We note that the information and analyses in the draft amended EA reflect comments and input received from the National Marine Fisheries Service and the Fish and Wildlife Service (collectively referred to as the Services) during a recent ESA technical assistance review initiated in June 2022 with initial discussions beginning in March 2021. FDA intends to initiate an Informal Consultation with the Services after the close of the public comment period if the current conclusions with respect to the ESA are not altered.

II. Topics for Comment Regarding the Draft Amended EA

The Agency is placing the draft amended EA on public display at the Dockets Management Staff (see **ADDRESSES**) and at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/virtual-public-meeting-aquadvantage-salmon-draft-amended-environmental-assessment-12152022* for public review and comment for 60 days.

Comments at the public meeting should be limited to the draft amended EA only, as described below. We will not review comments on topics outside of the scope of the draft amended EA. Given that FDA must comply with a court order and that the public can comment both by submitting comments to the docket and by participating in the public meeting, FDA believes that a 60-day comment period is appropriate and does not intend to grant requests for extension of the comment period.

The virtual public meeting will focus on the draft amended EA only and will not include discussion about AAS generally or the approved application. We are particularly interested in receiving comments from the public on the following:

1. Is the expanded conceptual model for risk assessment (Figure 4–1) in the draft amended EA complete?

2. Are the risk-related questions (Section 4.4) appropriate given the new expanded conceptual model?

3. Are there any exposure pathways to the U.S. environment that were not identified or evaluated in the draft amended EA?

4. Are there any potential harms (adverse consequences, effects, or impacts) to the U.S. environment from ABT Salmon that were not identified or evaluated in the draft amended EA?

5. Are there any potential environmental impacts on endangered Atlantic salmon or their critical habit in the United States that were not identified or evaluated in the draft amended EA?

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register no later than 11:59 p.m. Eastern Time on December 9, 2022. Interested persons can register online at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/virtual-public-meeting-aquadvantage-salmon-draft-amended-environmental-assessment-12152022* and will need to provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Early registration is recommended. Registrants will receive confirmation when their registration has been accepted and will be provided the webcast link.

If you need special accommodations due to a disability, please contact *CVMamendedEA@fda.hhs.gov* no later than December 9, 2022.

Requests for Oral Presentations: During online registration, you may indicate if you wish to make an oral presentation during the public meeting. To facilitate agenda development, registrants requesting to present will be contacted to provide information regarding which topics they intend to address and the title of their presentation. We will do our best to accommodate requests to make an oral presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation or submit requests for designated representatives to participate. All requests to make oral presentations must be received by November 28, 2022.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by December 1, 2022. Selected presenters planning to use an electronic slide deck must submit an electronic copy of their PowerPoint presentation to *CVMamendedEA@fda.hhs.gov* with the subject line ''Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada'' on or before December 8, 2022. If presenters choose not to use a slide deck, they are requested to submit a single slide with their name, affiliation, title of their presentation, and contact information. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Transcripts: A transcript of the public meeting will be accessible at *https://www.regulations.gov* and on the FDA website at: *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/virtual-public-meeting-aquadvantage-salmon-draft-amended-environmental-assessment-12152022* approximately 30 days after the meeting. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: November 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25002 Filed 11–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2672]

Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada; Availability; Request for Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a document entitled ''Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' This draft amended environmental assessment (EA) has been prepared by FDA in support of the approved new animal drug application (NADA 141–454) concerning AquAdvantage Salmon (AAS), in response to an order by the U.S. District Court, Northern District of California.

DATES: Submit either electronic or written comments on the draft amended EA by January 17, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 17, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2022–N–2672 for ''Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' 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.'' 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, 240–492–7500.

FOR FURTHER INFORMATION CONTACT: Holly Zahner, Center for Veterinary Medicine (HFV–162), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0834, *CVMamendedEA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

FDA is announcing the availability of a document entitled ''Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' This draft amended EA has been prepared by FDA in support of the approved application (NADA 141–454) concerning AAS, in response to an order by the U.S. District Court, Northern District of California, issued on November 5, 2020; *Inst. for Fisheries Res.* v. *U.S. Food and Drug Admin,* 499 F. Supp. 3d 657, 660 (N.D. Cal. 2020) and is available in the docket or at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/virtual-public-meeting-aquadvantage-salmon-draft-amended-environmental-assessment-12152022.*

On November 19, 2015, FDA approved NADA 141–454 concerning AAS, owned by AquaBounty Technologies (ABT). AAS are triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*) bearing a single copy of the α-form of the *opAFP–GHc2* recombinant DNA (rDNA) construct at the α-locus in the E.O.-1α lineage. AAS is designed to exhibit a rapid-growth phenotype. The November 19, 2015, NADA approval allowed for the AAS to be produced at a facility on Prince Edward Island (PEI), Canada, and grown at a facility in Panama (that has subsequently closed) and allowed for sale of food harvested from AAS in the United States.

As a part of the NADA review process under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, *et seq.*), and consistent with the mandates in the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321, *et seq.*) and FDA's environmental impact considerations regulations (21 CFR part 25), FDA's Center for Veterinary Medicine prepared an EA dated November 12, 2015, for the original approval of the rDNA construct as integrated in the genome of AAS. Based on the 2015 EA and the specific conditions that were established in the NADA, FDA determined the action would not individually or cumulatively have a significant effect on the quality of the human environment in the United States. Therefore, FDA prepared a finding of no significant impact (FONSI). Based on the findings in the 2015 EA, FDA also made a ''no effect'' determination under the Endangered Species Act (ESA) (16 U.S.C. 1531, *et seq.*), concluding that AAS, when produced and reared under the conditions in the application, and as described in the 2015 EA, would not jeopardize the continued existence of U.S. populations of threatened or endangered Atlantic salmon or result in the destruction or adverse modification of their critical habitat.

