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.

Dated: November 13, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-03-8001 (formerly 225-00-8000)

MEMORANDUM OF UNDERSTANDING

Between the

FOOD AND DRUG ADMINISTRATION

And the

CENTERS FOR DISEASE CONTROL AND PREVENTION

I. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) provides a framework for coordination and collaborative efforts between these two agencies which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information exchanges between FDA and CDC shall take place.

This memorandum supersedes the Memorandum of Understanding Between the Centers for Disease Control and the Food and Drug Administration, dated 6/26/00, regarding the exchange of information and coordination of actions.

II. BACKGROUND

FDA and CDC are sister agencies within the Department of Health and Human Services. Both FDA and CDC exist and work to protect the public health but have different statutory mandates and responsibilities.

FDA is a regulatory agency responsible for protecting the public health through the regulation of food, cosmetics, and medical products, including human drugs, biological products, animal drugs, and medical devices. FDA administers the Federal Food, Drug, and Cosmetic Act and relevant sections of the Public Health Service Act, among other statutes. Among its duties, FDA approves pre-market applications, conducts inspections of manufacturing facilities, and monitors post-marketing adverse events. FDA also initiates civil and criminal litigation to enforce applicable laws and regulations.

CDC is charged with protecting the public health by providing leadership and direction in the prevention and control of diseases and other preventable conditions and by responding to public health emergencies. CDC administers relevant sections of the Public Health Service Act, the Occupational Safety and Health Act, the Clinical Laboratory Improvement Act, and the Federal Mine Safety and Health Act. CDC, among other activities, administers national programs for the prevention and control of communicable and vector-borne diseases, enforces quarantine regulations, and works

to monitor and control disease outbreaks.

CDC's and FDA's respective missions to protect the public health may overlap in a variety of ways depending upon the subject matter. Each agency has a responsibility to work collaboratively to protect and improve public health. It may sometimes be the case that FDA or CDC will be in possession of information that could be useful to the other agency in that agency's performance of its responsibilities. Timely sharing of information between CDC and FDA is therefore critical to protecting the public health.

III. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

A. Coordination and Collaboration Relative to Public Health Activities

It is mutually agreed that:

1. Each agency will coordinate and collaborate with the other agency to protect and improve the public health. To achieve this, each agency will utilize the expertise, resources, and relationships of the other agency in order to increase its own capability and readiness to respond to emergency situations. In addition, each agency will designate central contact points where communications from the other agency, dealing with matters covered by this agreement, should be referred.

2. Each agency will participate in periodic joint meetings to promote better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for questions and problems that may arise.

3. Each agency will notify the other agency as soon as possible when issues of mutual concern become evident.

4. Each agency will collaborate with the other agency in all investigations of mutual concern. Such collaboration may include providing alerts to the other agency regarding disease outbreaks encountered as part of its activities; providing technical advice in areas of recognized expertise; providing results of analysis; making available expert witnesses; and exchanging information as described in section III B.

5. Each agency will consult with the other before issuing press or scientific releases or publications that may have a significant impact on the other agency.

6. Each agency will refer its proposed regulations, guidances, or recommendations that may have a significant impact on the other agency for review and comment by that agency before publication.

7. This agreement does not preclude CDC or FDA from entering into other agreements which may set forth procedures for special programs which can be handled more efficiently and expertly by other agreements.

B. Principles and Procedures for the Exchange of Information That is Not Publicly Available

FDA and CDC agree that the following principles and procedures will govern the exchange of nonpublic information between the two agencies.

Although there is no legal requirement that FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. As sister public health agencies within the Department of Health and Human Services, there are no legal prohibitions that preclude FDA or CDC from sharing with each other most agency records in the possession of either agency. Both agencies recognize and acknowledge, however, that it is essential that any confidential information that is shared between FDA and CDC must be protected from unauthorized public disclosure. See e.g., 21 U.S.C. sec. 331(j); 18 U.S.C. section 1905; 21 C.F.R. Parts 20 and 21; 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. section 301(d). Safeguards are important to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or pre-decisional agency records; and information protected for national security reasons. Such safeguards also help guarantee FDA's and CDC's compliance with applicable laws and regulations.

To facilitate the sharing of information with each other, it is necessary that FDA and CDC implement procedures to ensure, at a minimum, that such sharing of information is indeed appropriate and that the recipient agency guards the confidentiality of all information received. [1] There are separate procedures, as described below, for routine requests for information and for emergency requests. It is incumbent upon both agencies to respond to requests for information in a timely manner. Any unauthorized disclosure of shared confidential information by the agency receiving the information shall be the responsibility of that agency.

