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.

[FR Doc. 2021–06696 Filed 3–31–21; 8:45 am]

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

reduced fit and filtration performance, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety. Accordingly, FDA has revoked the Authorization, pursuant to section 564(g)(2)(B) and (C) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/* and *https://www.fda.gov/media/145913/download.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for the Nova2200 using the NovaClean decontamination process. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

February 12, 2021

Mr. Tony Eisenhut
NovaSterilis, Inc.
3109 N. Triphammer Rd.
Lansing, NY 14882

Re: Revocation of EUA201745

Dear Mr. Eisenhut:

This letter is in response to NovaSterilis, Inc.'s letter dated November 24, 2020, informing FDA that it is withdrawing the Emergency Use Authorization (EUA201745) for the Nova2200 using the NovaClean decontamination process (hereafter referred to as "Nova2200") issued on August 20, 2020. We interpret this letter to mean that NovaSterilis, Inc. will no longer make the Nova2200 available for the authorized emergency use. The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). FDA hereby notifies NovaSterilis, Inc. of the revocation of the EUA201745 for the Nova2200 pursuant to section 564(g)(2)(B) of the Act and section 564(g)(2)(C) of the Act.

On August 20, 2020, FDA authorized the emergency use of the Nova2200 for use in decontaminating compatible N95 respirators[1] that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of one (1) decontamination cycle per respirator, for single-user reuse[2] by healthcare personnel (HCP)[3] to prevent exposure to pathogenic biological airborne particulates during the Coronavirus Disease 2019 (COVID-19) pandemic. Based on the totality of scientific evidence available at the time, FDA concluded that it was reasonable to believe that the Nova2200 may be effective at

[1] For purposes of this EUA, "compatible N95 respirators" are limited to the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators.

[2] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.

[3] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic, and that the known and potential benefits of Nova2200 outweigh the known and potential risks of its use.

Since then, FDA has become aware of new data and evidence suggesting that 3M Model 1860 and Halyard FLUIDSHIELD N95 respirators, the only compatible N95 respirators identified in this EUA, may not maintain adequate fit and filtration efficiency following one (1) decontamination cycle using the Nova2200. Specifically, FDA has reviewed new data indicating that 3M Model 1860 N95 respirators may not maintain adequate fit and filtration efficiency after undergoing one (1) decontamination cycle using the Nova2200.[4] Additionally, FDA has become aware of preliminary evidence suggesting that duckbill N95 respirators, such as Halyard FLUIDSHIELD N95 respirators, may not maintain adequate fit to support reuse.[5]

As such, FDA can no longer conclude that it is reasonable to believe that Nova2200 may be effective in preventing HCP 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 Nova2200 outweigh the known and potential risks of its use; thus, the criteria under section 564(c) of the Act for issuance of an EUA are no longer met. Moreover, based on the same information, and the potential risks to HCP from using decontaminated respirators with reduced fit and filtration performance, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes EUA201745 for the Nova2200, pursuant to section 564(g)(2)(B) and section 564(g)(2)(C) of the Act. As of the date of this letter, the Nova2200 is no longer authorized for emergency use by FDA.

FDA encourages NovaSterilis Inc. to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.02.12 15:47:03 -05'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

[4] Detailed test results can be found in the publicly-available test report at https://www.cdc.gov/niosh/npptl/respirators/testing/results/Decon_039_Redacted-508.pdf.
[5] Degesys NF, Wang RC, Kwan E, Fahimi J, Noble JA, Raven MC. Correlation Between N95 Extended Use and Reuse and Fit Failure in an Emergency Department. JAMA. 2020;324(1):94–96. doi:10.1001/jama.2020.9843.

Dated: March 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06711 Filed 3–31–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0262]

Food and Drug Administration Science Forum 2021; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the following virtual public workshop entitled ''FDA Science Forum 2021.'' The purpose of the public workshop is to inform the public about the groundbreaking science conducted at the Agency and to show how scientific research is used in FDA's regulatory decisions to protect and promote public health.

DATES: The public workshop will be held virtually on May 26, 2021 (Day 1), from 9 a.m. to 3:30 p.m. Eastern Time, and May 27, 2021 (Day 2), from 9 a.m. to 2 p.m. Eastern Time. See the