designated susceptible bacteria. Subsequent to the NDA approvals, the USPTO received patent term restoration applications for BAXDELA (U.S. Patent Nos. 7,728,146 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]

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 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 seborrhoeic 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.