speakers may wish to provide printed copies of their presentations for distribution. Presentations will be strictly limited to a maximum of 5 minutes. After reviewing all requests, NIOSH will notify each speaker of the order and approximate timing of the presentations. Speakers who are not ready when the preceding speaker has finished will be skipped, and the remaining speakers will be heard in order. At the conclusion of the meeting, as time permits, an attempt will be made to include presentations by scheduled speakers who missed their assigned slot. Attendees who wish to speak but did not submit a prior request also may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Interested parties may make hotel reservations directly with the Courtyard Marriott, 1960–A Chain Bridge Road, McLean, VA, 22102, telephone, (703) 790–0207, before the cut-off date of February 1, 2004. A special rate has been negotiated for meeting guests of $150.00 per night. The NIOSH B Reader Meeting must be referenced to receive these special rates.

Comments on the topics presented in this notice and at the meeting should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone: (513) 533–8303, fax: (513) 533–8285. Comments may also be submitted by e-mail to *niocindocket@cdc.gov.* E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Comments should be submitted no later than April 5, 2004, and should reference Docket Number NIOSH–015, B Reader Program, in the subject heading.

Purpose: Chest radiographic imaging is a widely applied and important tool for assessing lung health in clinical medicine, research investigations, hazard evaluations, and medical monitoring of workers exposed to silica, asbestos, coal, beryllium, and other dusts capable of producing occupational pneumoconiosis. Valid reproducible categorization of chest radiographic images requires close adherence to standard methods of radiograph classification and adoption of procedures for quality assurance. The International Labour Office (ILO) (Geneva) has for many years provided a standardized system for classification of chest radiographs for pneumoconiosis, including specification of procedures for obtaining images. The ILO system has been widely used by physicians and epidemiologic researchers in the investigation of work-related respiratory hazards.

Under the U.S. Code of Federal Regulations [42 CFR part 37], since 1970, chest radiographic examinations have been provided to underground coal miners at approximate five year intervals. As part of this mandated Coal Workers' Health Surveillance Program (CWHSP), NIOSH arranges for the determination of the presence and degree of dust-related changes on those films by physicians who have demonstrated proficiency in the ILO system. NIOSH developed and currently administers the B Reader Certification Program, a unique quality assurance program for training and certifying physicians who classify chest radiographs of pneumoconiosis. Under this Program, physicians who wish to obtain B Reader Certification must successfully complete an extensive initial examination. To demonstrate ongoing competence and maintain certification, every four years each individual who passed the initial examination must complete a recertification examination. Because the B Reader Certification Program objectively documents proficiency in the evaluation of lung images for occupational disease, it has attained high visibility in the U.S. and throughout the world. The Program continues to have important impacts on occupational lung disease research, surveillance, clinical practice, regulation, and litigation. Numerous research studies and hazard evaluations have relied upon the classification of chest radiographs by certified B Readers as a useful health outcome in the investigation and assessment of occupational health risks. State-based surveillance programs have utilized B Reader classifications as a criterion for identifying silicosis cases. The Occupational Safety and Health Administration (OSHA) asbestos standard (§ 1910.1001, App. E) requires that roentgenograms be interpreted and classified only by a B Reader, a board eligible/certified radiologist, or an experienced physician with known expertise in pneumoconioses. OSHA also specifies B Readers and the ILO classification in its safety and health standards for general industry (§ 1910.1001, App. E), construction (§ 1926.1101, App. E), and shipyard employment (§ 1915.1001, App. E).

The ILO, with NIOSH involvement and support, has recently completed a revision of the classification system (ILO 2000). Additionally, in the years since the development of the B Reader Certification process, the field of professional competency testing, as well as the field of radiology, have experienced considerable advances in knowledge, techniques, and methodology. The B Reader Certification Program has not been substantially revised since its first development, and would benefit from critical evaluation and modification in order to assure optimal test validity, reliability, and efficiency, and overall effectiveness of the Program. In order for NIOSH to maintain the B Reader Program as a contemporary, relevant, and effective quality assurance program for the classification of chest radiographs for occupational lung disease research and prevention, and to assure the Program is adherent to the ILO 2000 system, ongoing refinements and modifications are required to the B Reader examinations and related training activities and materials. This open meeting is intended to serve as an important additional step in the continuing evolution and improvement of the NIOSH B Reader Program.

