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 FDA believes that this pilot will assist the agency in developing a draft guidance under its good guidance practice (GGP) procedures.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

because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ABILIFY (aripiprazole). ABILIFY is indicated for the treatment of schizophrenia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ABILIFY (U.S. Patent No. 5,006,528) from Otsuka Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ABILIFY represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ABILIFY is 3,416 days. Of this time, 3,035 days occurred during the testing phase of the regulatory review period, while 381 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: July 11, 1993. The applicant claims July 10, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 11, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: October 31, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for ABILIFY (NDA 21–436) was initially submitted on October 31, 2001.

3. *The date the application was approved*: November 15, 2002. FDA has verified the applicant's claim that NDA 21–436 was approved on November 15, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination by January 26, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 24, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 30, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–29464 Filed 11–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–03–8001]

Memorandum of Understanding Between the Food and Drug Administration and the Centers for Disease Control

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration (FDA) and the Centers for Disease Control. The purpose of the MOU is to provide a framework for coordination and cooperation between the two agencies and to provide the principles and procedures by which information exchanges shall take place.

DATES: The agreement became effective June 19, 2003.

FOR FURTHER INFORMATION CONTACT: Ellen F. Morrison, Emergency Operations Center (HFC–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5660.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.