

Questionnaire has been developed by the NEDSS program to gather information needed for formulating a technical and project management support strategy for 57 reporting jurisdictions (i.e., 50 states, 5 territories, and 2 cities (New York City, NY and Washington, DC)) as they implement NEDSS messaging using MMGs. A jurisdiction's response to the questionnaire will be used by the NEDSS implementation and management teams to assess the jurisdiction's IT system environment and capacity and help determine the

project schedule and level of human and technical support needed to complete the jurisdiction's implementation of a nationally notifiable condition message. NEDSS infrastructure implementation support includes, but is not limited to implementing NEDSS Message Subscription Service (MSS) and NEDSS Messaging Solution (NMS) software in requesting jurisdictions; providing MSS and NMS software training and ongoing technical support; and distributing funding via the CDC Epidemiology and

Laboratory Capacity cooperative agreement.

Questionnaires will be distributed to jurisdictions that initiate MMG implementation for a condition; therefore, the maximum annual frequency of responses per jurisdiction is three. The NEDSS team will request the jurisdiction to voluntarily complete the questionnaire, but a response is not a pre-requisite for support.

There is no cost to respondents other than their time to participate in the survey. The total estimated annual burden hours are 114.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State, Territory and Local Public Health Department.	National Notifiable Condition Messaging Support Strategy Questionnaire.	57	3	40/60

Dated: August 23, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0258]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using Food and Drug Administration Form 3503

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 September 29, 2010.

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. All comments should be identified with the OMB control number 0910-0016. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

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.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using FDA Form 3503—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179, and 180 (OMB Control Number 0910-0016)—Revision

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: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the FD&C Act that describes the condition(s) under which the additive may be safely used; (2) the additive and

its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the FD&C Act is effective. Food additive petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the FD&C Act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the agency's regulations (21 CFR 71.1) specifies the information that a

petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review color additive petitions to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a substance is Generally Recognized as Safe (GRAS) if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The FD&C Act historically has been interpreted to permit food manufacturers to make their own initial determination that use of a substance in food is GRAS and thereafter seek affirmation of GRAS status from FDA. FDA reviews petitions for affirmation of GRAS status that are submitted on a voluntary basis by the food industry and other interested parties under authority of sections 201, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 342, 348, and 371). To

implement the GRAS provisions of the act, FDA has set forth procedures for the GRAS affirmation petition process in § 170.35(c)(1) of its regulations (21 CFR 170.35(c)(1)). While the GRAS affirmation petition process still exists, FDA has not received a GRAS affirmation petition since the establishment of the voluntary GRAS notification program and is not expecting any during the period covered by this proposed extension of collection of information.

Currently, interested persons may transmit regulatory submissions to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503 for FAP and Form FDA 3504 for CAP. FDA is revising Form FDA 3503 to better enable its use for electronic submission and to permit its use for multiple types of submissions, which eliminates the need for Form FDA 3504. Because Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review, FDA now recommends that this form be used for FAPs and CAPs, whether submitted in electronic format or paper format. FDA estimates that the amount of time for respondents to complete the revised FDA Form 3503 will continue to be 1 hour. The revised Form FDA 3503 can be used to submit information to FDA in electronic format using the Electronic Submission Gateway portal. The revised Form FDA

3503 can be used to substitute for the "Dear Sir" section of 21 CFR 71.1(c) for a CAP and 21 CFR 171.1(c) for a FAP. The revised Form FDA 3503 provides for submitters to indicate the date of their most recent presubmission consultation activity with FDA. The revised Form FDA 3503 can also be used to organize information within a Master File submitted in support of petitions according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food and color additive approvals. The revised Form FDA 3503 is formatted to accept submissions for both FAP and CAP, thus making redundant Form FDA 3504 for collecting CAP submissions. Therefore, FDA is eliminating Form FDA 3504.

