owners, suppliers, and employees, as well as recommendations on how to ensure that disadvantaged communities are not denied the wide range of opportunities made possible by next-generation networks. This agenda may be modified at the discretion of the ACDDE Chair and the DFO.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2017–18550 Filed 8–31–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5079]

Determination That NIZORAL (Ketoconazole) Tablets, 200 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA or Agency) has determined that NIZORAL (ketoconazole) tablets, 200 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 NIZORAL, and it will allow FDA to continue to approve ANDAs that reference NIZORAL as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Robin Fastenau, Center for Drug Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 240–402–4510.

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 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NIZORAL (ketoconazole) tablets, 200 mg, is the subject of NDA 018–533 and was originally held by Johnson & Johnson Research and Development, L.L.C., now known as Janssen Research & Development, L.L.C. (Janssen). It was initially approved on June 12, 1981. NIZORAL should be used only when other effective antifungal therapy is not available or tolerated and the potential benefits are considered to outweigh the potential risks. NIZORAL is indicated for the treatment of the following systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis.

In a letter dated May 22, 2008, Janssen, which at that time was operating as Johnson & Johnson Pharmaceutical Research & Development, L.L.C., acting on behalf of Ortho-McNeil-Janssen Pharmaceuticals, Inc., notified FDA that NIZORAL (ketoconazole) tablets, 200 mg, were being discontinued and requested withdrawal of NDA 018–533. In the **Federal Register** of October 13, 2015 (80 FR 61426), FDA announced that it was withdrawing approval of NDA 018–533, effective November 12, 2015.

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NIZORAL (ketoconazole) tablets, 200 mg, were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NIZORAL (ketoconazole) tablets, 200 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NIZORAL (ketoconazole) tablets, 200 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to NIZORAL. Additional ANDAs that refer to NIZORAL (ketoconazole) tablets, 200 mg, may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. 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: August 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18548 Filed 8–31–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4302]

Electronic Study Data Submission; Data Standards; Support End Date for Study Data Tabulation Model Version 1.2, Implementation Guide Version 3.1.2, and Implementation Guide Version 3.1.2, Amendment 1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the end of support for Version 1.2 of Clinical Data Interchange Standards Consortium Study Data Tabulation Model (SDTM) and an

update to the FDA Data Standards Catalog. FDA will continue its support of the newer SDTM Version 1.3 and Version 1.4, which have been listed in the FDA Data Standards Catalog since December 2012 and August 2015, respectively. FDA support for SDTM Version 1.2 will end for studies that start 12 months after March 15, 2018.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4302 for ''Electronic Study Data Submission; Data Standards, Support End Date for Study Data Tabulation Model Version 1.2, Implementation Guide Version 3.1.2, and Implementation Guide Version 3.1.2, Amendment 1.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Fatima Frye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002, 301–796–4863, email: *cder-edata@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911, email: *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published final guidance for industry ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data guidance) posted on FDA's Study Data Standards Resources Web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in new drug applications, abbreviated new drug applications, biologics license applications, and investigational new drug applications submitted to CDER or CBER by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for updates to standards (with the month and day for the transition date corresponding to March 15).

The transition date for the end of FDA support for SDTM Version 1.2, Implementation Guide Version 3.1.2, and Implementation Guide Version 3.1.2, Amendment Version 1.2 is March 15, 2018. Therefore, FDA support for SDTM Version 1.2, Implementation Guide Version 3.1.2, and Implementation Guide Version 3.1.2, Amendment 1.2 will end for studies that start after March 15, 2019. The FDA Data Standards Catalog (see *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*) will be updated to list March 15, 2019, as the ''date support ends.''

II. Electronic Access

Persons with access to the internet may obtain the referenced material at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.*

Dated: August 29, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–18566 Filed 8–31–17; 8:45 am]

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