DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1551]

Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance is intended to assist applicants in complying with the new content and format requirements in the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling for human prescription drug and biological products, as described in the final rule, *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling.* The rule, which is being published concurrently with this draft guidance, is referred to as the ''Pregnancy and Lactation Labeling Rule'' (PLLR). The draft guidance will assist applicants in developing labeling for new products, revising existing labeling, and implementing the content and format requirements of the PLLR for human prescription drug and biological products.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 2, 2015.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993, or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G102, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 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Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–2200; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance provides recommendations on how to develop and revise professional labeling that meets the new content and format requirements of the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling for human prescription drug and biological products. Specifically, it provides information to assist applicants in preparing subsections 8.1 Pregnancy, 8.2 Lactation, and 8.3 Females and Males of Reproductive Potential of the USE IN SPECIFIC POPULATIONS section of the full prescribing information under 21 CFR 201.56(d)(1) and 201.57(c)(9)(i) through (iii), as described in the PLLR.

The PLLR provides a framework to clearly communicate information on the benefits and risks of drug use during pregnancy and lactation to help facilitate prescribing decisions. The PLLR also includes a subsection on females and males of reproductive potential to address issues in these populations that are linked to pregnancy either directly or indirectly. The draft guidance provides recommendations to applicants submitting new drug applications (NDAs), efficacy supplements to approved NDAs, biologics license applications (BLAs) (for biological products that are regulated as drugs), and efficacy supplements to BLAs, as well as to applicants that have previously submitted such applications during the time periods specified in the implementation plan set out in the preamble to the PLLR. FDA may revise other Agency guidances as needed and appropriate to reflect the PLLR content and format requirements and the recommendations in this guidance, once it has been finalized.

This draft guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3999), FDA announced the availability of final guidances on the content and format of the ''Adverse Reactions'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075057.pdf*) and ''Clinical Studies'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075059.pdf*) sections of labeling. In the **Federal Register** of October 19, 2009 (74 FR 53507), FDA announced the availability of final guidance on determining established pharmacologic class for use in the ''Highlights of Prescribing Information'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM186607.pdf*). In the **Federal Register** of March 23, 2010 (75 FR 13766), FDA announced the availability of final guidance on the content and format of the ''Dosage and Administration'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075066.pdf*). In the **Federal Register** of October 12, 2011 (76 FR 63303), FDA announced the availability of final guidance on the content and format of the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf*),and in the **Federal Register** of March 3, 2009 (74 FR 9250), FDA announced the availability of draft guidance on the content and format of the ''Clinical Pharmacology'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM109739.pdf*). In the **Federal Register** of February 25, 2013 (78 FR 12760), FDA announced the availability

of final guidance implementing the ''Physician Labeling Rule'' (January 24, 2006, 71 FR 3922) content and format requirements of labeling for human prescription drug and biological products under §§ 201.56(d) and 201.57 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075082.pdf*). In the **Federal Register** of February 28, 2013 (78 FR 13686), FDA announced the availability of draft guidance on the placement and content of pediatric information in the labeling for human prescription drug and biological products in accordance with the Physician Labeling Rule (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM341394.pdf*).

The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

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 implementing the PLLR content and format requirements for labeling for human prescription drug and biological products. 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 electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collection of information in 21 CFR 314.70 and 314.97 for submitting supplements to an approved application, the collection of information in 21 CFR 314.50(e) for submitting labeling for an application, and the collection of information in 21 CFR 314.90 for submitting waiver requests for an application have been approved under OMB control number 0910–0001. The collection of information in 21 CFR 601.12 for submitting supplements to an approved application has been approved under OMB control number 0910–0338. In addition, the information collection provisions of the PLLR have been submitted to OMB for review, as required by section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the PLLR, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: November 25, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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