practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Competitive Generic Therapies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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 314.94, including the submission of ANDAs and designations such as CGT product development, have been approved under OMB control number 0910–0001 (including 0910–0338 for Form FDA 356h). The collections of information associated with product development meetings, presubmission meetings, and mid-review cycle meetings between applicants and FDA have been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 12, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02598 Filed 2–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions

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.

DATES: Fax written comments on the collection of information by March 21, 2019.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0546. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Food Additive Petitions and Investigational Food Additive Exemptions—21 CFR 570.17, 571.1, and 571.6

OMB Control Number 0910–0546—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the FD&C Act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petitioner to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of § 409 of the FD&C Act, we issued procedural regulations under 21 CFR part 571. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 501, 573, and 579. The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

Regarding the investigational use of food additives, § 409(j) of the FD&C Act (§ 409(j)) (21 U.S.C. 348(j)) provides that any food additive, or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of § 409(j), we issued regulations under 21 CFR 570.17. These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in 21 CFR 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17, which is the subject of this same OMB clearance for investigational food additive files.

The information collected is necessary to protect the public health. We use the information submitted by food manufacturers or food additive manufacturers to ascertain whether the data establish the identity of the substance, justify its intended effect in/on the food, and establish that its intended use in/on food is safe.

Description of Respondents: Respondents to this collection of information are food manufacturers or food additive manufacturers.

In the **Federal Register** of August 3, 2018 (83 FR 38149), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions:					
571.1(c) Moderate Category	12	1	12	3,000	36,000
571.1(c) Complex Category	12	1	12	10,000	120,000
571.6 Amendment of Petition	2	1	2	1,300	2,600
Investigational Food Additive Files:					
570.17 Moderate Category	4	1	4	1,500	6,000
570.17 Complex Category	5	1	5	5,000	25,000
Total Hours					189,600

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

We base our estimate of the total annual responses on submissions received during fiscal years 2016 and 2017. We base our estimate of the hours per response upon our experience with the petition and filing processes.

§ 571.1(c) Moderate Category: For a food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 36,000 hours.

§ 571.1(c) Complex Category: For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 120,000 hours.

§ 571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, two respondents will each submit one such amendment, for a total of 2,600 hours.

§ 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, four respondents will each submit one such file, for a total of 6,000 hours.

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, five respondents will each submit one such file, for a total of 25,000 hours.

The burden for this information collected has not changed since the last OMB approval.

Dated: February 12, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02596 Filed 2–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary's Advisory Committee on Infant Mortality (ACIM) has scheduled a public meeting. Information about ACIM and the agenda for this meeting can be found on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: April 8, 2019, from 9:00 a.m. to 5:00 p.m. Eastern Time (ET) and April 9, 2019, from 9:00 a.m. to 3:30 p.m. ET.

ADDRESSES: This meeting will be held remotely via webinar. Instructions on how to access the meeting via webcast will be provided upon registration and on the committee's website at *https://www.hrsa.gov/advisory-committees/Infant-Mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: David S. de la Cruz, Ph.D., MPH, Designated Federal Official (DFO), Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18N–25, Rockville, Maryland 20857; 301–443–0543; or *dcruz@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIM was established under provisions of Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. ACIM is governed by provisions of the Federal Advisory Committee Act (Pub. L. 92–463). ACIM provides advice and recommendations to the Secretary of HHS regarding HHS programs and activities that focus on reducing infant mortality, improving the health status of infants and pregnant women, and factors affecting the continuum of care with respect to maternal and child health care. ACIM also focuses on: (1) Outcomes before, during, and following pregnancy and childbirth; (2) strategies to coordinate a myriad of federal, state, local, and private programs, and efforts that are designed to deal with the health and social problems impacting infant mortality; and (3) the implementation of the federal *Healthy Start Initiative: Eliminating Disparities in Perinatal Health.*

During the April 2019 meeting, ACIM will discuss updates from HRSA, MCHB, and other federal agencies pertinent to the work of the ACIM; the scope of work and priorities of the ACIM; feedback from ACIM members; and continue the discussion around how health equity is related to infant mortality. Agenda items are subject to change as priorities dictate; please refer to the ACIM website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to to ACIM should be sent to David S. de la Cruz, DFO, using the contact information above at least three business days prior to the meeting. Individuals who plan to attend and need special assistance or another reasonable accommodation should notify David S. de la Cruz at the address and phone number listed above