surveys, particularly during communications with the facility. Accrediting organization survey processes should emphasize facility compliance with Medicare's health and safety standards, rather than any educational function.

B. Term of Approval

Based on our review and observations described in section III. of this final notice, we approve TJC as a national accreditation organization for HHAs that request participation in the Medicare program. The decision announced in this final notice is effective March 31, 2020 through March 31, 2026.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, is delegating the authority to electronically sign this document to Evell J. Barco Holland, who is the Federal Register Liaison, for purposes of publication in the **Federal Register**.

Dated: March 26, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–06792 Filed 3–31–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1057]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' Due to the Coronavirus Disease 2019 (COVID–19) pandemic, FDA has been closely monitoring the medical product supply chain with the expectation that it may be impacted by the COVID–19 outbreak, potentially leading to supply disruptions or shortages of drug and biological products in the United States. The guidance is intended to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain drugs and biological products that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of such products. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices. In addition, this guidance is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by the Department of Health and Human Services (HHS). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its efforts to prevent and mitigate shortages, including under circumstances outside of the COVID–19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes following the public health emergency and in consideration of comments received on this guidance and the Agency's experience with implementation.

DATES: The announcement of the guidance is published in the **Federal Register** on April 1, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 No. FDA–2020–D–1057 for ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' Received comments 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jin Ahn, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6234, Silver Spring, MD 20993–0002, 301–796–1300; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' This guidance discusses the requirement in section 506C of the FD&C Act (21 U.S.C. 356c) and FDA's implementing regulations for applicants and manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain products or an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in supply of that product in the United States. The guidance recommends that applicants and manufacturers provide additional details and follow additional procedures to ensure FDA has the specific information it needs to help prevent or mitigate shortages. The guidance also explains how FDA communicates information about products in shortage to the public.

Timely and detailed notifications from applicants and manufacturers play a significant role in decreasing the incidence and duration of supply disruptions and shortages. Early, informative notifications are the best tool FDA has to help prevent a shortage from occurring or to mitigate the impact of an unavoidable shortage. When FDA does not receive timely, informative notifications, the Agency's ability to respond appropriately is limited and a shortage may result. Therefore, FDA is issuing this guidance to assist applicants and manufacturers in providing early, detailed notifications that will allow FDA to evaluate the situation and take appropriate action. Among other things, the guidance explains: (1) Who should notify FDA, (2) when and how such notifications should be submitted; and (3) what details to include in notifications that will ensure FDA has information it needs to help prevent or mitigate shortages.

In light of the public health emergency related to COVID–19 declared by the Secretary of HHS, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practice statute and regulation.

This guidance is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its efforts to prevent and mitigate shortages, including under circumstances outside of the COVID–19 public health emergency, and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

The guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Health and Human Services Secretary Alex M. Azar II (Secretary) determined that, as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV), a public health emergency (PHE) exists and has existed since January 27, 2020. On March 19, 2020, the Secretary waived, pursuant to section 319(f) of the PHS Act (42 U.S.C. 247d(f)) and the PHE, the requirements of the PRA for information to be collected by FDA pertaining to our guidance documents that relate to the COVID–19 pandemic public health emergency response. The Secretary has posted its determination of the waiver at: *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.* Pursuant to the waiver, the requirements of the PRA are not

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.

[FR Doc. 2020–06800 Filed 3–31–20; 8:45 am]

BILLING CODE 4164–01–P

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