Assistance Funding authorized by the American Rescue Plan Act of 2021.

DATES: *Comments due within 14 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above and below.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be submitted by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF programs require detailed financial information from their grantees that allows ACF to monitor various specialized cost categories within each program, to closely manage program activities, and to have sufficient financial information to enable periodic thorough and detailed audits. The Generic Clearance for Financial Reports used for ACF Mandatory Grant Programs allows ACF programs to efficiently develop and receive approval for financial reports that are tailored to specific funding recipients and the associated needs of the program. For more information about the umbrella generic, see: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202108-0970-002.*

This specific GenIC applies to all state, territory, and tribal grantees awarded TANF Pandemic Emergency Assistance Funding as authorized by the American Rescue Plan Act of 2021 (Pub. L. 117–2). Section 403(c)(6)(A) of the Social Security Act was augmented by the passage of Public Law 117–2 with this opportunity for funding to provide non-recurrent, short term benefits and associated administrative costs to supplement, but not supplant, other federal, state, tribal, territorial, or local funds in meeting the emergency needs of recipients. These federal funds will serve as payment for expenditures incurred from April 1, 2021, to September 30, 2022, and if available, any unspent funds will be reallotted and available for expenditure for another 12 months.

All grantees must complete reporting once a year in accordance with Office of Family Assistance program policy governing the administration of PEAF Statute. The accompanying instructions and terms and conditions of the grant will provide guidance and assist grantees with this requirement.

Respondents: States, Territories, Tribes, and Tribal Consortia awarded TANF Pandemic Emergency Assistance Funding funds authorized by the American Rescue Plan Act of 2021.

ANNUAL BURDEN ESTIMATES

Title of information collection	Number of respondents	Annual frequency of responses	Hourly burden per response	Annual hourly burden
ACF–196P	137	1	6	822

Estimated Total Annual Burden Hours: 822.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 14 days of this publication.

Authority: Pub. L. 117–2; Section 403(c)(6)(A) of the American Rescue Plan Act of 2021.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–19459 Filed 9–7–21; 8:45 am]

BILLING CODE 4184–56–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3263]

Request for Nominations for Voting Members on a Public Advisory Committee; the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Tobacco Products Scientific Advisory Committee, in the Center for Tobacco Products. 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 November 8, 2021 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after November 8, 2021 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 Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website by using the following link: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, the primary contact is:* Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of FDA (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates behavior, dependence, and health issues, among others, relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Criteria for Voting Members

The Committee shall consist of 12 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of science, medicine, medical ethics, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. The Committee shall include nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members shall be scientists, physicians, dentists, or healthcare professionals practicing in the areas of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, epidemiology, behavioral health, or any other relevant specialty. One member shall be an officer or employee of a state or local government or of the Federal Government. The final voting member shall be a representative of the general public. Members will be invited to serve for terms of up to 4 years.

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 and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19444 Filed 9–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5464]

Center for Drug Evaluation and Research Office of New Drugs Novel Excipient Review Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is announcing a Novel Excipient Review Pilot Program (Pilot Program). The Pilot Program is voluntary and intended to allow excipient manufacturers to obtain FDA review of certain novel excipients prior to their use in drug formulations. The Pilot Program seeks to foster development of excipients that may be useful in scenarios in which excipient manufacturers and drug developers have cited difficulty in using existing excipients.

DATES: FDA is seeking initial proposals for the voluntary Novel Excipient Review Pilot Program through December 7, 2021.

FOR FURTHER INFORMATION CONTACT: Felecia Wilson, Center for Drug Evaluation and Research, Food and Drug Administration, *Novel-Excipient-Program@fda.hhs.gov,* 301–796–9590.

SUPPLEMENTARY INFORMATION:

I. Background

Excipient manufacturers and drug developers have cited product development challenges related to the use of certain excipients (also known as inactive ingredients), including issues related to formulation and stability. Novel excipients might be able to address some of these issues and provide additional public health benefits, such as enhanced drug bioavailability, more comfortable drug administration, new abuse-deterrent opioid formulations, new routes of drug delivery, and facilitation of new technologies. However, drug developers report that they have been hesitant to use novel excipients in drug development programs due to the uncertainty surrounding their acceptability.

To address these issues, FDA issued a request for information in the **Federal Register** on December 5, 2019 (84 FR 66669), seeking comment on a potential pilot program for FDA review of novel excipients. FDA received several comments to the public docket on these issues. After considering these comments, CDER has decided to establish this Pilot Program.

A. Scope

For purposes of the Pilot Program, an *excipient* is any ingredient intentionally added to a drug product (including a biological drug product) that is not intended to exert therapeutic effects at the intended dosage, although it may improve product delivery (see FDA guidance for industry entitled ''Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients'' (Ref.1)). Examples of excipients may include fillers, extenders, diluents, surfactants, solvents, emulsifiers, preservatives, flavors, absorption enhancers, modified release matrices, and coloring agents. Also, for purposes of this Pilot Program, a *novel excipient* is any excipient that is not fully supported by existing safety data with respect to the currently proposed level of exposure, duration of exposure, or route of administration (Ref. 1). This parallels the definition of ''new excipients'' defined in Ref. 1.

CDER proposes a more limited scope for this Pilot Program. The Pilot Program will initially be available for novel excipients that (1) have not been previously used in FDA-approved drug products, and (2) do not have an established use in food. CDER recognizes that there may be novel excipients not meeting this scope that may also address product development challenges or provide public health benefits. However, because of the limited scope of the initial phase of the Pilot Program (described further below), CDER will not be able to consider submissions for all kinds of novel excipients. CDER may expand the scope of the Pilot Program in the future depending on its success and as resources allow.

The Pilot Program is voluntary. Existing processes for developing excipients for use in drug and biological products continue to be available.