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

and first episode psychosis,'' submitted to NIMH, NIH, on February 2, 2018.

Specifically, ORI finds that Respondent knowingly, intentionally, or recklessly falsified the Positron Emission Tomography (PET) data of the binding of radiopharmaceutical [^{11}C]NOP–1A (NOP) in brain regions between the patient group and healthy volunteer (HV) group. Respondent selectively included one (1) and excluded three (3) participants with their PET data in the HV group and selectively excluded four (4) participants with their PET data in the patient group, to falsely state that the NOP binding in the patient group was statistically higher than that in the HV group in Figure 3, right panel, and the corresponding text in grant application R01 MH118495–01.

Dr. Mizrahi entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of one (1) year beginning on November 3, 2022 (the ''Supervision Period''). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of one (1) year from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing her submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported and not plagiarized in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that her participation was not proposed on a research project for which an application for PHS support was submitted and that she has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude herself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

Dated: November 14, 2022.

Wanda K. Jones,

Acting Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2022–25031 Filed 11–16–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR22–171: NIDDK Central Repository Non-Renewable Sample Access (X01) Review.

Date: December 15, 2022.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2 Democracy, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov*.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 14, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25023 Filed 11–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special