

70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is \$2,600 and the maximum color additive petition fee for a Category B petition is \$3,000. Because an average of two color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to \$5,600 ($1 \times \$2,600 + 1 \times \$3,000$ listing fees = \$5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-15384 Filed 6-30-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0202]

Over-the-Counter Drug Monograph System—Past, Present, and Future; Public Hearing; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of public hearing, published in the **Federal Register** of February 24, 2014 (79 FR 10168), requesting comment on how to improve or alter the current Over-the-Counter (OTC) Monograph Process for reviewing nonprescription drugs marketed under the OTC Drug Review. FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by July 31, 2014.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-3519, mary.gross@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 24, 2014 (79 FR 10168), FDA announced a public hearing to obtain input on the OTC Drug Review (sometimes referred to as the OTC Monograph Process, OTC Monograph, or OTC Drug Review). As stated in the **Federal Register** notice, FDA has been assessing the OTC Monograph Process and, in particular, has been considering how effectively the monograph system is functioning in today's world, 40 years after its inception, from the scientific, policy, and process perspectives. In the February 24, 2014, notice of public hearing, FDA announced it was soliciting comments about whether and how to modernize the process for the future. The public hearing was held to obtain information and comments from the public on the strengths and weaknesses of the current OTC Monograph Process, and to obtain and discuss ideas about modifications or alternatives to this process. Interested persons were originally given until May 12, 2014, to comment on the OTC Monograph Process.

II. Request for Comments

On our own initiative, we are reopening the comment period to allow interested persons additional time to comment to respond fully to FDA's specific requests for comments and to allow potential respondents to

thoroughly evaluate and address pertinent issues.

III. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions identified by the topic to which they refer (see 79 FR 10168 at 10171, section III). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-15375 Filed 6-30-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0833]

Office of the Commissioner; Request for Comments on the Food and Drug Administration Fiscal Year 2014-2018 Strategic Priorities Document; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking public comments on its draft Strategic Priorities Fiscal Year (FY) 2014-2018 document. FDA has identified these cross-cutting strategic priorities and core mission goals that will guide its efforts to achieve its public health mission. FDA is seeking public comment to help further refine these priorities and goals.

DATES: Submit either electronic or written comments by July 31, 2014.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Darian Tarver, Office of the

Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3238, Silver Spring, MD 20993-0002, 301-796-4850.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is posting its draft Strategic Priorities FY 2014–2018 document to ensure that the public has an opportunity to comment on this document.

The purpose of this document is to outline FDA's strategic intentions and plans for the next 4 years. This document identifies five cross-cutting strategic priorities and four core mission goals that will guide efforts to achieve FDA's public health mission and to fulfill its role in supporting the larger mission and strategic goals of the Department of Health and Human Services. The five cross-cutting strategic priorities are: (1) Regulatory science, (2) globalization, (3) safety and quality, (4) smart regulation, and (5) stewardship. The four core mission goals are: (1) Enhance oversight of FDA-regulated products, (2) improve and safeguard access to FDA-regulated products to benefit health, (3) promote better informed decisions about the use of FDA-regulated products, and (4) strengthen organizational excellence and accountability.

For comparison purposes, the current FDA Strategic Priorities FY 2011–2015 document can be viewed at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527.htm>.

The text of the draft Strategic Priorities FY 2014–2018 document is available in a downloadable portable document format through FDA's Web site: <http://www.fda.gov/AboutFDA/>. We look forward to receiving your comments (see **DATES**).

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-15374 Filed 6-30-14; 8:45 am]

BILLING CODE 4164-01-P

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 materials, 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, Conflicts R01/K99.

Date: July 17, 2014.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301 Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Zoe E. Huang, MD, Scientific Review Officer, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892-7968, 301-594-4937, huangz@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: June 24, 2014.

Michelle Trout,

Program Analyst, Office of the Federal Advisory Committee Policy.

[FR Doc. 2014-15297 Filed 6-30-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Population Sciences and Epidemiology.

Date: July 10, 2014.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Julia Krushkal, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, 301-435-1782, krushkalj@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA: Cardiovascular and Respiratory Sciences.

Date: July 21–22, 2014.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 4136, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4136, Bethesda, MD 20892, 301-435-0904, sara.ahlgren@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Autoimmune Diseases, Regulatory T-cells and Transplantation.

Date: July 21, 2014.

Time: 3:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301-435-1223, haydenb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Academic Research Enhancement: Healthcare Delivery and Methodologies.

Date: July 22, 2014.