designated susceptible bacteria. Subsequent to the NDA approvals, the USPTO received patent term restoration applications for BAXDELA (U.S. Patent Nos. 7,728,143 and 8,252,813) from Melinta Therapeutics, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 2, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approvals of BAXDELA TABLETS and BAXDELA IV INJECTION represent the first permitted commercial marketing or use of the products. Thereafter, the USPTO requested that FDA determine the products' regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BAXDELA TABLETS is 5,813 days. Of this time, 5,569 days occurred during the testing phase of the regulatory review period, while 244 days occurred during the approval phase. These periods of time were derived from the following dates:

NDA 208610:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 22, 2001. Melinta Therapeutics, Inc., claims that July 27, 2001, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 22, 2001, which was 30 days after FDA receipt of the first IND.

2. *The date new drug application 208610 was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* October 19, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for BAXDELA (NDA 208610) was submitted on October 19, 2016.

3. *The date the application was approved:* June 19, 2017. FDA has verified the applicant's claim that NDA 208610 was approved on June 19, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,307 or 1,001 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12299 Filed 6–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–4812]

Determination That NIZORAL (Ketoconazole) Topical Cream, 2%, 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, Agency, or we) has determined that NIZORAL (ketoconazole) topical cream, 2%, 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. 6236, Silver Spring, MD 20993–0002, 301–796–8363.

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) topical cream, 2%, is the subject of NDA 019084, previously held by Johnson & Johnson Pharmaceutical Research and Development, LLC and initially approved on December 31, 1985. NIZORAL is indicated for the topical treatment of tinea corporis, tinea cruris, and tinea pedis caused by Trichophyton rubrum, T. mentagrophytes, and Epidermophyton floccosum; of tinea (pityriasis) versicolor caused by Malassezia furfur (Pityrosporum orbiculare); of cutaneous candidiasis caused by Candida spp.; and of seborrheic dermatitis.

In a letter dated August 25, 2004, Johnson & Johnson Pharmaceutical Research and Development, LLC requested withdrawal of NDA 019084 for NIZORAL (ketoconazole) topical cream, 2%. In the **Federal Register** of November 7, 2007 (72 FR 62858), FDA announced that it was withdrawing approval of NDA 019084, effective December 7, 2007.

Arent Fox LLP submitted a citizen petition dated December 19, 2018 (Docket No. FDA–2018–P–4812), under 21 CFR 10.30, requesting that the Agency determine whether NIZORAL (ketoconazole) topical cream, 2%, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NIZORAL (ketoconazole) topical cream, 2%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NIZORAL (ketoconazole) topical cream, 2%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NIZORAL (ketoconazole) topical cream, 2%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NIZORAL (ketoconazole) topical cream, 2%, 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 this drug product. Additional ANDAs for this drug product 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: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12308 Filed 6–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2039]

Development of Best Practices in Physiologically Based Pharmacokinetic Modeling To Support Clinical Pharmacology Regulatory Decision-Making; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), in collaboration with the Center for Biologics Evaluation and Research (CBER), is announcing a public workshop entitled ''Development of Best Practices in Physiologically Based Pharmacokinetic Modeling to Support Clinical Pharmacology Regulatory Decision-Making.'' The purpose of this public workshop is to discuss best practices and evidentiary criteria in the use of physiologically based pharmacokinetic (PBPK) modeling approaches to support regulatory decision-making; share experiences and cases where applying PBPK modeling and simulation highlight the opportunities and limitations of this approach; obtain input from stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making; and discuss the knowledge gaps and research needed to advance PBPK modeling sciences in drug development to support regulatory decisions. This public workshop is also being conducted to satisfy one of FDA's performance goals included in the sixth reauthorization of the Prescription Drug User Fee Amendments (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA), to hold a series of workshops related to model-informed drug development (MIDD).

DATES: The public workshop will be held on November 18, 2019, from 8 a.m. to 5 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, B and C), Silver Spring, MD 20993–0002. Entrance for public workshop participants (non-FDA employees) is through Building 1 where routine security procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Lauren Milligan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3159, Silver Spring, MD 20993–0002, 240–402–6421, email: *Lauren.Brum@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA, and in accordance with section I, part J of the PDUFA VI Performance Goals, FDA agreed to convene a series of workshops to identify best practices for MIDD (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf* at 27). FDA is conducting this workshop as part of the MIDD workshop series.

PBPK modeling is a drug development tool that mathematically integrates physiological, physicochemical, and drug-dependent preclinical and clinical information to predict an investigational drug's absorption, distribution, metabolism, excretion, and pharmacokinetics (PK). Over the past several decades, there has been extensive research using PBPK modeling and simulation to address a wide range of clinical questions, such as exploring the effects of extrinsic factors (*e.g.,* concomitant medications, food intake) and intrinsic factors (*e.g.,* age, organ dysfunction, disease status, genetics) on drug exposures.

FDA notes that PBPK modeling and simulation approaches are extensively used in regulatory submissions to predict the potential for drug-drug interactions and to support dosing recommendations for certain drugs when they are co-administered with metabolic enzyme modulators. However, challenges and knowledge gaps prevent PBPK modeling from being routinely used for specific regulatory decisions. Given the current limitations of the approach, it is important that the scientific community explore when, where, and how PBPK modeling and simulation may be applied in regulatory decision-making.

II. Objectives

The objectives of the workshop are to:

1. Discuss ''best practices'' in integrating in vitro and in vivo data to develop PBPK models and developing evidentiary criteria