

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Determination That ABILIFY (Aripiprazole) Solution Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.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The Food and Drug Administration (FDA or Agency) has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness.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:
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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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and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

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