

approximately 132 TPPs per year. Based on data received from the Pharmaceutical Research and Manufacturers of America, we estimate that approximately 20 sponsors would

submit TPPs and that each TPP would take approximately 20 hours to prepare and submit to FDA. Based on the previous methodology and assumptions, the following table provides an estimate

of the annual reporting burden for the voluntary submission of TPPs under the draft guidance. FDA requests comments on this analysis of information collection burdens.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Target Product Profiles (TPPs)	20	6.6	132	20	2,640

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

Dated: December 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Advisory Committee; Food Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Food Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Food Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the December 18, 2017.

DATES: Authority for the Food Advisory Committee will expire on December 18, 2017, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Karen Strambler, Center for Food Safety and Applied Nutrition, Office of Regulations, Policy, and Social Sciences, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2589, *karen.strambler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Food Advisory Committee. The committee is a discretionary Federal

advisory committee established to provide advice to the Commissioner.

I. Objectives and Scope of Activities

The Food Advisory Committee (the Committee) advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

II. Description of 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.

III. Membership and Designation

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or 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.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm120646.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Advisory Committee on