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

(*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 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. *United States Food and Drug Adm'n,* 499 F. Supp. 3d 657, 660 (N.D. Cal. 2020). However, the Court did not vacate the approval; the approval remains in effect.

To address the November 5, 2020, Court opinion, we prepared a draft amended EA, titled ''Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' We requested that the public review that draft amended EA and submit comments to the docket (87 FR 69032, November 17, 2022). We also held a virtual public meeting on December 15, 2022, at which we solicited comment on the draft amended EA (87 FR 69030, November 17, 2022).

In that draft amended EA, we 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 ABT Salmon) are assumed to be present in the U.S. aquatic environment. We outlined 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 evaluated 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 identified and evaluated 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 revisited 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.

We note that the information and analyses in the draft amended EA reflected comments and input received from the National Marine Fisheries Service and the Fish and Wildlife Service during an ESA technical assistance review.

We received 1,728 comment submissions on the draft amended EA. Please refer to ''Summary Responses to Public Comments on the November 2022 AAS Draft Amended Environmental Assessment'' (*https://www.fda.gov/media/181568/download?attachment*) for a summary and FDA review of these comments.

FDA is announcing the availability of an EA entitled ''Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada.'' This document can be found at *https://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/141-454#eaid.*

We have also prepared and are making available a FONSI and, based on the findings in the EA, have made a ''no effect'' determination under the ESA, concluding that AAS, when produced and reared under the conditions as described in the EA, will 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. This document can be found at *https://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/141-454#eaid.*

Dated: September 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22308 Filed 9–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4115]

Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment.'' This guidance provides clarification to industry and FDA staff of the Federal regulations that relate to diagnostic x-ray equipment. These regulations pertain to the recordkeeping, reporting, manufacturing, importing, and installation of an ''electronic product'' as defined in FDA regulations. This guidance supersedes FDA's 1989 guidance entitled ''Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment.''

DATES: The announcement of the guidance is published in the **Federal Register** on September 30, 2024.

ADDRESSES: You may submit either electronic or written comments on