(*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

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–2018–D–4115 for ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment.'' 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Laurel Burk, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3668, Silver Spring, MD 20993–0002, 301–796–5933.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides clarification to industry and FDA staff of the Federal regulations that relate to diagnostic x-ray equipment. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), diagnostic x-ray systems are considered to be both medical devices, under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), and electronic products, under section 531 of the FD&C Act (21 U.S.C. 360hh). As such, they are subject to the provisions of the FD&C Act that apply to medical devices (*e.g.,* sections 510 and 520 of the FD&C Act (21 U.S.C. 360 and 360j)), and their implementing regulations, as well as the provisions of the FD&C Act (sections 531 through 542 of the FD&C Act (21 U.S.C. 360hh through 360ss)) that apply to electronic products, known as the Electronic Product Radiation Control (EPRC) provisions and their implementing regulations. FDA's EPRC regulations pertain to the recordkeeping, reporting, manufacturing, importing, and installation of an ''electronic product'' as defined under 21 CFR 1000.3(j). This guidance supersedes FDA's guidance entitled ''Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment'' (HHS Publication FDA 89–8221 issued in March 1989).

A notice of availability of the draft guidance appeared in the **Federal Register** of December 17, 2018 (83 FR 64584). FDA considered the comments received and revised the guidance as appropriate. Revisions include the addition of new questions and updates to existing questions in the sections related to alternate test methods to demonstrate compliance with performance standards, as well as the applicability of performance standards to x-ray based image-guidance used with radiation therapy devices, certification and associated labeling of certifiable components, assembly instructions, accidental radiation occurrence, and defects. In addition, FDA revised other questions and responses throughout the guidance to provide additional clarification and for editorial accuracy. Questions and responses related to certain reports that are no longer required were also removed (see ''Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products'' published in the **Federal Register** of January 20, 2023 (88 FR 3638)).

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01500029 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following FDA table have been approved by OMB:

21 CFR Part or FDA Form	Topic	OMB Control No.
1002, 1005, 1010, 1020, 1030, 1040, and 1050; form FDA 2579 and form FDA 2877.	Reporting and Recordkeeping for Electronic Products—General Requirements.	0910–0025
800, 801, and 809	Labeling	0910–0485
812	Investigational Device Exemption	0910–0078
''Allegations of Regulatory Misconduct'' form	Voluntary Allegations of Regulatory Misconduct	0910–0769

Dated: September 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22332 Filed 9–27–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–N–0758, FDA–2024–N–2032, FDA–2023–N–3847, and FDA–2024–N–1201]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
New Plant Varieties Intended for Food Use	0910–0583	9/30/2027
Food and Cosmetic Export Certificates	0910–0793	9/30/2027
Biological Products; General Records and Postmarket Adverse Experience Reporting	0910–0308	9/30/2027
Voluntary Total Product Life Cycle Advisory Program Pilot	0910–0930	9/30/2027