

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:**

Heather Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993-0002, 301-796-3600, [heather.dorsey@fda.hhs.gov](mailto:heather.dorsey@fda.hhs.gov).

**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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

CUTIVATE (fluticasone propionate) ointment, 0.005 percent, is the subject of NDA 019957, held by Fougera Pharmaceuticals, Inc., and initially approved on December 14, 1990. CUTIVATE is indicated for the relief of the inflammatory and pruritic

manifestations of corticosteroid-responsive dermatoses in adult patients. CUTIVATE (fluticasone propionate) ointment, 0.005 percent, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

BF Innovation Inc., acting on behalf of Bright Future Pharmaceutical Laboratories Limited, submitted a citizen petition dated November 2, 2020 (Docket No. FDA-2020-P-2146), under 21 CFR 10.30, requesting that the Agency determine whether CUTIVATE (fluticasone propionate) ointment, 0.005 percent, 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 CUTIVATE (fluticasone propionate) ointment, 0.005 percent, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CUTIVATE (fluticasone propionate) ointment, 0.005 percent, 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 CUTIVATE (fluticasone propionate) ointment, 0.005 percent, 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: March 29, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-06721 Filed 3-31-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2019-E-3183 and FDA-2019-E-3184]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined the regulatory review period for TPOXX 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 June 1, 2021. 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 September 28, 2021. 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 June 1, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2021. 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-2019-E-3183 and FDA-2019-E-3184 for "Determination of Regulatory Review Period for Purposes of Patent Extension; TPOXX." 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

**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 for marketing the human drug product TPOXX (tecovirimat monohydrate). TPOXX is indicated for treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kilograms.

##### Limitations of Use:

- The effectiveness of TPOXX for treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible, and inducing smallpox disease in humans to study the drug's efficacy is not ethical.

- TPOXX efficacy may be reduced in immunocompromised patients based on studies demonstrating reduced efficacy in immunocompromised animal models.

Subsequent to this approval, the USPTO received a patent term restoration application for TPOXX (U.S. Patent Nos. 7,737,168 and 8,124,643) from SIGA Technologies, Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated October 29, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TPOXX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

##### II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TPOXX is 4,601 days. Of this time, 4,383 days occurred during the testing phase of the regulatory review period, while 218 days occurred during the approval phase. These periods of time were derived from the following dates:

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:* December 9, 2005. The applicant claims December 8, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 9, 2005, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act or section 351 of the Public Health Service Act:* December 8, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for TPOXX (NDA 208627) was initially submitted on December 8, 2017.

3. *The date the application was approved:* July 13, 2018. FDA has verified the applicant's claim that NDA 208627 was approved on July 13, 2018.

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 1,273 days or 1,585 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: March 26, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–N–1584]

#### Revocation of Authorization of Emergency Use of a Medical Device During COVID–19; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to NovaSterilis, Inc. for the Nova2200 using the NovaClean decontamination process. FDA revoked the Authorization on February 12, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

**DATES:** The Authorization for the Nova2200 using the NovaClean decontamination process is revoked as of February 12, 2021.

**ADDRESSES:** Submit written requests for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On August 20, 2020, FDA issued the Authorization. Notice of the issuance of the

Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. FDA authorized the Nova2200 using the NovaClean decontamination process for use in decontaminating compatible N95 respirators identified in the EUA consistent with the Authorization. Subsequent to the issuance of the Authorization, as described in the revocation letter reprinted in this notice, FDA considered new data and evidence, including from testing performed by the Centers for Disease Control and Prevention (CDC) and in published literature, indicating that the compatible N95 respirators identified in the EUA may not maintain adequate fit and filtration efficiency following one decontamination cycle using the authorized product.

##### II. EUA Criteria for Issuance No Longer Met and Other Circumstances Make Revocation Appropriate To Protect the Public Health or Safety

Under section 564(g)(2)(B) and (C) of the FD&C Act, the Secretary of HHS may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. On February 12, 2021, FDA revoked the Authorization because the criteria for issuance were no longer met and other circumstances made such revocation appropriate to protect the public health or safety. Under section 564(c)(2) of the FD&C Act, an EUA may be issued only if FDA concludes that, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition and that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product.

Given the new data and evidence from CDC and recently reported in the literature, FDA has concluded it is not reasonable to believe the product may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates. Additionally, based on this new information, FDA can no longer conclude that the known and potential benefits of the product outweigh the known and potential risks of its emergency use. Further, based on the same information and the risks to public health and to healthcare providers from using decontaminated respirators with