instructions and have it signed and dated by the authorized representative (see item 18d of the SF 424).

E. Lobbying Certification.

F. Program narrative no more than twenty pages.

G. Work Plan.

H. The application should be submitted through grants.gov using the funding opportunity # HSS–2013–ACL–AoA–SP–0049.

VI. Application Review Information

Three field reviewers external to the Office of Elder Rights will be assigned to review and score each application.

VII. Agency Contact

For further information or comments regarding this program expansion supplement, contact Rebecca Kinney, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Elder Rights, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 357–3520; fax (202) 357–3560; email *Rebecca.Kinney@acl.hhs.gov.*

Dated: April 8, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–08485 Filed 4–10–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0620]

Guidance for Industry on Self-Selection Studies for Nonprescription Drug Products; 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 ''Self-Selection Studies for Nonprescription Drug Products.'' This guidance is intended to provide recommendations to industry involved in developing and conducting self-selection studies to support an application for nonprescription drug products. A self-selection study assesses the ability of consumers to apply drug labeling information to their personal health situation to make correct decisions about whether or not it is appropriate for them to use a drug product. This guidance finalizes the draft guidance issued on September 19, 2011.

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

ADDRESSES: Submit written requests for single copies of this 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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: Barbara R. Cohen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5437, Silver Spring, MD 20993–0002, 301–796–2060.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Self-Selection Studies for Nonprescription Drug Products.'' A self-selection study assesses the ability of consumers to apply drug labeling information to their personal health situation to make correct decisions about whether or not it is appropriate for them to use a drug product. The guidance provides recommendations to industry involved in developing and conducting self-selection studies to support an application for nonprescription drug products.

The guidance includes recommendations regarding study design, study conduct, and final reporting of self-selection studies. The guidance should not be considered a substitute for an FDA review of specific protocols. This guidance finalizes the draft guidance issued on September 19, 2011 (76 FR 58018). FDA has reviewed the docket comments submitted in response to the draft guidance and the guidance was revised based on that review. The guidance also incorporates advice obtained from the Nonprescription Drugs Advisory Committee at a meeting on September 25, 2006, at which the committee considered issues related to analysis and interpretation of consumer studies conducted to support marketing of nonprescription drug products.

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 self-selection studies for nonprescription drug products. 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). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. 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*.

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: April 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08443 Filed 4–10–13; 8:45 am]

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