

review of inter-component organizational proposals. The Office develops policies and procedures for implementing organizational development activities and provides leadership of assigned ACF special initiatives arising from Departmental, Federal and non-Federal directives to improve service delivery to customers and to enhance employee work environment. The Office manages and coordinates designated incentive awards programs. The Office develops training policies and plans for ACF. It provides leadership in directing and managing Agency-wide staff development and training activities for ACF. OWPD is responsible for the functional management of all information technology and software training, common needs training, and management training in the Agency, including policy development, guidance, technical assistance, and evaluation of all aspects of career employee, supervisory, management and executive training. The Office provides leadership in managing/overseeing and monitoring the ACF Training Resource Center and the Computer Training and Information Centers. The Office develops and manages the consolidated training budget for the Agency.

V. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, KP. 20 Functions, add the following:

The Office of Diversity Management and Equal Employment Opportunity (ODME) serves as the principal advisor, through the Deputy Assistant Secretary for Administration, to the Assistant Secretary on all aspects of the Agency's Diversity Management and Equal Employment Opportunity programs.

The Office serves as the liaison between ACF and the HHS. ODME directs and manages the ACF Equal Employment Opportunity programs in accordance with Equal Employment Opportunity Commission (EEOC) regulations and HHS guidelines. The immediate oversight is provided by a staff under the direction of the ACF EEO Officer. ODME develops and evaluates programs and procedures designed to identify and eliminate discrimination in employment, training, incentive awards, promotion and career opportunities. They are responsible for implementing and evaluating a cost-effective, timely and impartial system for processing individual complaints of discrimination under the Title VII of the Civil Rights Act of 1964, as amended. The Staff provides information, guidance, advice and technical assistance to ACF supervisors and managers on affirmative employment planning and other means of achieving parity and promoting work force diversity. The Staff is responsible for ensuring that ACF-conducted programs create an environment that is free of discrimination, where all employees may work without fear of reprisal or discriminatory harassment; where qualified employees and applicants with disabilities receive reasonable accommodations; and where all employees are recognized for their individual performance and contributions to ACF, without regard to race, national origin, color, age, religion, sex (including pregnancy

and gender identity), sexual orientation, disability (physical or mental), status as a parent, genetic information, or other non-merit factor.

The staff is responsible for assessing current and future needs required to meet organizational goals and objectives and ensuring the diversity of ACF workforce. ODME works proactively to enhance the employment of women, minorities, veterans, and people with disabilities. This is achieved through policy development, oversight, complaints prevention, outreach, and education and training programs. The Staff implements the applicable provisions of the Americans with Disabilities Act of 1990.

Dated: November 1, 2012.

**George H. Sheldon,**

*Acting Assistant Secretary for Children and Families.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-1093]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions; Extension**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on food additive petitions regarding animal food.

**DATES:** Submit electronic or written comments on the collection of information by January 14, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Jonna Capezuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Drive, PI50-400B, Rockville, MD 20850, 301-796-3794.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### **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 (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.

FDA estimates 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 .....	1	1	1	3,000	3,000
571.1(c) Complex Category .....	1	1	1	10,000	10,000
571.6 Amendment of Petition .....	2	2	4	1,300	5,200
<b>Total Hours .....</b>	<b>4</b>	<b>4</b>	<b>6</b>	<b>14,300</b>	<b>18,200</b>

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

*§ 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 1 petition of this type is received on an annual basis, resulting in a burden of 3,000 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. An average of 1 petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

*§ 571.6:* For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of 4 petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup> INVESTIGATION 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 .....	9	1	9	1,500	13,500
570.17 Complex Category .....	4	1	4	5,000	20,000
<b>Total Hours .....</b>	<b>13</b>	<b>2</b>	<b>13</b>	<b>6,500</b>	<b>33,500</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. An average of 9 files of this type are received on an annual basis, resulting in a burden of 13,500 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. An average of 4 files of this type are received on an annual basis, resulting in a burden of 20,000 hours.

Dated: November 6, 2012.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public