

Determination must provide the State's or CMS' determination on whether a rate increases is 'unreasonable'. Section 154.301(a)(3) of the rule provides a list of actuarial review elements that must be taken into account as part of the rate review process. The Final Determination must provide a brief statement explaining how the review of elements set forth in § 154.301(a)(3) caused the State or CMS to arrive at its determination that the rate is unreasonable.

The Rate Review Final Determination will be entered into a data entry text box in the Rate Review Data Collection System. CMS is estimating that this statement would be approximately a paragraph in length. There is no specific form or set of instructions associated with this reporting requirement, apart from the reporting requirements provided in the rule. The information provided in the Rate Review Final Determination will be posted as part of the rate review consumer disclosure information on an HHS Web site.

### 3. Final Justification for An Unreasonable Rate Increase

The rule states that if a health insurance issuer implements a rate increase determined by CMS or a State to be unreasonable, the health insurance issuer must provide a Final Justification for an Unreasonable Rate Increase. In the Final Justification, issuers would have to provide a short statement about why they are electing to implement an unreasonable rate increase. This statement would be entered into a data entry text box in the Rate Review Data Collection System and would not need to be more than a paragraph or two in length. There is no form or instructions associated with this statement apart from the requirements provided in the regulation.

The Final Justification Statement will be posted on an HHS Web site in the same location as the Preliminary Justification and Rate Review Final Determination. Additionally, health insurance issuers implementing rate increases that were determined to be unreasonable, must post all of this information—the Preliminary Justification, the Rate Review Final Determination, and the Final Justification Statement on their Web sites for a period of 3 years.

In addition to the aforementioned requirements, we have revised the information collection request as a result of an amendment to the regulation discussed in the final rule that published September 6, 2011 (76 FR 54969). The amendment to the rate review final rule updated the

applicability of the rate review requirements to include products that would be considered part of the individual or small group market had they not been sold through associations, including those that are considered to be large group products under State law or have been otherwise excluded from State's existing definitions for individual and small group products. This change will result in an increase in the total number of rate increases that are subject to the rate review reporting requirements. The amendment did not propose any changes to the information that issuers must submit for each rate increase. Thus, burden associated with each rate increase submission remains unchanged from the final rate review rule. *Form Number:* CMS-10379; (OCN: 0938-1141) *Frequency:* Annually; *Affected Public:* Private Sector and States; *Number of Respondents:* 452; *Number of Responses:* 1,201; *Total Annual Hours:* 15,213. (For policy questions regarding this collection, contact Sally McCarty at (301) 492-4489. For all other issues call 410-786-1326.)

CMS is requesting OMB review and approval of this collection by *October 31, 2011*, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by *October 21, 2011*.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp> or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received via one of the following methods by *October 21, 2011*.

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs,

Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

3. *By E-mail to OMB.* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *E-mail:* [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: October 6, 2011.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0694]

#### Guidance for Industry on Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format; 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 "Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format." This guidance is intended to assist applicants and reviewers in drafting the "Warnings and Precautions, Contraindications, and Boxed Warning" sections 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.

**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, 10001 New Hampshire Ave., 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 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:**

Cheryl Grandinetti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3244, Silver Spring, MD 20993-0002, 301-796-3516; 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 “Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format.” The guidance provides recommendations on how to determine which adverse reactions are significant enough to warrant inclusion in the “Warnings And Precautions” section; how to decide what situations warrant a “Contraindication”; and when to include a “Boxed Warning.” The guidance also provides recommendations on how to organize each section and what information to include when describing warnings and precautions, in situations when the use of the product is contraindicated, and in a boxed warning.

This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants and reviewers with the content and format of certain sections of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3999), FDA issued final guidances on the content and format of the “Adverse Reactions” and “Clinical Studies” sections of labeling. In the **Federal Register** of October 19, 2009 (74 FR 53507), FDA issued a final guidance on determining established pharmacologic class for use in the highlights of prescribing information. In the **Federal Register** of March 23, 2010 (75 FR 13766), FDA issued a final guidance on the content and format of the “Dosage and Administration” section of labeling and in the **Federal Register** of March 3, 2009 (74 FR 9250), FDA issued a draft guidance on the content and format of

the “Clinical Pharmacology” section of labeling. The new labeling requirements (final rule, January 24, 2006, 71 FR 3922) and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

On January 18, 2006, FDA issued a draft of this guidance on the “Warnings and Precautions, Contraindications, and Boxed Warning” sections of the labeling to obtain public comment (71 FR 3998). FDA received a number of comments, most of which focused on clarifications and further illustrations of issues discussed in individual sections and subsections of the guidance. FDA reviewed all received comments carefully during the finalization of the guidance. Other than clarifying edits, no changes of significance were made to the final version of the guidance.

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 the content and format of the “Warnings and Precautions, Contraindications, and Boxed Warning” sections of 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

**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 21 CFR 201.57 and 201.56 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: October 6, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0212]

**Guidance for Industry on Incorporation of Physical-Chemical Identifiers Into Solid Oral Dosage Form Drug Products for Anticounterfeiting; 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 “Incorporation of Physical-Chemical Identifiers Into Solid Oral Dosage Form Drug Products for Anticounterfeiting.” This guidance provides recommendations on design considerations for incorporating physical-chemical identifiers (PCIDs) into solid oral dosage forms (SODFs), supporting documentation to be submitted in new drug applications (NDAs) or abbreviated new drug applications (ANDAs) to address the proposed incorporation of PCIDs in SODFs, supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change.

**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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**