TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/section of FD&C Act	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating & maintenance costs
Foreign letter of approval—§ 801(e)(2)	38	1	38	3	114	$9,500

[1] There are no capital costs associated with this collection of information.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07915 Filed 4–4–13; 8:45 am]

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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) 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 May 6, 2013.

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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@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—(OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the 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 specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of section 409 of the FD&C Act, procedural regulations have been issued under part 571 (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 parts 501, 573, and 579 (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.

With regard to the investigational use of food additives, section 409(j) of the FD&C Act 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 section 409(j) of the FD&C Act, regulations have been issued under § 570.17 (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 part 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. In the **Federal Register** of November 13, 2012, (75 FR 67655), 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	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions					
571.1(c) moderate category	1	1	1	3,000	3,000
517.1(c) complex category	1	1	1	10,000	10,000
517.1(c) complex category	2	2	4	1,300	5,200

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					18,200

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

Section 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. An average of one petition of this type is received on an annual basis, resulting in a burden of 3,000 hours.

Section 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. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

Section 571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Investigation Food Additive Files					
570.17 moderate category	9	1	9	1,500	13,500
570.17 complex category	4	1	4	5,000	20,000
Total					33,500

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

Section 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. An average of nine files of this type is received on an annual basis, resulting in a burden of 13,500 hours.

Section 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. An average of four files of this type is received on an annual basis, resulting in a burden of 20,000 hours.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07892 Filed 4–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Preparation for International Cooperation on Cosmetics Regulation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled, ''International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR–7 Meeting.'' The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR–7 meeting that will be held in Japan on July 8 to 10, 2013.

DATES: *Date and Time:* The meeting will be held on May 8, 2013, from 2 p.m. to 4 p.m.

Location: The meeting will be held at the Food and Drug Administration, University Station Building, 4300 River Rd., Conference Room 3172 (third floor), College Park, MD 20740.

Contact Person: If you intend to participate in the meeting, you should register with Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, by email: *maria.cook@fda.hhs.gov* or Fax: 301–436–2975.

Registration and Requests for Oral Presentations: Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral presentation, to the contact person by April 22, 2013.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook (see *Contact Person*) by May 1, 2013.

You may present data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by April 22, 2013, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.