

State	Grantee	Amount
New Hampshire	NH. Dept. of Health & Human Services	25,736
New Jersey	New Jersey Department of Human Services	25,736
New Mexico	New Mexico Human Services Department	25,736
New York	NY Office of Temporary and Disability Assistance	171,426
North Carolina	North Carolina Dept. of Health & Human Services	84,000
North Dakota	North Dakota Department of Public Instruction	25,736
Ohio	Ohio Department of Job and Family Services	73,746
Oregon	Lutheran Community Services Northwest	39,822
Pennsylvania	Commonwealth of Pennsylvania	100,488
Rhode Island	Rhode Island Department of Human Services	25,736
South Dakota	Lutheran Social Services of South Dakota	25,736
Tennessee	Catholic Charities of Tennessee, Inc.	56,671
Texas	Texas Health and Human Services Commission	171,426
Utah	Utah Department of Workforce Services	43,797
Vermont	Vermont Agency of Human Services	25,736
Virginia	Virginia Department of Social Services	66,428
Washington	WA State Department of Social & Health Services	107,083
Wisconsin	Wisconsin Department of Public Instruction	31,240
Total		2,500,000

ORR provides 28 States and ten Wilson-Fish agencies with Refugee School Impact funding to undertake a comprehensive statewide approach supporting local school systems that are impacted by significant numbers of newly arrived refugee children. As currently awarded, the FY14–16 Refugee School Impact funding period concludes on August 14, 2016.

Beginning in FFY17, ORR will award Refugee School Impact funding as a formula set-aside within the Refugee Social Services funding awarded to all States and Wilson-Fish programs coordinating refugee resettlement. This change in timing for Refugee School Impact funding will create a gap in Refugee School Impact program services between August 15, 2016 and October 1, 2016. The low-cost extensions will support refugee access to services critical to refugee student success at the beginning of the school year, when such services are greatest and most urgent.

**DATES:** Low-cost extension supplement grants will support activities from August 15, 2016, through September 30, 2016.

**FOR FURTHER INFORMATION CONTACT:** Carl Rubenstein, Director, Division of Refugee Assistance, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: [carl.rubenstein@acf.hhs.gov](mailto:carl.rubenstein@acf.hhs.gov).

**Statutory Authority:** This program is authorized by Section 412(c)(1)(A)(iii) of the Immigration and Nationality Act (INA), 8 U.S.C. 1522(c)(1)(A)(iii).

**Christopher Beach,**

Senior Grants Policy Specialist, Office of Administration, Office of Financial Services, Division of Grants Policy.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2010–D–0319]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Fax written comments on the collection of information by November 21, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0754. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information—OMB Control Number 0910–0754—Extension**

This final Guidance for Industry and FDA staff entitled “Dear Health Care Provider Letters: Improving Communication of Important Safety Information” offers specific guidance to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising.

This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information and have been unable to communicate it to patients because the letters’ content and length have made it difficult to find the relevant information. In addition, letters have

sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

Based on a review of FDA's Document Archiving, Reporting and Regulatory Tracking System for 2012 to 2015, we

identified DHCP letters that were sent and the identity of each sponsor sending out a DHCP letter for each year. We estimate that we will receive approximately 25 DHCP Letters annually from approximately 18 application holders. FDA professionals familiar with DHCP letters and with the recommendations in the guidance estimate that it should take an application holder approximately 100

hours to prepare and send DHCP letters in accordance with the guidance.

In the **Federal Register** of March 10, 2016 (81 FR 12734), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

FDA estimates the annual reporting burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Annual average .....	18	1.4	25	100	2,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 17, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-0001]

**Request for Nominations for Voting Members on a Public Advisory Committee; Food Advisory Committee**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Food Advisory Committee (the Committee), Office of Regulations, Policy, and Social Sciences, Center for Food Safety and Applied Nutrition.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before December 20, 2016, will be given first consideration for membership on the Food Advisory Committee. Nominations received after December 20, 2016, will be considered for nomination to the committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be sent electronically by logging into the FDA

Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

**FOR FURTHER INFORMATION CONTACT:** *Regarding all nomination questions for membership, the primary contact is:* Karen Strambler, 5001 Campus Drive, Rm. 1C-008, College Park, MD 20740, email: [karen.strambler@fda.hhs.gov](mailto:karen.strambler@fda.hhs.gov), 240-402-2589, Fax: 301-436-2367.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nomination for voting members on the Committee.

**I. General Description of the Committee Duties**

The Committee reviews and evaluates emerging food safety, nutrition, and other food- or cosmetic-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related issues, (2) the safety of food ingredients and new foods, (3) labeling of foods and cosmetics, (4) nutrient needs and nutritional adequacy, and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make

recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

**II. Criteria for Voting Members**

The Committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner of Food and Drugs (the Commissioner) designee from among authorities knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, epidemiology and other relevant scientific and technical disciplines. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this Committee serve as Special Government Employees. The core of voting members may include two technically qualified member(s), selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include two non-voting member(s) who are identified with industry interests.

**III. Nomination Procedures**

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also