Subsequently, several organizations filed suit in the U.S. District Court, Northern District of California, challenging, among other things, FDA's evaluations under NEPA and the ESA for the 2015 NADA approval. On November 5, 2020, the Court found that ''FDA did not . . . meaningfully analyze what might happen to normal salmon in the event the engineered salmon did survive and establish themselves in the wild. Even if this scenario was unlikely, the FDA was still required to assess the consequences of it coming to pass.'' The

Court ordered FDA to complete the analysis and reconsider its ''no effect'' determination under the ESA together with a revised NEPA evaluation. See *Inst. for Fisheries Res.* v. *U.S. Food and Drug Admin,* 499 F. Supp. 3d 657, 660. However, the Court did not vacate the approval; the approval is still in effect.

To address the November 5, 2020, Court opinion, we have prepared a draft amended EA, entitled ''Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' We request that the public review the draft amended EA and submit comments to the docket.

In this draft amended EA, we have expanded our assessment beyond that in the 2015 EA to include an exhaustive analysis of the likelihood and severity of harms that could occur if AAS and AquAdvantage broodstock (collectively referred to in the amended EA as AquaBounty Technology (ABT) Salmon) are assumed to be present in the U.S. aquatic environment. We outline the pathways necessary for ABT Salmon to escape confinement from the PEI facilities and migrate to and establish a persistent population in the United States. We also evaluate the potential pathways for disease (including pathogen and parasite) transmission from ABT Salmon and from the production of ABT Salmon at facilities on PEI to wild fish populations. In addition, we identify and evaluate the potential harms (consequences) to the U.S. environment and the endangered Atlantic salmon of the Gulf of Maine Distinct Population Segment if these highly unlikely scenarios were to occur. Finally, we revisit whether there is a potential for significant impacts on the U.S. environment under NEPA, and whether the action could result in effects on threatened and endangered Atlantic salmon and their critical habitat in the United States under the ESA. Ultimately, this analysis will aid the Agency in the decision of whether to prepare a FONSI or an environmental impact statement.

We note that the information and analyses in the draft amended EA reflect comments and input received from the National Marine Fisheries Service and the Fish and Wildlife Service during a recent ESA technical assistance review initiated in June 2022 with initial discussions beginning in March 2021. FDA intends to initiate an informal consultation with the services after the close of the public comment period if the current conclusions with respect to the ESA are not altered.

Elsewhere in this issue of the **Federal Register**, we are providing notice of a virtual public meeting on December 15, 2022. Further information, including the time the meeting will start, the agenda, and how to register to attend the meeting, can be found at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/virtual-public-meeting-aquadvantage-salmon-draft-amended-environmental-assessment-12152022.*

II. Topics for Comment Regarding the Draft Amended EA

The Agency is placing the draft amended EA on public display at the Dockets Management Staff (see **DATES** and **ADDRESSES**) and at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/virtual-public-meeting-aquadvantage-salmon-draft-amended-environmental-assessment-12152022* for public review and comment for 60 days.

Comments should be limited to the draft amended EA only, as described below. We will not review comments outside of the scope of the draft amended EA such as AquAdvantage Salmon generally or the approved application. Given that FDA must comply with a court order and that the public can comment both by submitting comments to the docket and by participating in the public meeting, FDA believes that a 60-day comment period is appropriate and does not intend to grant requests for extension of the comment period.

We are particularly interested in receiving comments from the public on the following:

1. Is the expanded conceptual model for risk assessment (Figure 4–1) in the draft amended EA complete?

2. Are the risk-related questions (Section 4.4) appropriate given the new expanded conceptual model?

3. Are there any exposure pathways to the U.S. environment that were not identified or evaluated in the draft amended EA?

4. Are there any potential harms (adverse consequences, effects, or impacts) to the U.S. environment from ABT Salmon that were not identified or evaluated in the draft amended EA?

5. Are there any potential environmental impacts on endangered Atlantic salmon or their critical habitat in the United States that were not identified or evaluated in the draft amended EA?

Dated: November 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25001 Filed 11–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Romina Mizrahi, M.D., Ph.D. (Respondent), who was a Clinician Scientist, Positron Emission Tomography Centre, Centre for Addiction and Mental Health (CAMH), and an Associate Professor, Department of Psychology, University of Toronto (UT). Respondent engaged in research misconduct in research reported in a grant application submitted for U.S. Public Health Service (PHS) funds, specifically National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant application R01 MH118495–01. The administrative actions, including supervision for a period of one (1) year, were implemented beginning on November 3, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Romina Mizrahi, M.D., Ph.D., Centre for Addiction and Mental Health and University of Toronto: Based on the report of an investigation conducted by CAMH and analysis conducted by ORI in its oversight review, ORI found that Dr. Romina Mizrahi, former Clinician Scientist, Positron Emission Tomography Centre, CAMH, and an Associate Professor, Department of Psychology, UT, engaged in research misconduct in research reported in a grant application submitted for PHS funds, specifically NIMH, NIH, grant application R01 MH118495–01.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying data in the following grant application:

- R01 MH118495–01, ''Imaging nociceptin receptors in clinical high risk