



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-D-0153] (formerly 2005D-0011)

Guidance for Industry on Labeling for Human Prescription Drug and Biological Products--

Implementing the Physician Labeling Rule Content and Format Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Labeling for Human Prescription Drug and Biological Products-- Implementing the PLR Content and Format Requirements." This guidance is intended to assist applicants in complying with the content and format requirements of labeling for human prescription drug and biological products. The recommendations in this guidance will help ensure that the labeling is clear; useful; informative; and to the extent possible, consistent in content and format. It will assist applicants in developing labeling for new products, revising existing labeling, and implementing the requirements on content and format of labeling for human prescription drug and biological products (71 FR 3922), which appeared in the Federal Register of January 24, 2006. The rule is commonly referred to as the "Physician Labeling Rule" (PLR) because it addresses prescription drug labeling that is used by prescribers and other health care practitioners.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 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 guidance document.

Submit electronic comments on the 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:

Lori Bickel,

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Food and Drug Administration,

10903 New Hampshire Ave.,

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Silver Spring, MD 20993-0002,

301-796-0210; or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852-1448,

301-827-6210.

## SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Labeling for Human Prescription Drug and Biological Products--Implementing the PLR Content and Format Requirements." The guidance provides recommendations on how to create professional labeling consistent with the requirements on content and format of labeling for human prescription drug and biological products under §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) (71 FR 3922). The guidance also provides recommendations on how to organize labeling sections and what information should be included in each.

This 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 3998), 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>). 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.

On January 24, 2006, FDA announced the availability of draft guidance entitled “Labeling for Human Prescription Drug and Biological Products--Implementing the New Content and Format Requirements” to obtain public comment (71 FR 3998). FDA received a number of comments, most of which sought clarifications and illustrations of the issues discussed in individual sections of the guidance. FDA reviewed all received comments carefully during the finalization of the guidance and made clarifying changes based on input from these comments and comments from FDA reviewers with labeling expertise.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on implementing the PLR 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 found in FDA regulations. These collections of information 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 collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910-0572.

## IV. Electronic Access

Persons with access to the Internet may obtain the document 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: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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