

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0002]

Determination That ABILIFY (Aripiprazole) Solution Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,”

which is generally known as the “Orange Book.” Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug product listed in the table is no longer being marketed.

Application No.	Drug	Applicant
NDA 021713	ABILIFY (aripiprazole) Solution; Oral, 1 milligram/1 milliliter.	Otsuka Pharmaceutical Development and Commercialization Inc., 2440 Research Blvd., Rockville, MD 20850.

FDA has reviewed its records and, under § 314.161, has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug product listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDA listed in this document are unaffected by the discontinued marketing of the products subject to that NDA. Additional ANDAs that refer to this product may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 16, 2015.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015-15327 Filed 6-22-15; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis and Sexually Transmitted Diseases (STD) Prevention and Treatment; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT).

Date and Time: July 28, 2015, 3:00 p.m.–4:00 p.m.

Place: This meeting is accessible via audio conference call and Adobe Connect Pro.

Status: This meeting is open to the public. The virtual meeting is available via teleconference line and Adobe Connect Pro Meeting and will accommodate approximately 100 people. Join the meeting by:

1. (Audio Portion) Calling the Toll-free Phone Number 1-800-369-3340 and providing the Public Participant Pass Code 8527572; and

2. (Visual Portion) Connecting to the Advisory Committee Adobe Connect Pro Meeting using the following URL: https://hrsa.connectsolutions.com/cdc-hrsa_AC/. (Copy and paste the above link into your browser if it does not work directly). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. Call (301) 443-9684 or send an email to sgordon@hrsa.gov if you have any questions, or send an email to CWilliams2@hrsa.gov if you are having trouble connecting to the meeting site.

Purpose: This Committee is charged with advising the Director, CDC, and the Acting Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs, the support of health care services to persons living with HIV/AIDS, and the education of health professionals and the public about HIV/AIDS, Viral Hepatitis, and other STDs.

Agenda: Agenda items include: (1) Discuss and vote on the "Resolution to express CHACHSPT's recognition on the 25th Anniversary of the Ryan White CARE Act"; and (2) hear the orientation session and discuss the purpose and role of the CHACHSPT. Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT:

Shelley B. Gordon, Senior Public Health Analyst, Health Resources and Services Administration, HIV/AIDS Bureau, Division of Policy and Data, 5600 Fishers Lane, Room 7C-26, Rockville, Maryland 20857, telephone (301) 443-9684, fax (301) 443-3343, or email sgordon@hrsa.gov.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015-15283 Filed 6-22-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999.

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Announcement of the elimination of the Public Health Service (PHS) review of non-federally funded research protocols involving marijuana and the utilization of the existing Food and Drug Administration (FDA) Investigational New Drug (IND) process for drug development.

DATES: Effective June 2015.

ADDRESSES: Not applicable.

FOR FURTHER INFORMATION CONTACT:

Christine Cichetti, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services; telephone (202) 619-0242; email: Christine.Cichetti@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: On May 21, 1999, the PHS review process was established in response to enhanced interest by the biomedical research community in determining the potential therapeutic benefits of marijuana. The original notice of policy change can be found at <http://grants.nih.gov/grants/guide/notice-files/not99-091.html>. The PHS review process, which includes a committee review of study protocols, helped create a pathway for non-federally funded researchers to conduct these studies. In order to further facilitate research, HHS recently re-evaluated the PHS review procedures to identify opportunities for increased efficiency. The Office of the Assistant Secretary for Health (OASH), in consultation with the National Institutes of Health (NIH) and FDA, determined that the PHS review overlaps in several important ways with FDA's IND process and is no longer necessary to support the conduct of scientifically-sound studies into the potential therapeutic uses of marijuana. The PHS review committee considers the following: Research quality; incorporation of elements of good clinical and laboratory research practices; emphasis on adequate and well-controlled clinical studies; and development of dosage forms of marijuana that would be an alternative to smoked marijuana. The FDA's IND review process considers similar research characteristics: Adherence to good clinical and laboratory practices; whether pivotal clinical trials to support the marketing of proposed drug products are adequate and well-controlled; and the therapeutic benefits and risks to study subjects, favoring dosage forms that would provide measured and consistent dosing to patients as well as reduced exposure to potentially harmful constituents. Therefore, while not identical, the two processes have similar goals (e.g., guiding research on drug development and assuring appropriate treatment of human subjects), share similar criteria for protocol reviews, and possess similar capacity to engage with federal experts for consultation. Based on these considerations, and in order to streamline the application and approval processes for cannabis research, the committee that conducts the PHS review shall be eliminated. Below are instructions for researchers interested in the acquisition of cannabis for medical research. Complete guidance can be found on the NIH/National Institute on Drug Abuse (NIDA) Web site: (<http://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program>).

Background

Under the 1961 international *Single Convention on Narcotic Drugs* (amended in 1972), cannabis is designated a Schedule I substance, and participating countries are required to restrict production, manufacture, possession, and distribution of marijuana except for medical and scientific purposes. The Drug Enforcement Administration (DEA) regulates the cultivation of marijuana for research purposes through licensing requirements and establishment of annual aggregate production quotas under the authority of the 1970 Controlled Substances Act (CSA), which implements the Single Convention.

Marijuana for use in research can be obtained through the NIDA Drug Supply Program. All applicants must fulfill the following criteria:

For non-NIH funded human research projects:

1. Demonstrate scientific validity and ethical soundness through review by the FDA's IND process. Research protocols will undergo a scientific review which assures the safety and rights of subjects and the scientific quality of the clinical investigations, and assesses the likelihood that investigations will yield data capable of meeting the statutory standards for drug marketing approval; and
2. Possess a DEA registration for marijuana, a Schedule I controlled substance under the CSA.

For NIH-funded projects:

1. Demonstrate scientific validity and ethical soundness through the NIH grant review process which consists of three steps: (1) The NIH peer review system, which assesses the scientific and technical merit of all grant applications; (2) the National Advisory Council of the funding institute, comprising eminent scientists as well as public members; and (3) the funding institute's Director, who makes the final funding decision on the merit of an application, based on peer review, public health significance, and institute priorities. To find studies approved through the NIH review process go to: <http://projectreporter.nih.gov/reporter.cfm>;
2. Have an active-status IND application on file with the FDA (for human research only), which has been evaluated by FDA and found safe to proceed. For additional information go to: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>; and