requester to acknowledge receipt and forward the request to the OIT unit responsible for providing the service.

EFFECTIVE DATE

This MAPP is effective on the date of publication.