understanding the health effects of asbestos and mineral fibers, and

(5) The appropriateness and relevancy of the discussion of the path forward and whether the ultimate vision is a reasonable outcome for the proposed research strategy for asbestos and mineral fibers.

Status: The forum will include scientists and representatives from various government agencies, industry, labor, and other stakeholders, and is open to the public, limited only by the space available. Persons wanting to attend and provide oral comments at the meeting are requested to notify Diane Miller no later than May 1, 2007 to reserve time for their comments. Those interested in attending without providing oral comments at the meeting also are requested to notify Ms. Miller by May 1, 2007 to reserve a seat. Ms. Miller can be reached by telephone at 513/533–8450 or by e-mail at *niocindocket@cdc.gov.* Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved walk-in attendees will be accommodated on the day of the meeting if space is available.

Persons wanting to provide oral comments will be permitted up to 15 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting will be recorded and included in the docket. Written comments will also be accepted at the meeting. Written comments may also be submitted to Diane Miller, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226, telephone 513/533–8450. All material submitted to the Agency should reference docket number NIOSH–099 and must be submitted by May 31, 2007 (public review closing date) to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. Please make reference to docket number NIOSH–099.

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, relevant to the characterization of exposures and possible health risks of occupational exposure to asbestos and other mineral fibers. Examples of requested information include, but are not limited to, the following:

(1) Identification of industries, occupations, and processes where exposure to mineral fibers may occur, including exposure to fiber-like cleavage fragments and thoracic-sized fibers (as defined in the draft NIOSH document).

(2) Current and historical mineral fibers exposure measurement data, including exposure to fiber-like cleavage fragments and thoracic-sized fibers at various types of industries and jobs.

(3) Case reports or other health information demonstrating health effects in workers exposed to mineral fibers, including exposure to fiber-like cleavage fragments and thoracic-sized fibers.

(4) Reports of experimental *in vivo, in vitro,* and inhalation studies with rodents that provide evidence of biopersistence and/or of a dose-relationship between the particle dimension (*e.g.*, fiber) of the mineral and its biological activity.

(5) Information on sampling and analytical methods that could be used to improve the identification and differentiation of ''fibers'' of different dimensions and composition.

(6) Information on technologies that could be used to separate thoracic-sized fibers, including fiber-like cleavage fragments, into discrete size dimensions in quantities sufficient for conducting chronic rodent inhalation studies.

NIOSH will use this information to assess the scientific basis for the draft document and the need to revise research recommendations.

Contact Person for Technical Information: Paul Middendorf, telephone (513) 533–8606, M/S C–9, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Contact Person for Submitting Comments/Meeting Attendance: Diane Miller, Robert A. Taft Laboratories, 4676 Columbia Parkway, M/S C–34, Cincinnati, Ohio 45226, telephone (513) 533–8450. All material submitted to the Agency should reference Docket Number NIOSH–099.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: April 18, 2007.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–7882 Filed 4–24–07; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0014]

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; 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 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 May 25, 2007.

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: 202–395–6974. 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: 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: 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; Electronic Submission Using Food and Drug Administration Forms 3503 and 3504 (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 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 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. 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.

In the **Federal Register** of January 19, 2007 (72 FR 2533), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment that was outside the scope of the request for comments.

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 & 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 3 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 through 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: April 18, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–7813 Filed 4–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0475]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Tissue Intended for Transplantation

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 May 25, 2007.

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: 202–395–6974. All comments should be identified with the OMB control number 0910–0302. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Tissue Intended for Transplantation (OMB Control Number 0910–0302)—Extension

Under section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, through the use of human tissue for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are