CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Dated: January 12, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–700 Filed 1–18–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0014]

Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Electronic Submission Using Food and Drug Administration Forms 3503 and 3504

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 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 the information collection provisions of FDA's regulations for submission of petitions, including food and color additive petitions (including labeling) and generally recognized as safe (GRAS) affirmations, and electronic submission using FDA Forms 3503 and 3504. This notice also notifies the public of, and solicits comments on, FDA's proposal to transfer the collection of information and burden associated with petitions submitted to amend the indirect food additive regulations from the subject collection of information Office of Management and Budget (OMB) control number 0910–0016 to the collection of information for the Food Contact Substances Notification System (OMB control number 0910–0495).

DATES: Submit written or electronic comments on the collection of information by March 20, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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 Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Electronic Submission Using FDA Forms 3503 and 3504—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179, and 180 (OMB Control Number 0910–0016)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the 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 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 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 (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 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 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 (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.

Under section 201(s) of the act (21 U.S.C. 321(s)), a substance is 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 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 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) (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.

In the **Federal Register** of July 31, 2001 (66 FR 39517), FDA announced the availability of a draft guidance entitled ''Draft Guidance for Industry on Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions.'' This guidance describes the procedures for electronic submission of FAPs and CAPs using FDA Form 3503 and FDA Form 3504, respectively.

FDA scientific personnel review food and color additive and GRAS affirmation petitions to ensure the safety of the intended use of the substance in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food (or for color additives, its use in food, drugs, cosmetics, or medical devices).

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.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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
CAPs						
70.25, 71.1	3	1	3	1,337	$8,200	4,010
FDA Form 3504	1	1	1	1	0	1
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	0	2,614
FAPs						
171.1	6	1	6	7,093	0	42,560
FDA Form 3503	1	1	1	1	0	1
Total					$8,200	49,186

[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 2003, 2004, and 2005, 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 3 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 two category A and one category B color additive petitions are 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. Since an average of three color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this start-up cost would be less than or equal to $8,200 ((2 x $2,600) + (1 x $3,000) = $8,200). There are no capital costs associated with color additive petitions.

The estimated burden reported in table 1 of this document does not include the previously estimated burden for the preparation of FAPs submitted to amend parts 175 throuhg 178 (21 CFR parts 175 through 178). The burden to respondents is similar between the preparation of petitions submitted to amend parts 175 through 178 and the preparation of a food contact substance notification. In this request for extension of OMB approval for the collection of information for FAPs, FDA proposes to transfer the collection of information and burden associated with petitions submitted to amend the indirect food additive regulations (parts 175 through 178) from this collection of information (OMB control number 0910–0016) to the existing collection of information for the Food Contact Substances Notification System (OMB control number 0910–0495).

FDA estimates the annual reporting burden associated with petitions submitted to amend parts 175 through 178 to be transferred from OMB control number 0910–0016 to OMB control number 0910–0495. An average of two indirect food additive petitions are expected per calendar year. The estimated total annual hour burden to

petitioners per petition is 10,995 hours, for a total burden of 21,990 hours. There are no capital costs or operating and maintenance costs associated with the burden hours being transferred from OMB control number 0910–0016 to OMB control number 0910–0495.

Electronic submissions of petitions contain the same petition information required for paper submissions. The agency estimates that one petitioner for both food and color additives will take advantage of the electronic submission process per year. By using the guidelines and forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (Form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

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 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 under § 70.25, labeling requirements 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.

In cases where a regulation implements a statutory information collection requirement, only the additional burden attributable to the regulation, if any, has been included in FDA's burden estimate.

Dated: January 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–681 Filed 1–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 as Amended by Section 102 of the REAL ID Act of 2005 and as Amended by the Secure Fence Act of 2006

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations and other legal requirements in order to ensure the expeditious construction of physical barriers and roads in the vicinity of the international land border of the United States in Arizona. The Secretary's waiver is effective upon publication of this Notice.

DATES: This Notice is effective on January 19, 2007.

Determination and Waiver: In section 102(a) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104–208, Div. C, 110 Stat. 3009–546, 3009–554 (Sept. 30, 1996) (8 U.S.C. 1103, note), Congress provided that the Attorney General shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. Pursuant to sections 1511 and 1517 of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 2309, 2311 (Nov. 25, 2002) (6 U.S.C. 551, 557), the authorities of the Attorney General contained in section 102 of the IIRIRA were transferred to the Secretary of Homeland Security (Secretary).

In section 3 of the Secure Fence Act of 2006 (Secure Fence Act), Public Law 109–367), Congress amended Section 102(b) of IIRIRA to provide for the installation of fencing, barriers, roads, lighting, cameras, and sensors along five segments of the southern border of the United States, including much of the border between Arizona and Mexico. In section 102(c) of the IIRIRA, as amended by section 102 of the REAL ID Act of 2005, Public Law 109–13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (REAL ID Act) (8 U.S.C. 1103 note), Congress granted the Secretary ''authority to waive all legal requirements such Secretary, in such Secretary's sole discretion, determines necessary to ensure the expeditious construction of barriers and roads under'' section 102 of IIRIRA.

I have determined that the area in the vicinity of the United States border known as the Barry M. Goldwater Range (BMGR), as described in the Bureau of Land Management's ''Legal Description of Barry M. Goldwater Range Withdrawal, AZ'' (66 FR 59813 (November 30, 2001)), in southwestern Arizona, including the adjacent area to the west of the BMGR, is an area of high illegal entry. This area is also within the footprint of infrastructure provided for in Section 102(b)(1)(A)(ii) of IIRIRA as amended by the Secure Fence Act. There is presently a need to construct fixed and mobile barriers (such as fencing, vehicle barriers, towers, sensors, cameras, and other surveillance, communication, and detection equipment) and roads in the vicinity of the border of the United States within and in the vicinity of the BMGR. In order to ensure the expeditious construction of the barriers and roads that Congress prescribed in sections 102(a) and 102(b) of the IIRIRA in the BMGR, which is an area of high illegal entry into the United States, I have determined that it is necessary to exercise the authority that was transferred to me by sections 1511 and 1517 of the HSA and that is vested in me by section 102(c) of the IIRIRA as amended by section 102 of the REAL ID Act.

Accordingly, with respect to the construction, as prescribed in sections 102(a) and 102(b) of the IIRIRA, of roads and fixed and mobile barriers within the BMGR and within five miles to the west of the BMGR (including, but not limited to, accessing the project area, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of fences, roads, supporting elements, drainage, erosion controls, safety features, surveillance, communication, and detection equipment of all types, radar and radio towers, and lighting), I hereby waive, in their entirety, all Federal, State, or other laws, regulations and legal requirements of, deriving from, or related to the subject of, the following laws, as amended: the National Environmental Policy Act (Pub. L. 91–190, 83 Stat. 852, (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*)); the Endangered Species Act (Pub. L. 93–205, 87 Stat. 884 (Dec. 28, 1973) (16 U.S.C. 1531 *et seq.*)); the Federal Water Pollution Control Act (commonly referred to as the Clean Water Act) (Act of June 30, 1948, c. 758, 62 Stat. 1155 (33 U.S.C. 1251 *et seq.*)); the Wilderness Act (Pub. L. 88–577, 16 U.S.C. 1131 *et*