4160-01-P

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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:

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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[1]
Food Additive Petitions

21 CFR Section	No. of Respondents	No. 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
Total Hours	4	4	6	14,300	18,200

[1] 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[1]
Investigation Food Additive Files

21 CFR Section	No. of Respondents	No. 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
Total Hours	13	2	13	6,500	33,500

[1] 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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