

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	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
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	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
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.

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

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy, and/or safety issues, the

comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: The National Health Service Corps (NHSC) Site Retention Assessment Questionnaire (OMB No. 0915-xxxx)—New

Abstract: The National Health Service Corps (NHSC) provides health professionals with loan repayment and scholarships in return for their service to underserved areas. The NHSC's mission is to improve access to primary care, which is supported by clinicians who remain in their sites well beyond their contracted periods of service. However, many sites are unaware of their influence and impact on clinician retention levels. The purpose of this project is to gather survey information from administrative officials at NHSC-approved sites that will guide NHSC initiatives and assist sites in improving their retention outcomes. The survey will ask site administrators to rate how difficult it is to retain clinicians, their general attitudes about the feasibility of good retention and awareness of its principles, their practices' current approaches to promoting retention, ratings on various aspects of their practices' organizational culture and

administrative style, and their sites' interest in and preferred ways of learning how to bolster retention. Survey data will be gathered anonymously and presented in aggregate, to promote administrators' participation and full disclosure.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and, to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC Site Retention Assessment Questionnaire	7,000	1	7,000	0.507	3,549
Total	7,000	1	7,000	0.507	3,549

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: November 7, 2012.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form

AGENCY: Indian Health Service, HHS.
ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review. This proposed information collection project was previously published in the **Federal Register** (77 FR 52748) on August 30, 2012, and allowed 60 days for public

comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917-0034, "Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form." *Type of Information Collection Request:* Extension without revision of the currently approved information collection, 0917-0034, "IHS Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form," which was previously approved under the title "Director's 3 Initiative Best Practice, Promising Practice, and Local Efforts Form." Although the name of the form has changed, the contents of the form remain the same. *Forms:* 0917-0034, "IHS Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form." *Need and Use of Information Collection:* The IHS goal is to raise the health status of the American Indian and Alaska Native (AI/