

I. Background

FDA is announcing the availability of a guidance for industry entitled "Residual Solvents in Drug Products Marketed in the United States." On August 7, 2008 (73 FR 46020), FDA announced the availability of the draft version of this guidance. The public comment period closed on October 6, 2008. A number of comments were received, which the agency considered carefully as it finalized the guidance. In response to the comments, FDA made appropriate changes. The guidance provides information on how new drug application (NDA) and abbreviated new drug application (ANDA) applicants for noncompendial drug products should limit residual solvents as described in the International Conference on Harmonisation guidance for industry "Q3C Impurities: Residual Solvents;" how manufacturers of compendial drug products that are not marketed under an approved NDA or ANDA can comply with the new General Chapter <467> and the Federal Food, Drug, and Cosmetic Act; and how holders of NDAs or ANDAs for compendial drug products should report changes in chemistry, manufacturing, and controls specifications to FDA to comply with the USP General Chapter <467> "Residual Solvents" and § 314.70 (21 CFR 314.70).

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 USP General Chapter <467> "Residual Solvents." 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 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). Information submitted in the chemistry, manufacturing, and controls section of an application under 21 CFR 314.50(d)(1), as well as in amendments to pending applications under 21 CFR 314.60, is approved by OMB under Control Number 0910–0001. Information submitted in an annual report under § 314.70(d)(2)(i) and (d)(3) is approved by OMB under Control

Number 0910–0001. Recordkeeping required under 21 CFR 211.165(e) and 211.194(a)(2) is approved by OMB under Control Number 0910–0139.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 19, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28247 Filed 11–24–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, November 30, 2009, 6:30 p.m. to December 2, 2009, 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, 10, Bethesda, MD, 20892 which was published in the **Federal Register** on November 4, 2009, 74FR57182.

This **Federal Register** Notice is being amended to reflect the change in the start and end times of the closed session on December 1, 2009 to 3:45 p.m. to 4:30 p.m.

Dated: November 19, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–28279 Filed 11–24–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Institutes of Health Peer Review Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Institutes of Health Peer Review Advisory Committee.

Date: February 1, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: Provide technical and scientific advice and recommendations to the NIH Director, the Deputy Director for Extramural Research, and the Director of the Center for Scientific Review (CSR) on all procedures and policies related to the process of peer review by which the scientific and technical merit of NIH grant applications is assessed.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Cheryl A. Kitt, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, 301–435–1112, kittc@csr.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 17, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–28287 Filed 11–24–09; 8:45 am]

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