POLICY AND PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

Requesting and Accepting Non-Archivable Electronic Materials for CDER Applications

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PURPOSE

This MAPP clarifies CDER's policy and procedures in the Center for requesting and accepting electronic material in formats that CDER has deemed not suitable to serve as records or archives.

BACKGROUND

21 Code of Federal Regulations (CFR) Part 11, Electronic Records; Electronic Signatures, sets forth the criteria under which the agency considers electronic materials, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. Electronic materials meeting the requirements of this part may be used in lieu of paper records, in accordance with §11.2 of 21 CFR Part 11, unless paper records are specifically required. 21 CFR part 11 applies to materials in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations.

Agency Guidance identifies the electronic formats that are considered acceptable for submitting materials in an electronic format. Occasionally, a submitter may wish to

submit, or the Agency may request to receive material in a format that is not acceptable for a record (e.g. Microsoft word or Excel files), and therefore, cannot be considered a record.

This MAPP clarifies the policy and procedures in CDER for requesting and accepting electronic materials in non-archivable format.

POLICY

1. CDER encourages the submission and review of electronic records as described by law, regulation or guidance.

2. CDER discourages the submission of material in electronic formats that are not archivable as records. The only electronic materials that are considered archivable records are those provided as described by law, regulation or guidance.

3. In cases in which materials, such as draft labeling, are submitted in an electronic format that is not archivable (such as Microsoft Word or Excel files), the submission must be accompanied by an electronically archivable version, containing the same information, to serve as the record.

4. Requests from CDER staff for word processing files for the purpose of copying and pasting text, figures, or tables on individual pages are not consistent with Agency policy. Center staff must use the archival files to perform such functions.

5. If a sponsor or applicant is asked or offers to provide electronic material that will require the installation of hardware or software on any component of the FDA information technology infrastructure, or if the use of the material requires Office of Business Informatics (OBI) staff support beyond that needed for the electronic submission described in the guidance, advance approval from OBI will be needed. If approved, the requester must follow all applicable Office of Information Management (OIM) guidelines governing the installation of hardware or software on the FDA Information Technology Infrastructure.

RESPONSIBILITIES

The division reviewing the application is responsible for:

- Providing a description of the agreed upon electronic material and associated record to the appropriate electronic submission coordinator.
    - In OBI, the electronic submission coordinator for Electronic Review is the Director of Division of Data Management Services & Solutions (DDMSS).

- If OBI support is needed, the review organization should request the support no later than 30 days prior to the proposed submission date of the electronic material. The review organization should send the request to OBI through the appropriate electronic submission coordinator.

The electronic submission coordinator is responsible for:

- Monitoring agreements made between the division and sponsors/applicants.
- Forwarding requests for OBI support.

OBI is responsible for:

- Ensuring that any agreements made between reviewers and sponsors/applicants for electronic material is consistent with CDER policy.
- Reviewing any proposal forwarded by the review organization.
- Determining if resources are available to support the electronic material.
- Negotiating with the review organization to determine the appropriate level of support to be provided.
- Providing the review organization with technical advice on the acceptance of the proposed electronic material, and providing this response at least 15 days prior to the proposed submission date of the electronic material.

PROCEDURES

1. The review organization sends a copy of meeting requests, correspondence, meeting minutes, or other documentation describing proposed agreements made with the sponsor or applicant in regard to requests for and acceptance of non-archivable electronic material to the electronic submission coordinator at esub@fda.hhs.gov. If it is anticipated that a request of non-archivable electronic material will be made in an industry meeting, OBI staff should be included in the meeting.

2. The Electronic Submission Coordinator or designee will contact the review organization to make a determination on the acceptability of the proposed agreement and make alternative recommendations, when appropriate.

REFERENCES

1. 21 CFR Part 11, Electronic Records; Electronic Signatures, §11.2.

2. Guidance for Industry: *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. January 2013.

3. Guidance for Industry*: Providing Regulatory Submissions in Electronic Format Standardized Study Data.* February 2012.

4. Guidance for Industry: *Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing.* May 2009.

5. FDA Portable Document Format (PDF) Specifications. Version 3.1. January 2012.

DEFINITIONS

Archivable – The ability of document or file to be considered suitable for long-term preservation and use. For electronic documents or files this is determined by its format. CDER considers only those formats that are publicly and openly documented and non-proprietary to be acceptable formats.

CDER Applications – Electronic dossiers filed by sponsors or applicants to CDER's review divisions for the review and approval of the use of human drugs. These dossiers are referred to as applications namely, New Drug Applications (NDAs), Biologics Licensed Applications (BLAs), Abbreviated New Drug Applications, (ANDAs), Investigational New Drug Applications (INDs) and Drug Master Files (DMFs).

Records in electronic format – include any combination of text, graphics, data, or other information represented in digital form submitted for regulatory purposes in an archivable format.

Electronic Submission Coordinator -- OBI staff member assigned to monitor and coordinate all efforts and agreements made between the division and sponsor/applicant, regarding the Requesting and Accepting of Non-Archivable Electronic Materials for CDER Applications. The Coordinator works for the Division of Data Management Services & Solutions (DDMSS) and reports to the Director, Office of Business Informatics (OBI).

SUMMARY OF CHANGES

This version of 7600.6 references the eCTD Specifications Guidance, Portable Document Format (PDF) Specifications; Study Data Specifications and the Structured Product Labeling Guidance.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
11/17/99	Initial	n/a.
8/28/13	1	OBI (not review organization) is responsible for ensuring that any agreements made between reviewers and sponsors/applicants for electronic material is consistent with CDER policy Consultation lead time changed from 20 to 30 days Response time from OBI to review organization was changed from 10 to 15 days MAPP applies to all CDER applications, not just NDAs Added: eCTD Specifications Guidance Portable Document Format (PDF) Specifications Standardized Study Data Guidance Structured Product Labeling Guidance Registration and Drug Listing Guidance