1. Routine Requests for Information

a. The requesting agency must demonstrate, in writing, why it is necessary for it to obtain the requested information. This demonstration should consist of a summary that describes in detail the information requested (to facilitate identification of relevant records) and a brief statement of the purpose for which the information is needed. This request shall state which internal agency offices and/or individuals requested the
information. A model request letter is attached.

b. The agency receiving the request for information shall, based upon the

[1] It is assumed that each agency has implemented or will implement all data and information security requirements and has implemented or will implement, to the extent necessary and practicable, all data and information security recommendations.

sufficiency of the need-to-know demonstration described in section III B 1a above, determine whether it is appropriate to share the requested information with the requesting agency. The need-to-know threshold is a low one. As stated above, there is a presumption in favor of information exchange between FDA and CDC. An agency should only decide not to share information in response to a request if it has credible information and a reasonable belief that the requesting agency may not be able to comply with applicable laws or regulations governing the protection of non-public information or with the principles or procedures set forth in this MOU. If an agency decides that it is not appropriate to share information with the requesting agency, it shall describe to the requesting agency the reasons for such decision.

c. The requesting agency agrees that it shall comply with the following conditions:

– The requesting agency shall limit the dissemination of shared information it receives to internal agency offices and/or individuals that have been identified in its written request and/or have a need-to-know. The agency official who signs the request letter will be responsible for ensuring that there are no other recipients of the information.

– The requesting agency shall agree in writing not to publicly disclose any shared information in any manner including publications and public meetings. If the requesting agency wishes to disclose shared information, including information that it believes is publicly releasable, it shall first request and obtain the written permission of the agency that has shared the information. If the requesting agency receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the information-sharing agency for it to respond directly to the requester regarding the releasability of the information. In such cases, the agency making the referral will notify the requester that a referral has been made and that a response will issue directly from the other agency.

– The agency that shares information with the requesting agency shall include a transmittal letter, along with any agency records exchanged. The transmittal letter shall indicate the type of information (e.g., confidential commercial information, personal privacy, or pre-decisional). A model transmittal letter is attached.

– The requesting agency shall promptly notify the appropriate office of the information-sharing agency when there is any attempt to obtain shared information by compulsory process, including but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

– The requesting agency shall notify the information-sharing agency before

complying with any judicial order that compels the release of such information so that the agencies may determine the appropriate measures to take, including where appropriate the filing of a motion or an appeal with the court.

2. Emergency Requests for Confidential Information

In cases in which the requesting agency has a need to obtain certain information as soon as possible due to emergency circumstances, such as a foodborne illness outbreak, FDA and CDC may utilize the following procedures. These procedures are intended for use only in the case of an actual emergency situation and are not appropriate for routine requests for information.

a. The requesting agency shall indicate orally or in writing to the agency in possession of the relevant information that it has the need to obtain certain identifiable information as soon as possible due to the existence of emergency circumstances. The requesting agency shall also describe what the emergency circumstances are.

b. The requesting agency shall verbally agree to protect from unauthorized public disclosure any and all information that is shared, according to all applicable laws and regulations.

c. The existence of an actual emergency situation shall warrant, as determined by the agency in possession of the requested records, the waiver of the need-to-know demonstration and determination described above in section III B 1a and B 1b. However, once the requesting agency has obtained the information it seeks, it shall comply with those procedures set forth in section III B 1c above.

IV. NAME AND ADDRESS OF PARTICIPATING PARTIES

A. Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

B. Centers for Disease Control and Prevention
Public Health Service
Department of Health and Human Services
Atlanta, Georgia 30333

V. LIAISON OFFICERS

A. Contact for FDA:

Ellen F. Morrison, Director
Office of Crisis Management
Emergency Operations Center
Food and Drug Administration

Rockville, MD 20857
(301) 827-5660

B. Contact for CDC:

Associate Director for Science
Centers for Disease Control and Prevention
Atlanta, Georgia 30333
(404) 639-7240

VI. PERIOD OF AGREEMENT

This agreement becomes effective upon signature of both parties and will continue for three years. It may be modified by mutual consent or terminated by either party upon 120 days written notice.

