EXHIBIT 3—ESTIMATED COST

Cost component	Total cost	Annualized cost
Review of literature	$20,000	$13,334
Cognitive interviews	60,000	40,000
Field test	90,000	60,000
Data analyses	40,000	26,667
Finalize survey	35,000	23,334
AHRQ project management	50,000	33,334
Total	295,000	196,669

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 health care research and health care 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: May 4, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–11012 Filed 5–12–09; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0122] (formerly Docket No. 2004D–0327)

Compliance Guidance for Small Business Entities on Labeling Over-the-Counter Human Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses better understand and comply with the agency's over-the-counter (OTC) labeling requirements and to prepare new labeling. This compliance guidance finalizes the draft compliance guidance published on December 9, 2004.

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

ADDRESSES: Submit written requests for single copies of this compliance 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 compliance 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 compliance guidance document.

FOR FURTHER INFORMATION CONTACT: Marina Y. Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5418, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This is one of several guidances the agency has developed to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (21 CFR 201.66). This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively. The regulation requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format requires revision of all existing labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug application, abbreviated new drug application, or OTC drug monograph (or drug product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquiries from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. To address these inquiries, FDA published a notice in the **Federal Register** of December 9, 2004 (69 FR 71420), announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' The draft compliance guidance summarizes the new Drug Facts labeling requirements set forth in § 201.66. The

draft compliance guidance also describes how to list those inactive ingredients that are different when a finished OTC drug product is obtained from multiple suppliers.

The notice invited interested persons to submit comments on the draft compliance guidance by February 7, 2005. FDA did not receive any comments in response to the notice, and is announcing the availability of this final compliance guidance with only editorial revisions to the draft guidance.

This compliance guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The compliance guidance represents the agency's current thinking on how OTC drug product labeling can be converted to the new OTC Drug Facts format labeling. 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.

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*.

May 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–11089 Filed 5–12–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: May 18–19, 2009.

Closed: May 18, 2009, 1:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Open: May 19, 2009, 8:30 a.m. to 4 p.m.

Agenda: Discussions will focus on FIC activities and plans. Topics to be discussed: The pros/cons of creating an FIC centers-type grant; Priorities in distance learning applications and public health informatics; and future directions for the FIC framework program.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Contact Person: Robert Eiss, Public Health Advisor, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, (301) 496–1415, *EISSR@MAIL.NIH.GOV*.

This meeting is being published less than 15 days prior to the meeting due to timing limitations imposed by administrative matters.

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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, drivers license, or passport) and to state the purpose of their visit. Information is also available on the Institutes/Centers home page: *http://www.nih.gov/fic/aboutladvisory.html*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: May 5, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–11002 Filed 5–12–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel; Competitive Revision.

Date: June 12, 2009.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Arthur A. Petrosian, Scientific Review Administrator, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–496–4253, *petrosia@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)