DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Lamotrigine; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry on lamotrigine extended-release tablets entitled ''Draft Guidance on Lamotrigine.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for lamotrigine extended-release tablets.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic submissions in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Lamotrigine.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific 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 to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for lamotrigine extended-release tablets.

On May 29, 2009, FDA initially approved new drug application 022115 for LAMICTAL (lamotrigine) extended-release tablets. There are eight approved ANDAs for this product. In April 2010, we issued a draft guidance for industry on BE recommendations for lamotrigine extended-release tablets, which we subsequently revised in May 2010; July 2010; and August 2010. We are now issuing a further revised draft guidance for industry on BE recommendations for generic lamotrigine extended-release tablets (''Draft Guidance on Lamotrigine'').

In October 2006, UCB, Inc., submitted a citizen petition requesting that FDA

take several actions with respect to anti-epileptic drugs (AEDs), including that FDA narrow the bioequivalence range for all such drugs (Docket No. FDA–2006–P–0461). FDA is reviewing the issues raised in the petition. Although lamotrigine is not the sole focus of the petition, lamotrigine is discussed and it is indicated for use as an AED; therefore, FDA will consider any comments on the draft guidance on lamotrigine in responding to the 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 lamotrigine extended-release tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. 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: January 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01683 Filed 1–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0044]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Recordkeeping for Exempt Infant Formula Production

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 29, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—NEW. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recommended Recordkeeping for Exempt Infant Formula Production—OMB Control Number 0910—NEW

I. Background

Section 412(h)(1) (21 U.S.C. 350a(h)(1)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) exempts an infant formula which is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of section 412(a), (b), and (c) of the FD&C Act (21 U.S.C. 350a(a), (b), and (c)). These formulas are customarily referred to as ''exempt infant formulas.'' In the **Federal Register** of June 10, 2014 (79 FR 33057), we published a final rule that adopted, with some modifications, an interim final rule published on February 10, 2014 (79 FR 7934), that established requirements for quality factors for infant formulas and current good manufacturing practices (CGMPs), including quality control procedures, under section 412 of the FD&C Act. The final rule will help prevent the manufacture of adulterated infant formula, ensure the safety of infant formula, and ensure that the nutrients in infant formula are present in a form that is bioavailable.

In the **Federal Register** of February 10, 2014 (79 FR 7610), we published a notice of availability of the draft guidance document entitled, ''Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports'' (the draft guidance). The draft guidance, when finalized, will describe our current thinking on the manufacturing of exempt infant formula in relation to the requirements in part 106 (21 CFR part 106) for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to nonexempt infant formulas. Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances.*

II. Analysis of the Proposed Information Collection

The proposed information collection seeks OMB approval of the recordkeeping recommendations of the draft guidance. Our estimate of the burden of the recordkeeping recommendations includes the one-time burden of developing production and in-process control systems and the annual burdens of developing and maintaining production aggregate production and control records, records pertaining to the distribution of infant formula, and records pertaining to regularly scheduled audits. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Description of Respondents: The respondent recordkeepers are manufacturers of exempt infant formula.

Description: The records recommended, to the extent practicable, in the draft guidance include records required by part 106, subparts A, B, C, D, and F for non-exempt infant formulas. Because the records and reporting requirements related to part 106 subparts E and G are not generally applicable to exempt infant formula manufacturers, FDA is not recommending in the draft guidance that exempt infant formula manufacturers follow these requirements. As such, the records and reporting requirements in part 106 subparts E and G are not part of this new information collection.

In the **Federal Register** of March 18, 2015 (80 FR 14134), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one letter responsive to the notice, which contained comments.

(Comment 1) One comment suggested that we clarify the action level for end-of-shelf-life verification testing and how this testing differs for exempt infant formulas as compared to non-exempt infant formulas.

(Response) We appreciate the concerns discussed in the comment.