

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.

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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]

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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