

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and Administration” section of labeling and in the **Federal Register** of March 3, 2009 (74 FR 9250), FDA issued a draft guidance on the content and format of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**

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: John L. Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 2619, Silver Spring, MD 20993, 301-796-1757.

SUPPLEMENTARY INFORMATION:

I. Background

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." For the purpose of this guidance, a PCID is a substance or combination of substances possessing a unique physical or chemical property that unequivocally identifies a drug product or dosage form as authentic and distinguishes it from counterfeits. To thwart drug product counterfeiting, pharmaceutical manufacturers have been investigating technologies that may make drug products more difficult to duplicate, including the incorporation of PCIDs into SODFs. One approach that manufacturers appear to be considering involves adding a trace amount of one or more inactive ingredients to an existing section of the dosage form (in the guidance, section is the term used for a discrete, contained solid or a layer in a solid oral dosage form). Any section can be described by its composition, the functional characteristics that distinguish it from other sections in that dosage form, and its position relative to other sections that may be present (e.g., coatings, capsule shells, encapsulated particles, a layer in a bilayer tablet, and compressed powders). A unique physical-chemical characteristic of that ingredient makes it possible to detect and authenticate legitimate dosage forms, and to identify counterfeits. Examples of substances that may be incorporated into SODFs as PCIDs include inks, pigments, flavors, and molecular taggants. Such PCIDs may allow product authentication by their presence alone or may be used to code the product identity into or onto the SODF.

This guidance provides recommendations to pharmaceutical manufacturers on the following topics: (1) Design considerations for PCIDs into SODFs, (2) supporting documentation to

be submitted in NDAs or ANDAs to address the proposed incorporation of PCIDs in SODFs, (3) supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and (4) procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change. Although not addressed in this guidance, FDA is considering whether to address the incorporation of a PCID into a drug's packaging or labeling in a future guidance.

In the **Federal Register** of July 14, 2009 (74 FR 34021), FDA announced the availability of a draft guidance for industry entitled "Draft Guidance for Industry on Incorporation of Physical-Chemical Identifiers Into Solid Oral Dosage Form Drug Products for Anticounterfeiting." The notice gave interested persons an opportunity to comment by October 13, 2009. We have carefully considered the comments we received and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments.

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 use of PCIDs in SODF drug products to prevent counterfeiting. 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. The 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 documentation in premarketing regulatory submissions recommended for applicants incorporating PCIDs into SODFs would be covered under 21 CFR 314.50 and 314.94, and the documentation in postapproval regulatory submissions would be covered under 21 CFR 314.70. This information collection has been approved under OMB control number 0910-0001. The recommendations for labeling would be covered under 21 CFR 201.57. This information collection has been approved under OMB control number 0910-0572.

III. 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.

IV. Electronic Access

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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-2011-N-0400]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2011-0014]

Approaches To Reducing Sodium Consumption; Public Meeting

AGENCY: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS) and the Center for Nutrition Policy and Promotion (CNPP) are announcing a public meeting entitled "Approaches to Reducing Sodium Consumption." FDA and FSIS recently published a **Federal Register** notice that announced the establishment of dockets to obtain comments, data, and evidence relevant to the dietary intake of sodium as well as current and emerging approaches designed to promote sodium reduction. The purpose of the public meeting is to provide interested persons an opportunity to