this AD. This service information is not incorporated by reference in this AD.


(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to the appropriate inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Kalhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: 9-ANM-116-AMOC-REQUEST@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards District Office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Required for Compliance (RC): If any service information contains procedures or tests that are RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(3) Contacting the Manufacturer For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0217R1, dated February 26, 2015, for related information. This MCAI may be found in the AD docket on the Internet at http://www.regulations.gov/#/documentDetail;D=FAA–2015–0251–0003

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(3) and (p)(4) of this AD.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.


(3) For service information identified in this AD, contact Airbus, Airworthiness Office—ELAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet http://www.airbus.com.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federalregister/ed1–lib–locations.html.

Issued in Renton, Washington, on November 9, 2015.

Michael Kaszycki,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–29702 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–1869; Airspace Docket No. 15–AGL–9]

Establishment of Class E Airspace;
Newberry, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the legal description of a final rule published in the Federal Register of September 24, 2015, that establishes Class E airspace at the Newberry VHF Omni-Directional Range/Distance Measuring Equipment (VOR/DME), Newberry, MI. The legal description noted exclusionary language for Federal Airways and Canadian airspace not required for this airspace.

DATES: Effective date: 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under 1 Code of Federal Regulations, Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Raul Garza, Jr., Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway., Fort Worth, TX 76177; telephone 817–222–5874.

SUPPLEMENTARY INFORMATION:

History

On September 24, 2015, a final rule was published in the Federal Register establishing Class E airspace at the Newberry VOR/DME, Newberry, MI (80 FR 57522) Docket No. FAA–2015–1869. Subsequent to publication, the FAA found that the exclusionary language for Federal Airways and Canadian airspace noted in the airspace description is not required and, therefore, is removed.

Final Rule Correction

Accordingly, pursuant to the authority delegated to me, in the Federal Register of September 24, 2015, (80 FR 57522) FR Doc. 2015–23987, on
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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) construct at the α-locus in the EO–1 lineage triploid, hemizygous, all-female Atlantic salmon (Salmo salar) known as AQUADVANTAGE Salmon.

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)(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.

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 086053 for an approved application. A sponsor of an approved application.

PART 510—NEW ANIMAL DRUGS

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:

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

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

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:

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

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


4. Add § 528.1092 to read as follows:

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

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


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.