

Dated: April 11, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0008]

#### Patient Engagement 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 CDRH Patient Engagement Advisory Committee. The general function of the committee is to provide advice to the Commissioner of Food and Drugs, or designee, on complex scientific issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on July 12, 2022, from 10 a.m. to 4 p.m. Eastern Time and on July 13, 2022, from 10 a.m. to 2 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at <https://www.fda.gov/peac>.

**FOR FURTHER INFORMATION CONTACT:** Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002, [letise.williams@fda.hhs.gov](mailto:letise.williams@fda.hhs.gov), 301-796-8398, 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/advisory-committees> and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

#### SUPPLEMENTARY INFORMATION:

**Agenda:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On July 12 and 13, 2022, the committee will discuss and make recommendations on the topic of "Augmented Reality (AR) and Virtual Reality (VR) Medical Devices." AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties. These devices have novel attributes and considerations for the end users that impact FDA's evaluation of the device's safety and effectiveness. The novel attributes of digital health visualization, tracking techniques, embedded software among other factors present unique challenges for pre- and postmarked evaluation. The recommendations provided by the committee will address factors FDA and industry should consider when evaluating the benefits, risks, and the extent of uncertainty in the benefit-risk information for AR/VR medical devices. The committee will also consider specific challenges related to specific populations (e.g., pediatric or cognitively impaired) who may use this technology. Additionally, the committee will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider decision-making process related to using or prescribing the technology.

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 on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2022 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of

materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled on July 12, 2022, between approximately 2:30 p.m. Eastern Time to 3:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 June 10, 2022. 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 June 14, 2022. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the committee may send written submissions to the contact person on or before June 20, 2022.

**Virtual Breakout Session:** Individuals interested in participating in the virtual breakout scenario discussions will need to sign up to participate on or before June 28, 2022. The sign-up sheet, as well as additional information pertaining to the virtual scenario discussions, will be available at <https://www.fda.gov/peac>. Everyone who signs up in advance and provides a valid email address will receive an email at least 2 days prior to the meeting with information on how to access the virtual platform that will host the virtual breakout scenario discussions. Please note that due to limited technology capacity, participation in the virtual breakout scenario discussions will be limited to 150 participants. Once capacity reaches 150 participants, the breakout session will be closed to additional participants. Additional information regarding the virtual breakout scenario discussions will be provided at <https://www.fda.gov/peac>.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

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](mailto: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/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings. Please be advised that, during the virtual scenario breakout discussions, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

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

Dated: April 11, 2022.

**Lauren K. Roth,**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-D-3324]

### Reconditioning of Fish and Fishery Products by Segregation; Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled “Reconditioning of Fish and Fishery Products by Segregation.” This guidance is intended to provide industry with an explanation of two potential approaches to recondition fish and fishery products by effectively segregating adulterated portions of an article from portions not containing the adulterant to ensure that only safe and wholesome product reaches consumers.

**DATES:** The announcement of the guidance is published in the **Federal Register** on April 14, 2022.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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-2019-D-3324 for “Reconditioning of Fish and Fishery Products by Segregation.” 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, 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.” We will review this copy, including the claimed confidential information, in our

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, 240-402-7500.

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 Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Steven Bloodgood, Division of Seafood Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-5316; or Lauren Kleinman, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a guidance for industry entitled “Reconditioning of Fish and Fishery Products by Segregation.” We are issuing the guidance consistent with our