

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food from very small businesses; § 121.5.	18,080	1	18,080	0.5 (30 minutes) .....	9,040

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Certain facilities may qualify for an exemption under the regulations. Because these facilities must provide documentation upon request to verify

their exempt status, we have characterized this as a reporting burden. We estimate 18,080 respondents will prepare and update relevant files an

average of 30 minutes annually, for a total annual burden of 9,040 hours (30 minutes × 18,080 firms).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Food Defense Plan; § 121.126 .....	3,247	1	3,247	23 .....	74,681
Actionable Process Steps; § 121.130 .....	9,759	1	9,759	20 .....	195,180
Mitigation Strategies; § 121.135(b) .....	9,759	1	9,759	20 .....	195,180
Monitoring Corrective Actions, Verification; §§ 121.140(a) and 121.145(a)(1).	9,759	1	9,759	175 .....	1,707,825
Training; § 121.4 .....	367,203	1	367,203	0.67 (40 minutes) ....	246,026
Records; §§ 121.305 and 121.310 .....	9,759	1	9,759	10 .....	97,590
Total .....	.....	.....	.....	.....	2,516,482

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Under the regulations, an owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan, including written identification of actionable process steps, written mitigation strategies, written procedures for defense monitoring, written food defense corrective actions, and written food defense verification procedures. The estimated recordkeeping burden associated with these activities totals 2,516,482 annual recordkeeping burden hours and 409,486 annual recordkeeping responses.

We estimate an average of 3,247 firms will continue to need to create a food defense plan under § 121.126, that a one-time burden of 60 hours will be needed to create a plan, and that a burden of 10 hours will be required to update the plan. We annualize this estimate by dividing the total number of burden hours (70) over a 3-year period as reflected in table 2, row 1.

Under § 121.130, each of the estimated 9,759 food production facilities will identify and specify actionable process steps for its food defense plan. We estimate that an individual at the level of an operations manager incurs a burden of 20 hours for this activity, as reflected in table 2, row 2.

Under § 121.135(b), each of the estimated 9,759 food production

facilities must identify and implement mitigation strategies to provide assurances that any significant vulnerability at each step is significantly minimized or prevented, ensuring that the food manufactured, processed, packed, or held by the facility will not be adulterated. We do not specify a specific number or set of mitigation strategies to be implemented. Some of the covered facilities are already implementing mitigation strategies. We estimate that it requires an average of 20 hours per facility to satisfy the recordkeeping burden associated with these activities for a total of 195,180 hours, as reflected in table 2, row 3.

We estimate that the recordkeeping activities associated with monitoring, documenting mitigation strategies, and implementing necessary corrective actions require first-line supervisors or others responsible for quality control an average of 175 hours for each recordkeeping, and that these provisions apply to each of the 9,759 facilities. This results in a total of 1,707,825 annual burden hours, as reflected in table 2, row 4.

We estimate that recordkeeping activities associated with training under § 121.4 total 244,802 annual burden hours, as reflected in table 2, row 5. We estimate that there are 1.2 million employees working at the regulated facilities and that 30 percent of them

(367,203) require training. We estimate that the average burden for the associated recordkeeping activity is approximately 40 minutes (or 0.67 hours) per record.

Finally, we estimate the 9,759 food production facilities will fulfill the recordkeeping requirements under §§ 121.305 and 121.310, and that it will require an average of 10 hours per record, as reflected in table 2, row 6.

Dated: June 6, 2019.

**Lowell J. Schiller,**  
Principal Associate Commissioner for Policy.  
[FR Doc. 2019-12288 Filed 6-10-19; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2017-E-6740 and FDA-2017-E-6744]

**Determination of Regulatory Review Period for Purposes of Patent Extension; BAXDELA TABLETS—NDA 208610**

**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 BAXDELA TABLETS under NDA 208610 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 Nos. FDA-2017-E-6740 and FDA-2017-E-6744 for "Determination of Regulatory Review Period for Purposes of Patent Extension; BAXDELA TABLETS." 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 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 § 10.20 (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](https://www.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:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved NDA 208610 for marketing the human drug product, BAXDELA TABLETS (delafloxacin meglumine) indicated in adults for the treatment of acute bacterial skin and skin structure infections caused by

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.*

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## 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.