FOR FURTHER INFORMATION CONTACT: CWHSP, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888, *Telephone:* (304) 285–6263/5724, *Fax:* (304) 285–6058, *E-mail: CWHSP@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 21, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–29630 Filed 11–25–03; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0513]

Electronic Submissions of Food Contact Notifications; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking volunteers to participate in the Food Contact Notification (FCN) Electronic Submissions Pilot Project developed by

the Office of Food Additive Safety (OFAS) in the Center for Food Safety and Applied Nutrition (CFSAN). The purpose of the project is to test the efficiency and practicality of a prototype procedure for filing FCNs in electronic format as an alternative to the current paper-based process. FDA believes that this pilot will assist the agency in developing a draft guidance under its good guidance practice (GGP) procedures.

DATES: Submit written requests to participate in the pilot project by December 26, 2003. Comments on this pilot project may be submitted at any time. The pilot is anticipated to last 180 days beginning January 26, 2004.

ADDRESSES: Submit written requests to participate and comments regarding the pilot project to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Kenneth McAdams, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3392, e-mail: *kenneth.mcadams@cfsan.fda.gov*, or

Kimberly Smeds, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3424, e-mail: kimberly.smeds@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1997, the Food and Drug Administration Modernization Act of 1997 (FDAMA) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a premarket notification process as the primary method for authorizing new uses of food additives that are ''food contact substances.'' A food contact substance is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' The act further states that the notification process is to be utilized for authorizing the marketing of food contact substances except in instances where the Secretary of Health and Human Services determines that the submission and review of a food additive petition would be necessary to provide adequate assurance of safety, or where FDA and any manufacturer or supplier agree that a petition may be submitted. In the **Federal Register** of May 21, 2002 (67 FR 35724), the agency issued a final rule on premarket notification for food contact substances (21 CFR 170.100 through 170.106).

The FCN process has improved the efficiency of the FDA premarket approval of new food contact substances. More than 200 FCNs have become effective since the process began. FDA FORM 3480 currently provides the format by which information submitted in an FCN is organized to facilitate review by the agency. In order to further improve the efficiency of the FDA premarket approval of new food contact substances, FDA is developing a procedure to allow for the submission of FCNs in electronic format. This procedure includes the use of a software tool to assist a notifier in assembling an FCN. The present pilot project represents the final phase of the agency's development of the software tool for FCN submissions prior to FDA's announcing the availability of such a tool and accompanying guidance in accordance with the agency's GGPs under 21 CFR 10.115. FDA is initiating this pilot to obtain useful feedback during this initial phase in order to maximize efficiency and practicality of the electronic submission process before making it available to the general public for comment.

After completion of the pilot, FDA expects to issue guidance to the public for the electronic filing of FCNs in accordance with GGPs under 21 CFR 10.115.

II. Pilot Project Description

Due to the fact that a limited number of voluntary participants will be needed for the pilot, FDA will use its discretion in selecting the volunteers based on their previous experience in filing FCNs and on the number of FCNs they expect to file during the pilot. The sponsors who participate in the pilot will be asked to submit at least four FCNs in an electronic format during the pilot, using the procedure being tested. Existing regulatory requirements for the submission of FCNs will not be waived, suspended, or modified for the purposes of this pilot project.

The procedure uses an electronic fillable portable document format (PDF) version of FDA FORM 3480 that serves as an organizational backbone to which notifiers may attach studies, data, and other information in electronic format via a software package provided by the agency. It is designed to enable the notifier to submit all the items that constitute a complete FCN in a prescribed structure, removing the need for pagination and providing definitive locations within a set file structure for each type of information, so that the agency in turn can more efficiently review the submission. Pilot participants will be asked to use the procedure and software tool to submit FCNs electronically, and to provide feedback on the process to FDA. Because the process of receiving electronic submissions will be under development during the pilot, FDA will require that participants submit a signed paper copy of each submission along with the electronic version. The paper copy will serve as the official copy under existing regulations during the pilot project. FDA will provide written instructions to individual participants on using the software tool, on assembling and submitting an electronic FCN, and on how to provide feedback. Feedback from pilot participants will assist the agency in improving the software tool and completing development of the procedure.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29462 Filed 11–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0150]

Determination of Regulatory Review Period for Purposes of Patent Extension; ABILIFY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ABILIFY and is publishing this notice of that determination as required by law. FDA has made the determination