Description of respondents:

Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the **Federal Register** of June 14, 2010 (75 FR 33624), 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 BURDEN¹

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating and Maintenance Costs	Total Hours
70.25, 71.1	2	1	2	1,337	\$5,600	2,674
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	0	2,614
FAPs						
171.1	3	1	3	7,093	0	21,279
FDA Form 3503	6	1	6	1	0	6
Total					\$5,600	26,573

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

The estimate of burden for food additive, color additive, or GRAS affirmation petitions is based on FDA's experience and the average number of new petitions received in calendar years 2006, 2007, 2008, and 2009, and the total hours expended in preparing the petitions. In compiling these estimates, FDA consulted its records of the number

of petitions received in the past 4 years. The figures for "Hours per Response" are based on estimates from experienced persons in the Agency and in industry. Although the estimated hour burden varies with the type of petition submitted, an average petition involves analytical work and appropriate toxicological studies, as well as the

work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from \$1,600 to

\$3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is \$2,600 and the maximum color additive petition fee for a Category B petition is \$3,000. Because an average of two color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to \$5,600 (1 x \$2,600 + 1 x \$3,000 listing fees = \$5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: August 19, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Funding Opportunity

Purpose of Notice: Availability of funding opportunity announcement.

Funding Opportunity Title/Program Name: Older Americans Act (OAA),

Title VI, Part A: Grants for Native Americans; Part B: Grants for Native Hawaiian Programs; and Part C: Grants for the Native American Caregiver Support Program.

Announcement Type: This is the initial announcement for this funding opportunity.

Funding Opportunity Number: Program Announcement No. is HHS-2011-AoA-TitleVI-1101.

Statutory Authority: The Older Americans Act, Public Law 109-365.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.047, Title VI Parts A and B and 93.054, Title VI Part C.

Dates: The deadline date for the submission of applications is November 30, 2010.

I. Funding Opportunity Description

This announcement seeks proposals for grants to provide nutritional and supportive services to Indian elders and Alaskan Natives under Part A; Native Hawaiian elders under Part B; and Family Caregiver support services under Part C of the OAA. The goal of these programs is to increase home and community-based services to older Indians, Alaskan Natives and Native Hawaiians, that respond to local needs and are consistent with evidence-based practices. A detailed description of the funding opportunity may be found at <http://www.grants.gov>, <http://www.aoa.gov> under Grant Opportunities → Funding Opportunities, or <http://www.olderindians.org>.

II. Award Information

1. Funding Instrument Type

Grant.

2. Anticipated Total Priority Area Funding per Budget Period

The Administration on Aging (AoA) will accept applications for funding for a three-year project period, April 1, 2011 to March 31, 2014, in FY 2011 under the OAA, Title VI, Part A: Grants for Native Americans; Part B: Grants for Native Hawaiian Programs; and Part C: Grants for the Native American Caregiver Support Program. Current annual funding levels for Title VI, Part A and Part B range from \$76,160 to \$186,000. Current annual funding levels for Title VI, Part C range from \$14,410 to \$57,680. Distribution of funds among tribal organizations and Native Hawaiian organizations is subject to the availability of appropriations to carry out Title VI. Funding is based on the number of eligible elders age 60 and older in your proposed service area. Successful applications from current

grantees will receive priority consideration. Successful applications from new applicants will be funded pending the availability of funds or at the discretion of the Assistant Secretary for Aging. For those applying for Title VI, Parts A or B funding you have the option to also apply for Part C. However, to apply for Part C, you must apply for both Part A and Part C or Part B and Part C.

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants

Eligibility for grant awards is limited to all current Title VI, Part A and Part B grantees; current grantees who wish to leave a consortium; and eligible federally recognized Indian tribal organizations that are not now participating in Title VI and would like to apply as a new grantee. Those tribes who were a part of a consortium receiving a Title VI grant in 1991 and applying individually will be considered a "current grantee." Proof of being a part of a consortium that was funded in FY 1991 must be submitted as part of the application. A tribal organization or Indian tribe must meet the application requirements contained in sections 612(a), 612(b), and 612(c) of the OAA and 45 CFR 1326.19. A public or nonprofit private organization serving Native Hawaiians must meet the application requirements contained in sections 622(1), 622(2), and 625 of the OAA and 45 CFR 1328.19. Under the Native American Caregiver Support Program, a tribal or Native Hawaiian organization must meet the requirements as contained in section 631 of the OAA. These sections are described in the application kit.

2. Cost Sharing or Matching

Cost Sharing or matching does not apply to these grants.

3. D-U-N-S Number

All grant applicants must obtain a D-U-N-S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number is free and easy to obtain from http://www.dnb.com/US/duns_update/ or by calling their live help line at 1-888-814-1435. Applicants are also encouraged to check their Web site for other pertinent information regarding this process.

4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal