

## EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of hospitals	Total burden hours	Average hourly wage rate*	Total cost burden
Culture Questionnaire .....	7	525	\$38.28	\$20,097
Implementation Assessment Questionnaire .....	7	84	\$45.33	\$3,808
Patient Healthcare Use Questionnaire .....	200	50	\$21.90	\$1,095
Total .....	226	2,430	na	\$76,118

\*Based upon the mean of the average wages for Nursing Care Providers (\$30.03), Primary Care Physicians (\$84.97), Allied Health Providers (\$20.98), Administrators, Chief Executives (\$76.23) and All Workers (\$21.90); National Compensation Survey: Occupational wages in the United States May 2008, "U.S. Department of Labor, Bureau of Labor Statistics."

**Estimated Annual Costs to the Federal Government**

Exhibit 3 shows the total and annualized cost of this project to the

Federal Government over a two-year period. The total cost of this project is \$1.8 million dollars which includes \$785,000 for project development, \$70,000 for data collection activities,

\$235,000 for data analysis, \$125,000 for publication of the results, \$170,000 for project management and \$415,000 for overhead costs.

## EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development .....	\$785,000	\$262,000
Data Collection Activities .....	\$70,000	\$35,000
Data Processing and Analysis .....	\$235,000	\$78,000
Publication of Results .....	\$125,000	\$125,000
Project Management .....	\$170,000	\$57,000
Overhead .....	\$415,000	\$138,000
Total .....	\$1,800,000	\$900,000

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 16, 2009.

**Carolyn M. Clancy,**  
*Director.*

[FR Doc. E9-28211 Filed 11-24-09; 8:45 am]

**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

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

**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 guidance for industry entitled "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 guidance reflects FDA's

recommendations on how to comply with those USP changes.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Chris Watts, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4142 Silver Spring, MD 20993-0002, 301-796-1625.

**SUPPLEMENTARY INFORMATION:**

## 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]

**BILLING CODE 4160–01–S**

## 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]

**BILLING CODE 4140–01–P**

## 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](mailto: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]

**BILLING CODE 4140–01–P**