

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under 21 CFR 10.30, requesting that the Agency determine whether NIZORAL (ketoconazole) topical cream, 2%, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that NIZORAL (ketoconazole) topical cream, 2%, was not withdrawn for reasons of safety or effectiveness.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petitioner has identified no data or other information suggesting that NIZORAL (ketoconazole) topical cream, 2%, was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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]

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## 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](mailto: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

for PBPK models to be used for regulatory decision-making.

2. Share experiences and cases applying PBPK modeling and simulation that highlight the opportunities and limitations of this approach.

3. Obtain input from the stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making.

4. Discuss the knowledge gaps and research needs to advance PBPK modeling sciences in drug development and regulatory evaluation.

A detailed agenda will be posted in advance of the workshop at <https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm>.

### III. Participating in the Public Workshop

**Registration:** Persons interested in attending this public workshop must register online by November 8, 2019, at <https://www.eventbrite.com/e/pbpk-modeling-to-support-clinical-pharmacology-regulatory-decision-making-tickets-59005519096>. Please provide complete contact information for each attendee.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lauren Milligan (see **FOR FURTHER INFORMATION CONTACT**) no later than November 8, 2019.

**Streaming Webcast of the Public Workshop:** This public workshop will also be webcast. A live webcast of this workshop will be available at <https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm> on the day of the workshop. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm>. It may be viewed at the Dockets

Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm>.

Dated: June 6, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-E-0047]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; ALUNBRIG

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ALUNBRIG and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 12, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 9, 2019. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 12, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery

service acceptance receipt is on or before that date.

#### 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-2018-E-0047 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ALUNBRIG." Received comments, those filed in a timely manner (see **ADDRESSES**), 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