Visit: $15,588, Follow up Visit: $6,894 (based on $18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Blood donors at Baseline Visit	2,340	1	0.37	866
Blood donors at Follow-up Visit	1,530	1	0.25	383
Total				1,249

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Suite 361, 6700 Rockledge Drive, Bethesda, MD 20892, or call non-toll free number 301–435–0075, or e-mail your request, including your address to *nemog@nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received *within 30 days* of the date of this publication.

Dated: May 15, 2009.

George Nemo,

Project Officer, NHLBI.

[FR Doc. E9–12210 Filed 5–26–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0253]

Draft Guidance for Industry on Presenting Risk Information in Prescription Drug and Medical Device Promotion; Availability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 ''Presenting Risk Information in Prescription Drug and Medical Device Promotion.'' This guidance responds to stakeholder requests for specific guidance on how FDA evaluates prescription drug and device promotional pieces to determine whether they adequately present risk information. The guidance describes and discusses the factors FDA considers when evaluating prescription drug advertisements (ads), restricted device ads, and prescription drug and device promotional labeling for their compliance with the Federal Food, Drug, and Cosmetic Act (the act) and relevant regulations. The guidance gives examples to illustrate FDA's thinking on these factors and is intended to help regulated industry gain a better understanding of what they should consider as they develop the content and format of their promotional communications.

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 comments 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 August 25, 2009. General comments on agency guidance documents are welcome at any time.

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: *Regarding human prescription drugs*: Kristin Davis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human biological products: Ele Ibarra-Pratt, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852–1448, 301–827–3028.

Regarding medical device products: Ann Simoneau, Center for Devices and Radiological Health (HFZ–302), 2094 Gaither Rd., Rockville, MD 20850, 240–276–0100.

Regarding prescription animal drug products: Martine Hartogensis, Center for Veterinary Medicine (HFV–216), 7519 Standish Pl., Rockville, MD 20855, 240–453–6833.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Presenting Risk Information in

Prescription Drug and Medical Device Promotion.'' FDA has responsibility under the act for regulating promotional labeling for prescription drugs and devices and advertising for prescription drugs and restricted devices. As required by the act and regulations, FDA evaluates the promotional materials for these products to determine whether the promotional materials for the product convey an accurate and nonmisleading net impression about the risks and benefits of the product. The draft guidance describes factors FDA considers when evaluating the risk information in promotional materials for these products.

FDA relies on an extensive body of knowledge regarding human cognition in assessing which factors to consider in evaluating promotional materials and making regulatory decisions about the presentation of risk information. In this draft guidance, FDA discusses both the content and format factors that are relevant to its determination of whether promotional materials adequately present risk information and provides numerous examples to illustrate FDA's thinking on these factors. The agency also makes recommendations about how manufacturers can develop the content and format of their promotional materials to comply with the requirements. The recommendations in the guidance apply to both consumer- and professional-directed promotional materials.

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 risk information in prescription drug and medical device promotion. 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*.

Dated: May 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–12255 Filed 5–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Institute of Child Health and Human Development Initial Review Group; Health, Behavior, and Context Subcommittee.

Date: June 15–16, 2009.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Michele C. Hindi-Alexander, PhD, Division Of Scientific Review, National Institutes Of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room, 5B01, Bethesda, MD 20812–7510, (301) 435–8382, *hindialm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–12195 Filed 5–26–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: June 15, 2009.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Boulevard, Rm 5B01, Rockville, MD 20852, (301) 435–6889, *bhatnagg@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–12197 Filed 5–26–09; 8:45 am]

BILLING CODE 4140–01–P