

applicable with respect to the voluntary collection of information contained in the guidance during the immediate investigation of, and response to, COVID-19. Furthermore, the requirements of the PRA shall not be applicable with respect to the voluntary collection of information contained in the guidance during the immediate post-response review regarding the public health emergency.

As noted above, while the requested information and process described in the guidance are critical during national emergencies, such as the COVID-19 outbreak, the guidance recommends submission of information that is expected to assist the Agency more broadly in its efforts to address shortages. Accordingly, following the termination of the PHE, FDA intends to revise and replace the guidance with any appropriate changes based on comments received on this guidance and our experience with implementation. Upon determining that the circumstances necessitating the COVID-19 PRA waiver no longer exist, the Secretary will promptly update its website to reflect the termination of the waiver. The period of this waiver will not exceed the period of time for the public health emergency related to COVID-19, including any immediate post-response review. The Secretary will ensure that compliance with the requirements of the PRA occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the waiver related to COVID-19.

This guidance also refers to previously approved collections of information found in FDA regulations. The guidance describes, among other things, the requirements in §§ 310.306, 314.81(b)(3)(iii), and 600.82 (21 CFR 310.306, 314.81(b)(3)(iii), and 600.82) for applicants or manufacturers of certain drugs and biological products to notify FDA of a permanent discontinuance in the manufacture of certain products or an interruption in manufacture of certain products that is likely to lead to a meaningful disruption in the supply of such products in the United States. These notifications must provide particular information, including the name of the product and a description of the reason for the permanent discontinuance or interruption in manufacturing (see Section II of the guidance). The collections of information in §§ 310.306, 314.81(b)(3)(iii), and 600.82 have been approved under OMB control number 0910-0759.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: March 27, 2020.

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-2020-N-0008]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on June 9, 2020, from 8 a.m. to 6 p.m.

ADDRESSES: DoubleTree by Hilton Washington, DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. The hotel's website is <https://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-washington-dc-north-gaithersburg-GAIGWDT/index.html>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, 301-796-0400, Aden.Asefa@fda.hhs.gov; or FDA

Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On June 9, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the VisAbility Micro Insert sponsored by Refocus Group, Inc. The proposed Indication for Use for the VisAbility Micro Insert, as stated in the PMA, is as follows:

The VisAbility Micro Insert is indicated for bilateral scleral implantation to improve unaided near vision in phakic, presbyopic patients between the ages of 45 and 60 years of age, who have a manifest spherical equivalent between -0.75D and +0.50D with less than or equal to 1.00D of refractive cylinder in both eyes, and require a minimum near correction of at least +1.25D reading add.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 19, 2020. Oral presentations from the public will be scheduled on June 9, 2020, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the

evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 11, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 12, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 2020.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

AGENCY: Department of Health and Human Services.

ACTION: Notice of Emergency Use Authorization Declaration.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health

emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 27, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear ("CBRN") agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military

forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for drugs and biological products to allow the Department to take response measures based on information currently available about the virus that causes COVID-19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of drugs and biological products by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for drugs and biological products for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

III. Declaration of the Secretary of Health and Human Services

On March 27, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, I declared that circumstances exist justifying the authorization of emergency use of drugs