Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal governments.

Number of Respondents and Responses: 750 respondents and 750 responses.

Estimated Time per Response: 1.5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection 47 U.S.C. 154, 254 and 303(r).

Total Annual Burden: 1,125 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality. Information collected in each application for universal service support will be made available for public inspection, and the Commission is not requesting that respondents submit confidential information to the Commission as part of the pre-auction application process. Respondents seeking to have information collected on an application for universal service support withheld from public inspection may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules, 47 CFR 0.459.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Commission will use the information collected to determine whether applicants are eligible to participate in auctions for Universal Service Fund support. On November 18, 2011, the Commission released an order comprehensively reforming and modernizing the universal service and intercarrier compensation systems to ensure that robust, affordable voice and broadband service, both fixed and mobile, are available to Americans throughout the nation. Connect America Fund et al., Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011) (USF/ICC Transformation Order). In adopting the USF/ICC Transformation Order, the Commission created the Connect America Fund (CAF) to help make broadband available to homes, businesses, and community anchor institutions in areas that do not, or would not otherwise, have broadband. In addition, the Commission created the Connect America Mobility Fund (MF) to ensure the availability of mobile broadband networks in areas where a private-sector business case is lacking and a separate and complementary one-time Tribal Mobility Fund Phase I to accelerate mobile voice and broadband availability in Tribal areas. Finally, the Commission created the Remote Areas Fund (RAF) to ensure that Americans living in the most remote areas in the nation, where the cost of deploying traditional terrestrial broadband networks is extremely high, can obtain affordable access through alternative technology platforms, including satellite and unlicensed wireless services.

To implement these reforms and conduct competitive bidding for CAF, MF, and RAF support, the Commission adopted new rules containing information collection requirements that would be used to determine whether an applicant is generally qualified to bid for universal service support. The Commission also adopted rules containing information collection requirements that would be used to determine whether an applicant is specifically qualified to bid for Phase I of the Mobility Fund and Tribal Mobility Fund.

Because support under Phase I of the Mobility Fund and Tribal Mobility Fund has been awarded, the Commission is revising the currently approved information collection to remove the information collections requirements that apply specifically to applicants seeking to participate in competitive bidding for Mobility Fund Phase I and Tribal Mobility Fund Phase I support and to retain only those information collections requirements that apply generally to applicants seeking to participate in competitive bidding for universal service support. The Commission also requests that the title of this information collection be changed to ''Section 1.21001, Participation in Competitive Bidding for Support; Section 1.21002, Prohibition of Certain Communications During the Competitive Bidding Process'' to reflect the revised information collection.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2017–18542 Filed 8–31–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee, Diversity and Digital Empowerment

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) announces the first meeting and agenda of the Advisory Committee on Diversity and Digital Empowerment (ACDDE).

DATES: Monday, September 25, 2017, beginning at 10:00 a.m.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Room TW–C305, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jamila Bess Johnson, Designated Federal Officer, Federal Communications Commission, Media Bureau, (202) 418–2608, *Jamila-Bess.Johnson@fcc.gov;* or Brenda Villanueva, Deputy Designated Federal Officer, (202) 418–7005, *Brenda.Villanueva@fcc.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to members of the public. The FCC will accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will also provide audio and video coverage of the meeting over the Internet at *www.fcc.gov/live.* Oral statements at the meeting by parties or entities not represented on the ACDDE will be permitted to the extent time permits and at the discretion of the ACDDE Chair and the DFO. Members of the public may submit comments to the ACDDE in the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the ACDDE should be filed in GN Docket No. 17–208.

Open captioning will be provided for this event. Other reasonable accommodations for persons with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please include a way for the FCC to contact the requester if more information is needed to fulfill the request. Please allow at least five days' notice; last minute requests will be accepted, but may not be possible to accommodate.

Proposed Agenda: At this meeting, the agenda will include introduction of members of the ACDDE, including the Committee Chair and Vice Chair, establish working groups that will assist ACDDE in carrying out its work, and generally discuss the Committee's mission to provide recommendations to the FCC on how to empower disadvantaged communities and accelerate the entry of small businesses, including those owned by women and minorities, into the media, digital news and information, and audio and video programming industries, including as

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