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, 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 listed in the animal drug regulations as 086053. AquaBounty Technologies, Inc., is not currently 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(o)(2)(iii), 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

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

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
</tr>
</thead>
<tbody>
<tr>
<td>AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754</td>
<td>086053</td>
</tr>
</tbody>
</table>

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

§ 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) 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.

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


■ 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:

§ 528.1092 Names, addresses, and drug labeler codes of sponsors of approved applications.

<table>
<thead>
<tr>
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§ 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.
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 (l) 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.H.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

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. 101–464), 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
Issues/USGovtRelDetail.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.imopo.org/OurWork/Environment/Ballast
WaterManagement/Pages/AquaticInvasive
Species(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://nais.er.usgs.gov. The database is searchable
by several variables, including by state and species.