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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. FDA-2008-D-0413]

Draft Guidance for Industry on Residual Solvents in Drug Products Marketed in the United States; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Control of Residual Solvents in Drug Products Marketed in the United States." On July 1, 2008, the United States Pharmacopeia (USP) published a new test requirement for the control of residual solvents, General Chapter <467> "Residual Solvents," which replaced USP General Chapter <467> "Organic Volatile Impurities." The change affects all compendial drug products marketed in the United States. This draft guidance reflects FDA's recommendations on how to comply with those USP changes.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm.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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Larry Ouderkirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4125, Silver Spring, MD 20993, 301–796–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Residual Solvents in Drug Products Marketed in the United States.” Beginning July 1, 2008, FDA will require that drug products marketed in the United States with an official USP monograph meet the residual solvents requirements in the revised General Chapter <467> “Residual Solvents.”

For compendial drug products approved under a new drug application (NDA) or abbreviated new drug application (ANDA), changes made to the specifications in the approved application regarding the revised General Chapter <467> should be in accordance with applicable regulations described in 21 CFR 314.70 and the recommendations in the guidance for industry on “Changes to an Approved NDA or ANDA, April 2004.” FDA expects that in most cases, an annual report can be used to report changes.

FDA recommends that applicants who have submitted NDAs or ANDAs to the agency for drug products that are not the subject of an official USP

monograph control and limit the presence of residual solvents in the subject drug product as described in the guidance on “Q3C Impurities: Residual Solvents.”

Marketed compendial drug products that are not approved under an NDA or ANDA (for example, over-the-counter (OTC) drug products that are marketed under an FDA OTC monograph) are also subject to the provisions of the Federal Food, Drug, and Cosmetic Act, the revised General Chapter <467>, and current good manufacturing practice requirements in 21 CFR 211.165(e) and 211.194(a)(2).

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 control of residual solvents in drug products marketed in the United States. 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

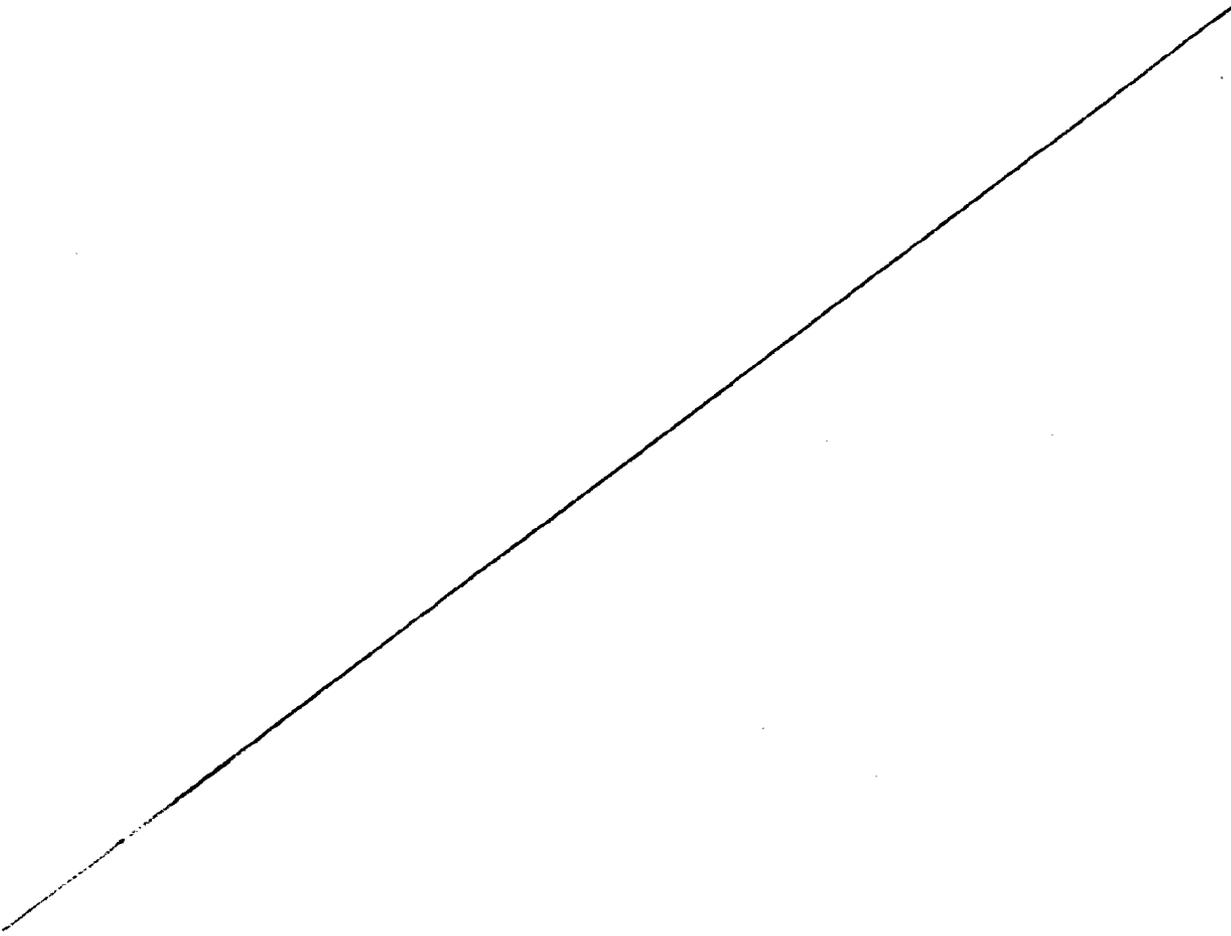
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System

(FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.



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July 29, 2008
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Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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