page 57523, column 2, beginning on line 26, remove '', excluding that airspace within Federal airways and within Canadian airspace''.

Issued in Fort Worth, TX, on November 10, 2015.

Robert W. Beck,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2015–29704 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 528

[Docket No. FDA–2015–N–0002]

New Animal Drugs in Genetically Engineered Animals; opAFP–GHc2 Recombinant Deoxyribonucleic Acid Construct

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency) is amending the animal drug regulations to reflect the approval of a new animal drug application (NADA) filed by AquaBounty Technologies, Inc. The NADA provides for use of a recombinant deoxyribonucleic acid (rDNA) gene construct in a lineage of genetically engineered Atlantic salmon.

DATES: This rule is effective November 24, 2015.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8247, email: *abig@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754 filed NADA 141–454 for an *opAFP–GHc2* rDNA construct at the α-locus in the EO–1α lineage triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*) known as AQUADVANTAGE Salmon. Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators. The NADA is approved as of November 19, 2015, and the regulations are amended in 21 CFR part 528 to reflect the approval.

In addition, AquaBounty Technologies, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application (FOI Summary) may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an environmental assessment (EA), may be seen in the Division of Dockets Management (address in the previous paragraph) between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the FOI Summary, EA, and FONSI at the Center for Veterinary Medicine FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 528

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 528 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''AquaBounty Technologies, Inc.'' and in the table in paragraph (c)(2), numerically add an entry for ''086053'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754	086053
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
086053	AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754 * * *
* * * * *	

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

■ 3. The authority citation for 21 CFR part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 4. Add § 528.1092 to read as follows:

§ 528.1092 opAFP–GHc2 recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of the α-form of the *opAFP–GHc2* recombinant deoxyribonucleic acid (rDNA) construct at the α-locus in the EO–1 α lineage of triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*).

(b) *Sponsor.* See No. 086053 in § 510.600 of this chapter.

(c) *Indications for use.* Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.

(d) *Limitations.* These Atlantic salmon are produced as eyed-eggs and grown-out only in physically-contained, freshwater culture facilities specified in an FDA-approved application.

Dated: November 19, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–29902 Filed 11–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[Docket No. USCG–2012–0924]

RIN 1625–AB68

Ballast Water Management Reporting and Recordkeeping

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Coast Guard's ballast water management reporting and recordkeeping requirements. Upon the effective date of this rule, the Coast Guard will require vessels with ballast tanks operating exclusively on voyages between ports or places within a single Captain of the Port Zone to submit an annual report of their ballast water management practices. This rule also simplifies and streamlines the ballast water report form. Finally, this rule will allow most vessels to submit ballast water reports after arrival at a port or place of destination, instead of requiring submission of such reports prior to arrival. This rule will reduce the administrative burden on the regulated population, while still providing the Coast Guard with the information necessary to analyze and understand ballast water management practices.

DATES: This final rule is effective February 22, 2016, except for the amendments to 33 CFR 151.2060(b) through (f) and 151.2070, which contain collection of information requirements that have not yet been approved by the Office of Management and Budget (OMB). The Coast Guard will publish a document in the **Federal Register** announcing the effective date of those sections.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0924 and are available on the Internet by going to *http://www.regulations.gov,* inserting USCG–2010–0924 in the ''Keyword'' box, and then clicking ''Search.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ms. Regina Bergner, Environmental Standards Division (CG–OES–3), Coast Guard; telephone 202–372–1431, email *Regina.R.Bergner@uscg.mil.*

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I. Abbreviations

BWM Ballast Water Management
CFR Code of Federal Regulations
COTP Captain of the Port
EPA Environmental Protection Agency
EEZ Exclusive Economic Zone
FR Federal Register
IMO International Maritime Organization
MISLE Marine Information for Safety and Law Enforcement
NANPCA Non-Indigenous Aquatic Nuisance Prevention and Control Act of 1990
NBIC National Ballast Information Clearinghouse
NISA National Invasive Species Act of 1996
OMB Office of Management and Budget
Pub. L. Public Law
RFA Regulatory Flexibility Act
SANS Ship Arrival Notification System
U.S.C. United States Code

II. Background

A vessel brings water into its ballast tanks to control or maintain trim, draft, stability or stress of the vessel when it is fully or partially empty of cargo. Generally, the vessel will discharge ballast water when it loads cargo, often at another port of call. Vessels discharge more than 80 million tons of ballast water annually into U.S. waters.[1]

Many invasive species have been introduced into U.S. waters through ballast water discharge because ballast water often contains organisms indigenous to the area where it was loaded. These organisms can become invasive species when they are discharged in a new location, often with damaging results.[2]

The Great Lakes provide many examples of the damage invasive species can inflict on an environment. According to the U.S. Environmental Protection Agency (EPA),[3] no fewer than 25 invasive species of fish have entered the Great Lakes. Invasive filter-feeders such as zebra mussels have caused severe problems at power plants and municipal water supplies, clogging intake screens, pipes, and cooling systems. Fast-growing invasive plants have displaced native plant populations that support wildlife habitat and prevent erosion. The prevalence of these invasive plant species has also hindered commercial and recreational activities. Similar problems with invasive species have occurred in U.S. waters throughout the country.[4]

III. Basis and Purpose

A. Legal Authority

The Non-Indigenous Aquatic Nuisance Prevention and Control Act of 1990 (NANPCA, Pub. L. 101–646), as amended by the National Invasive Species Act of 1996 (NISA), (Pub. L. 104–332), requires the Secretary of Homeland Security (Secretary) to ensure, to the maximum extent practicable, that aquatic nuisance species are not discharged into U.S. waters from vessels (16 U.S.C. 4701 *et seq.*). These statutes also direct the Secretary to issue regulations and collect records regarding vessel ballasting practices as a means for determining vessel compliance with the

[1] See the American Association of Port Authorities Web site at *http://www.aapa-ports.org/Issues/USGovRelDetail.cfm?itemnumber=880.*

[2] For a list of examples of aquatic bio-invasions causing major impact internationally, see the International Maritime Organization's Web site at: *http://www.imo.org/OurWork/Environment/BallastWaterManagement/Pages/AquaticInvasiveSpecies(AIS).aspx.*

[3] See the EPA's Web site at *http://www.epa.gov/glnpo/invasive.*

[4] The U.S. Geological Survey maintains an online database of non-indigenous aquatic species at *http://nas.er.usgs.gov.* The database is searchable by several variables, including by state and species.