

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of the annual reporting burden for the voluntary submission of TPPs under the draft guidance.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.

[FR Doc. 2015-33171 Filed 1-4-16; 8:45 am]

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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

Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for both public attendance and comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should email OMH-ACMH@hhs.gov.

DATES: The meeting will be held on Thursday, January 28, 2016, from 9:00 a.m. to 5:00 p.m. and on Friday, January 29, 2016, from 9:00 a.m. to 1:00 p.m.

ADDRESSES: The meeting will be held at the Omni Shoreham Hotel, 2500 Calvert St. NW., Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: Dr. Minh Wendt, Alternate Designated Federal Officer, ACMH; Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-8222, Fax: 240-453-8223; OMH-ACMH@hhs.gov

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health in improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the Office of Minority Health.

Topics to be discussed during this meeting will include strategies to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities, as well as other related issues.

Public attendance at this meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person at least fourteen (14) business days prior to the meeting. Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to three minutes per speaker. Individuals who would like to submit written statements should mail or fax their comments to the Office of Minority Health at least seven (7) business days prior to the meeting. Any members of the public who wish to have printed material distributed to ACMH committee members should submit their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business on Thursday, January 21, 2016.

Dated: December 29, 2015.

Minh Wendt,

Alternate Designated Federal Officer, ACMH, Office of Minority Health, U.S. Department of Health and Human Services.

[FR Doc. 2015-33157 Filed 1-4-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA) will be holding a meeting to continue discussions and possibly develop recommendations regarding People Living with HIV/AIDS. PACHA members will have discussions regarding Health System Transformations, community approaches to implementing the Updated National HIV/AIDS Strategy, and food as medicine. The meeting will be open to the public.

DATES: The meeting will be held on January 28, 2016, from 8:30 a.m. to approximately 5:00 p.m. (ET) and January 29, 2016, from 9:00 a.m. to approximately 12:30 p.m. (ET).

ADDRESSES: 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue SW., Room 443H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 205-1178. More detailed information about PACHA can be obtained by accessing the Council's Web site www.aids.gov/pacha.

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective treatment, prevention, and cure of HIV disease and AIDS, including considering common co-morbidities of those infected with HIV as needed to promote effective prevention and treatment and quality

services to persons living with HIV disease and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. The agenda for the upcoming meeting will be posted on the Council's Web site at www.aids.gov/pacha. PACHA was established by Executive Order 12963, dated June 14, 1995 as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies to promote effective prevention and cure of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

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Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at caroline.talev@hhs.gov. Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at caroline.talev@hhs.gov by close of business on January 21, 2016. Members of the public will have the opportunity to provide comments at the meeting. Any individual who wishes to participate in the public comment session must register with Caroline Talev at caroline.talev@hhs.gov by close of business on January 21, 2016; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for