

sufficient for the purposes of reporting in the PETNet and LivestockNET portals of the Animal Feed Network. Therefore, FDA believes that the proposed collection of information does not have additional recordkeeping requirements.

Dated: August 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0724]

Documents to Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on the Agency Web site of revised final versions of the following four documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications: “The eCTD Backbone Files Specification for Module 1,” version 2.2 (which includes the U.S. regional document type definition (DTD), version 3.2); “The Comprehensive Table of Contents Headings and Hierarchy,” version 2.2; “Specifications for eCTD Validation Criteria,” version 3.0; and “Example Submissions using eCTD Backbone Files Specification for Module 1,” version 1.2. Technical files that support these documents are also available on the Agency Web site. A complete summary of the revisions made is included in the updated documents. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.2 by June 2014, and will give 30 days’ advance notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-

addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT:

Constance Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1105, Silver Spring, MD 20993, 301-796-1065, email: constance.robinson@fda.hhs.gov; or Joseph Montgomery, Center for Biologics Evaluation and Research, Food and Drug Administration, 11400 Rockville Pike, HFM-165, Rm. 4155, Rockville, MD 20857, 301-827-1332, email: joseph.montgomery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA’s Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBRE since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, provide clarification of business rules for submission processing and review, refine the characterization of promotional marketing and advertising material, and facilitate automated processing of submissions. FDA previously announced availability of final versions of technical documentation in a **Federal Register** notice dated February 13, 2013 (Docket No. FDA-2011-N-0724). The Agency has revised the final documentation and is making available revised versions of the following documents:

- “The eCTD Backbone Files Specification for Module 1, version 2.2,” which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBRE (This document should be used in conjunction with the guidance for industry *Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications*, which will be revised as part of the implementation of the updated eCTD backbone files

specification (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf>)).

- “The Comprehensive Table of Contents Headings and Hierarchy,” version 2.2, which reflects updated headings that are specified in the document entitled “The eCTD Backbone Files Specification for Module 1,” version 2.2

- “Specifications for eCTD Validation Criteria,” version 3.0

- “Example Submissions using eCTD Backbone Files Specification for Module 1,” version 1.2

Supporting technical files are being made available on the Agency Web site.

A complete summary of the revisions made are included in the updated documents. The revisions include the following:

eCTD Backbone Files Specification for Module I

- changed DTD version references from 3.1 to 3.2, where applicable
 - replaced the copy of DTD Version 3.1 in Appendix I with DTD Version 3
 - revised text, revised Table 1, and added Table 13 to indicate the new required attribute *material-id* and the new optional attribute *issue-date* which applies to m1-15-2-1
- The Comprehensive Table of Contents Headings and Hierarchy
- added two new attributes for 1.15.2.1

Specifications for eCTD Validation Criteria

- incorporated changes to US eCTD Module 1

Example Submissions using eCTD Backbone Files Specification for Module 1

- modified example 7 to reference the Form FDA 356h in the Admin section
- modified examples 13 through 17 to reference the material-id and issue date attributes as applicable, and include the Promotional Labeling and Advertising Regulatory Contact

FDA is not prepared at present to accept submissions utilizing this new version of the eCTD Backbone Files Specification for Module 1, version 2.2, because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.2 by June 2014, and will give 30 days advance notice to industry.

II. Electronic Access

Persons with access to the Internet may obtain the documents at either <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissions/Requirements/ElectronicSubmissions/ucm253101.htm>, <http://www.regulations.gov>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: August 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369] (Formerly Docket No. 2007D-0168)

Draft Guidance for Industry on Bioequivalence Recommendations for Risperidone Injection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "Draft Guidance on Risperidone." The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for risperidone injection.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 25, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written

comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris Andre, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific bioequivalence (BE) recommendations available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. FDA finalized that guidance and announced its availability in the **Federal Register** of June 11, 2010 (75 FR 33311). This notice announces the availability of revised draft BE recommendations for risperidone injection.

New drug application 021346 for Risperdal Consta (risperidone) Long-Acting Injection was initially approved by FDA in October 2003. In February 2010, FDA issued a draft guidance for industry on BE recommendations for generic risperidone injection (Draft BE Recommendations for Risperidone Injection). FDA is now issuing a revised version of the Draft BE Recommendations for Risperidone Injection (Revised Draft BE Recommendations).

In February 2011, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. submitted a citizen petition requesting that FDA require that any ANDA referencing Risperdal Consta (risperidone) Long-Acting Injection meet certain requirements, including requirements related to demonstrating BE (Docket No. FDA-2011-P-0086). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Revised Draft BE Recommendations in responding to the citizen petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for risperidone injection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Implementation of the Revised International Guiding Principles for Biomedical Research Involving Animals

SUMMARY: The National Institutes of Health (NIH) is providing guidance to Public Health Service (PHS) awardee institutions on implementation of the revised International Guiding Principles for Biomedical Research Involving Animals ("Guiding Principles"). The NIH is seeking input from the public on any concerns they may have regarding the revised Guiding Principles.

DATES: Public concerns regarding the revised Guiding Principles must be submitted electronically at <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=35> by September 30, 2013 in order to be considered.