Attachments
Model Request Letter
Model Transmittal Letter

APPROVED AND ACCEPTED FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

By: _____
Julie Louise Gerberding, M.D., M.P.H.
Director, Centers for Disease Control and Prevention

Date: JUN 19 2003

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By: _____
Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

Date: June 17, 2003

Model Language for Request

The Centers for Disease Control and Prevention (CDC) has requested the following information from FDA for the following purposes: [Identify information and purpose]

or

CDC hereby requests the following information from FDA that it will use for the following purposes: [Identify information and purpose]

CDC agrees that it will not publicly disclose any such information that FDA shares with it without prior written permission from FDA and that it will comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between CDC and FDA. Applicable laws and regulations prohibit the disclosure of such information. See, e.g., 21 U.S.C. §331(j); 18 U.S.C. §1905, 21 C.F.R. Parts 20 and 21, 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. §301(d).

CDC will limit dissemination of any shared information to the following CDC offices and/or employees: [Identify office(s) and/or employee(s)]

_____ _____

Name Date

[Signature and Date by CDC official with requisite responsibility and authority.]

Model Language for Request

The Food and Drug Administration (FDA) has requested the following information from the Centers for Disease Control and Prevention (CDC) for the following purposes: [Identify information and purpose]

or

FDA hereby requests the following information from CDC for the following purposes: [Identify information and purpose]

FDA agrees that it will not publicly disclose any such information that CDC shares with it without prior written permission from CDC and that it will comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between FDA and CDC. Applicable laws and regulations prohibit the disclosure of such information. See, e.g., 21 U.S.C. §331(j); 18 U.S.C. §1905, 21 C.F.R. Parts 20 and 21, 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. §301(d).

FDA will limit dissemination of any shared information to the following FDA offices and/or employees: [Identify office(s) and/or employee(s)]

_____ _____

Name Date

[Signature and Date by FDA official with requisite responsibility and authority.]

[Model Transmittal letter from CDC to FDA]

This letter accompanies agency records that the Center for Disease Control and Prevention (CDC) is sharing with the Food and Drug Administration (FDA) in response to FDA's request, dated _____ . These agency records contain one or more of the following categories of non-public information, including information the public disclosure of which may be prohibited by law:

[CDC checks applicable numbers below]

__ trade secrets;
__ confidential commercial or financial information;
__ information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
__ information subject to the Privacy Act;
__ intra-agency records;
__ records or information compiled for law enforcement purposes; or
__ information protected for national security reasons.

FDA shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that FDA and/or CDC may take appropriate measures, including filing a motion with the court or an appeal.

FDA has agreed, by this letter or e-mail and by a signed request letter dated _____ , not to publicly disclose the above-described information without prior written permission of CDC. FDA acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.C.§331(j); 18 U.S.C. §1905, 21 C.F.R. Parts 20 and 21, 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. §301(d). FDA also agrees to comply with the principles and procedures set forth in the Memorandum of Understanding between FDA and CDC, *cite*.

[Model Transmittal letter from FDA to CDC]

This letter accompanies agency records that the Food and Drug Administration (FDA) is sharing with the Center for Disease Control and Prevention (CDC) in response to CDC's request, dated _____. These agency records contain one or more of the following categories of non-public information, including information the public disclosure of which may be prohibited by law:

[FDA checks applicable numbers below]

__ trade secrets;
__ confidential commercial or financial information;
__ information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
__ information subject to the Privacy Act;
__ intra-agency records;
__ records or information compiled for law enforcement purposes; or
__ information protected for national security reasons.

CDC shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

CDC shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that the FDA and/or CDC may take appropriate measures including filing a motion with the court or an appeal.

CDC has agreed, by this letter or e-mail and by a signed request letter dated _____, not to publicly disclose the above-described information without prior written permission of FDA. CDC acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.C. §331(j); 18 U.S.C. §1905, and 21 CFR Parts 20 and 21, 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. §301(d). CDC also agrees to comply with the principles and procedures set forth in the Memorandum of Understanding between FDA and CDC, *cite*.

[FR Doc. 03–29497 Filed 11–25–03; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0504]

Medical Devices; Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Bundling Multiple Devices or Multiple Indications in a Single Submission." This guidance describes FDA's policy on bundling multiple devices or multiple indications in a single premarket submission. Under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the bundling policy takes on additional importance because of the fees that are now associated with certain submissions as well as the performance goals the agency has committed to meet. The guidance is being issued as final for immediate implementation with an