panel, according to its specialty area: (1) advises on the classification or reclassification of devices into one of three regulatory categories and advises on any possible risks to health associated with the use of devices; (2) advises on formulation of product development protocols; (3) reviews premarket approval applications for medical devices; (4) reviews guidelines and guidance documents; (5) recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (6) advises on the necessity to ban a device; and (7) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) demonstrate an affiliation with and/or active participation in consumer or community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within 45 days of the end of this 30-day period, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations must also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms of up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. After selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22292 Filed 9–27–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Veterinary Medicine's (CVM), Office of Management (OM) and Office of New Animal Drug Evaluation (ONADE) have modified their organizational structures. The new organizational structures were approved by the Secretary of Health and Human Services on July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation, and Risk Management, Office of Finance, Budget, Acquisitions, and Planning, Food and Drug Administration, 4041 Powder Mill Rd., Beltsville, MD 20705–4304, 301–796–3843.

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995,

64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect the reorganization of CVM OM and ONADE.

The reorganization of OM merged the Budget Planning and Evaluation Staff (BPES) and the Program and Resource Management Staff (PRMS) and retitled the PRMS to the Financial Management Staff (FMS) and abolished BPES. The reorganization retitled ONADE to the Office of New Animal Product Evaluation (ONAPE), established the Regulatory Counsel Staff and the Administrative Staff, established branches within the Division of Food Animal Drugs, the Division of Companion Animal Drugs, the Division of Human Food Safety, the Division of Manufacturing Technologies, the Division of Business Information Science and Management, the Division of Animal Bioengineering and Cellular Therapies (DABCT), and the Division of Scientific Support (DSS). The reorganization retitled DABCT to the Division of Biotechnology and retitled DSS to the Division of Statistical and Biological Sciences. The reorganization established the Office of Generic Animal Drugs (OGAD), established the Business Management and Operations Staff and the Division of Manufacturing Technologies (DMT) under OGAD, realigned the Division of Generic Animal Drugs (DGAD) from ONADE to OGAD, and established branches under DGAD and DMT.

DCGB. ORGANIZATION. CVM's OM is headed by the Associate Director for Management, and includes the following:

Financial Management Staff (DCGB1)
Human Capital Management Staff (DCGB2)
Talent Development Staff (DCGB3)
Business Informatics Staff (DCGB5)

DCGC. ORGANIZATION. CVM's ONAPE is headed by the Director, and includes the following:

Office of New Animal Product Evaluation (DCGC)
Regulatory Counsel Staff (DCGC1)
Administrative Staff (DCGC2)
Division of Food Animal Drugs (DCGCA)
Food Animal Branch 1 (DCGCA1)
Food Animal Branch 2 (DCGCA2)
Division of Companion Animal Drugs (DCGCC)
Companion Animal Branch 1 (DCGCC1)
Companion Animal Branch 2 (DCGCC2)
Companion Animal Branch 3 (DCGCC3)
Division of Human Food Safety (DCGCD)
Human Food Safety Branch 1 (DCGCD1)
Human Food Safety Branch 2 (DCGCD2)
Division of Manufacturing Technologies (DCGCE)
Feed and Topical Branch (DCGCE1)
Sterile Drugs Branch (DCGCE2)
Biotherapeutics Branch (DCGCE3)
Chemotherapeutics Branch (DCGCE4)
Drug Substance Branch (DCGCE5)
Division of Statistical and Biological Sciences (DCGCF)
Environmental Branch (DCGCF1)
Biostatistics Branch 1 (DCGCF2)
Biostatistics Branch 2 (DCGCF3)
Clinical Pharmacology Branch (DCGCF4)
Division of Business Information Science and Management (DCGCH)
Business Informatics Branch (DCGCH1)
Quality Assurance Branch (DCGCH2)
Project Management Branch (DCGCH3)
Division of Biotechnology (DCGCI)
Animal Biotechnology Branch (DCGCI1)
Biologic Products Branch (DCGCI2)

DCGG. ORGANIZATION. CVM's OGAD is headed by the Director, and includes the following:

Office of Generic Animal Drugs (DCGG)
Business Management and Operations Staff (DCGG1)
Division of Generic Animal Drugs (DCGGA)
Generics Review Branch 1 (DCGGA1)
Generics Review Branch 2 (DCGGA2)
Generics Review Branch 3 (DCGGA3)
Generics Review Branch 4 (DCGGA4)
Generics Review Branch 5 (DCGGA5)
Division of Manufacturing Technologies (DCGGB)
Generic Drug Manufacturing Branch 1 (DCGGB1)
Generic Drug Manufacturing Branch 2 (DCGGB2)
Generic Drug Manufacturing Branch 3 (DCGGB3)
Generic Drug Substances and Facilities Assessment Branch (DCGGB4)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

(Authority: 44 U.S.C. 3101)

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–22147 Filed 9–26–24; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2672]

Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada; 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 document entitled ''Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' This 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.

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

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a document entitled ''Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' This 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. *United States Food and Drug Adm'n,* 499 F. Supp. 3d 657, 660 (N.D. Cal. 2020) and is available in the docket.

On November 19, 2015, FDA approved NADA 141–454 concerning AAS, owned by AquaBounty Technologies (ABT). AAS are triploid, hemizygous, all-female Atlantic salmon