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

SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all participants will be joining this public workshop via an online teleconferencing platform.

FOR FURTHER INFORMATION CONTACT: Rokhsareh Shahidzadeh, Office of Scientific Professional Development, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2383, Silver Spring, MD 20993, 301–796–8740, *FDASciProDev@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Science Forum is held biennially 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. Open to the public, industry, academia, patient advocates, government agencies, and current and potential collaborators, the 2-day event offers an opportunity to hear FDA scientific experts and nationally renowned scientists speak on a range of topics associated with regulatory science.

II. Topics for Discussion at the Public Workshop

The theme for the 2021 FDA Science Forum, ''Science as the Foundation for Protecting and Promoting Public Health'', will highlight areas of FDA research, including: (1) Improving clinical and postmarket evaluation; (2) substance use, misuse, and addiction; (3) product development and manufacturing; and (4) medical countermeasures, infectious disease, and pathogen-reduction technologies.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/scienceforum.* Registration is free. Persons interested in attending this public workshop must register by May 21, 2021, by 5 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Rokhsareh Shahidzadeh (see **FOR FURTHER INFORMATION CONTACT**) no later than May 21, 2021, by 5 p.m. Eastern Time.

Streaming Webcast of the Public Workshop: This public workshop will be streamed via a webcast only. To register for the webcast, please visit the following website: *https://www.fda.gov/scienceforum.* Participants interested in viewing via webcast must register by May 21, 2021, by 5 p.m. Eastern Time.

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.* To get a quick overview of the Connect Pro program, visit *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.

Dated: March 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06705 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–2306]

TG United, Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 15, 2021. The document announced the withdrawal of approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants as of February 16, 2021. The document indicated that FDA was withdrawing approval of the following three ANDAs after receiving a withdrawal request from Upsher-Smith Laboratories, LLC., 6701 Evenstad Dr., Maple Grove, MN 55369: ANDA 084041, Chlordiazepoxide Hydrochloride (HCl) Capsules, 10 milligrams (mg); ANDA 084678, Chlordiazepoxide HCl Capsules, 5 mg; and ANDA 084679, Chlordiazepoxide HCl Capsules, 25 mg. Before FDA withdrew the approval of these ANDAs, Upsher-Smith Laboratories, LLC., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Upsher-Smith Laboratories, LLC., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 084041, 084678, and 084679 is still in effect. In addition, the document indicated that FDA was withdrawing approval of ANDA 206061, Pravastatin Sodium Tablets, 20 mg, 40 mg, and 80 mg, after receiving a request from Hisun Pharmaceutical (Hangzhou) Co., Ltd. However, the document published with the incorrect applicant name for ANDA 206061. This document corrects that error. All other information for ANDA 206061 remains the same.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, January 15, 2021 (86 FR 4081), appearing on page 4081 in FR Doc. 2021–00833, the following corrections are made on page 4082 in the table:

1. The entries for ANDAs 084041, 084678, and 084679 are removed.

2. In the third column, third item from the bottom, the applicant name ''Hisun Pharmaceuticals USA, Inc.'' is corrected to read ''Hisun Pharmaceuticals USA, Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd.'' for ANDA 206061.

Dated: March 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06745 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–2021–N–0270]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.