

enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

**Obtaining Copies of Proposals:** Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755.

Please cite OMB Control No. 9000-0070, Payments, in all correspondence.

Dated: February 23, 2016.

**Lorin S. Curit,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2016-04280 Filed 2-26-16; 8:45 am]

**BILLING CODE 6820-EP-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[CDC-2013-0025; Docket Number NIOSH-266]

#### Issuance of Final Publication

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of issuance of final publication.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), announces the availability of the following publication: *NIOSH Criteria for a Recommended Standard: Occupational Exposure to Heat and Hot Environments* [2016-106].

**ADDRESSES:** This document may be obtained at the following link: <http://www.cdc.gov/niosh/docs/2016-106/>.

**FOR FURTHER INFORMATION CONTACT:** Brenda Jacklitsch, NIOSH Education and Information Division, 1090 Tusculum Ave, Mail Stop C-32, Cincinnati, OH 45226, email address: [gwe6@cdc.gov](mailto:gwe6@cdc.gov).

Dated: February 19, 2016.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2016-04297 Filed 2-26-16; 8:45 am]

**BILLING CODE 4163-19-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0147]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On July 16, 2015, the Agency submitted a proposed collection of information entitled "Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910-0673. The approval expires on January 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 23, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-04222 Filed 2-26-16; 8:45 am]

**BILLING CODE 4164-01-P**

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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 March 30, 2016.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto: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 and 571 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 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. 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), regulations have been issued 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 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 October 21, 2015 (80 FR 63795), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup> FOOD ADDITIVE PETITIONS

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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
<b>Total Hours</b> .....					<b>158,600</b>

<sup>1</sup> 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 2014 and 2015. 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, 2 respondents will each submit 1 such amendment, for a total of 2,600 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup> INVESTIGATIONAL FOOD ADDITIVE FILES

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
570.17 Moderate Category .....	4	1	4	1,500	6,000
570.17 Complex Category .....	5	1	5	5,000	25,000
<b>Total Hours</b> .....					<b>31,000</b>

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

*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, 4 respondents

will each submit 1 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, 5 respondents will each submit 1 such file, for a total of 25,000 hours.

Dated: February 23, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-04228 Filed 2-26-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0921]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Reporting; Electronic Submissions

**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 March 30, 2016.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0645. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

##### II. Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803 (OMB Control Number 0910-0645)—Revision

The Safety Reporting Portal (SRP) and the Electronic Submission Gateway (ESG) are the Agency's electronic systems for collecting, submitting, and processing adverse event reports, product problem reports, and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, the Agency needs to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification process is the first necessary step that allows the Agency to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56, and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56, and 1271.350(a)). While adverse event reports submitted to FDA in paper format using Forms FDA 3500, 3500A, 1932, and 1932a, are approved under OMB control numbers 0910-0284 and 0910-0291, this notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, and currently approved under OMB control number 0910-0645.

##### III. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive several types of adverse event reports electronically via the SRP using rational questionnaires. In this notice, FDA seeks comments on the extension of OMB approval for the existing rational questionnaires; the proposed revision of the existing rational questionnaire for dietary supplements; the proposed revision of the existing

rational questionnaire for tobacco products; a proposed new rational questionnaire that will be used for a new safety reporting program for clinical trials and/or investigational use by the Center for Tobacco Products (CTP); and proposed new rational questionnaires that will be used for food, infant formula, and cosmetic adverse event reports.

##### A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-085) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines "reportable food" as an "article of food (other than infant formula or dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals." (See section 417(a)(2) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of FDA the responsibility for administering the FD&C Act, including section 417. The Congressionally identified purpose of the RFR is to provide "a reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health" (121 Stat. 965). We designed the RFR report rational questionnaire to enable FDA to quickly identify, track, and remove from commerce an article of food (other than infant formula and dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA's Center for Food Safety and Applied Nutrition (CFSAN) uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. The data elements for RFR reports remain unchanged in this request for extension of OMB approval.

##### B. Reports Concerning Experience With Approved New Animal Drugs

Section 512(l) of the FD&C Act (21 U.S.C. 360b(l)) and § 514.80(b) of FDA's regulations (21 CFR 514.80) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report