February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of amending ATS routes V–82, V–217, and T–383 due to the planned decommissioning of the Baudette VOR has no potential to cause any significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment. Therefore, this airspace action has been categorically excluded from further environmental impact review in accordance with the National Environmental Policy Act (NEPA) and its implementing regulations at 40 CFR parts 1500–1508, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–82 [Amended]

From Gopher, MN; Farmington, MN; Rochester, MN; Nodine, MN; to Dells, WI.

* * * * *

V–217 [Amended]

From INT Madison, WI, 138° and Badger, WI, 193° radials; Badger; Green Bay, WI; Rhinelander, WI; Duluth, MN; to Hibbing, MN.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–383 Gopher, MN (GEP) to Baudette, MN (BDE) [Amended]

Gopher, MN (GEP)	VORTAC	(Lat. 45°08′44.47″ N, long. 093°22′23.45″ W)
BRNRD, MN	WP	(Lat. 46°20′53.81″ N, long. 094°01′33.54″ W)
BLUOX, MN	FIX	(Lat. 47°34′33.13″ N, long. 095°01′29.11″ W)
Baudette, MN (BDE)	DME	(Lat. 48°43′22.07″ N, long. 094°36′26.24″ W)

Issued in Washington, DC, on February 12, 2020.

Mark Gauch,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–03282 Filed 2–20–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0686; Airspace Docket No. 18–AGL–21]

RIN 2120–AA66

Amendment of VOR Federal Airway V–7 in the Vicinity of Sheboygan, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends VHF Omnidirectional Range (VOR) Federal airway V–7 in the vicinity of Sheboygan, WI. The modifications are necessary due to the planned decommissioning of the VOR portion of the Falls, WI, VOR/Distance Measuring Equipment (VOR/DME) navigation aid (NAVAID), which provides navigation guidance for portions of the affected air traffic service (ATS) route. The Falls VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Effective date 0901 UTC, May 21, 2020. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is

promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2019–0686 in the **Federal Register** (84 FR 50347; September 25, 2019), amending VOR Federal airway V–7 due to the planned decommissioning of the VOR portion of the Falls, WI, VOR/DME NAVAID. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11D dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document will be subsequently published in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying VOR Federal airway V–7. The planned decommissioning of the VOR portion of the Falls, WI, VOR/DME has made this action necessary. The VOR Federal airway change is outlined below.

V–7: V–7 extends between the Dolphin, FL, VOR/Tactical Air Navigation (VORTAC) and the Muscle Shoals, AL, VORTAC; and between the Central City, KY, VORTAC and the Sawyer, MI, VOR/DME. The airspace below 2,000 feet mean sea level (MSL) outside the United States is excluded. The portion outside the United States has no upper limit. The PETTY fix in the airway description is amended to describe it as the intersection of the Chicago Heights, IL, VORTAC 358° and Badger, WI, VOR/DME 117° radials. Additionally, the airway segment between the intersection of the Chicago Heights, IL, VORTAC 358° and Badger, WI, VOR/DME 117° radials (PETTY fix) and the Green Bay, WI, VORTAC is removed. The unaffected portions of the existing airway remain as charted.

All radials in the route description are stated in True degrees.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of amending the PETTY fix NAVAID radial computations in VOR Federal airway V–7 and removing airway segment between the PETTY fix and the Green Bay, WI, VORTAC has no potential to cause any significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment. Therefore, this airspace action has been categorically excluded from further environmental impact review in accordance with the National Environmental Policy Act (NEPA) and its implementing regulations at 40 CFR parts 1500–1508, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–7

From Dolphin, FL; INT Dolphin 299° and Lee County, FL, 120° radials; Lee County; Lakeland, FL; Cross City, FL; Seminole, FL; Wiregrass, AL; INT Wiregrass 333° and Montgomery, AL, 129° radials; Montgomery; Vulcan, AL; to Muscle Shoals, AL. From Central City, KY; Pocket City, IN; INT Pocket City 016° and Terre Haute, IN, 191° radials; Terre Haute; Boiler, IN; Chicago Heights, IL; to INT Chicago Heights 358° and Badger, WI, 117° radials. From Green Bay, WI; Menominee, MI; to Sawyer, MI. The airspace below 2,000 feet MSL outside the United States is excluded. The portion outside the United States has no upper limit.

* * * * *

Issued in Washington, DC, on February 12, 2020.

Mark Gauch,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–03283 Filed 2–20–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA–2018–N–2732]

RIN 0910–AH57

Definition of the Term ''Biological Product''

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulation that defines ''biological product'' to incorporate changes made by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) and the Further Consolidated Appropriations Act, 2020 (FCA Act), and to provide its interpretation of the statutory term ''protein.'' Under this final rule, the term *protein* means any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. This final rule is intended to clarify the statutory framework under which such products are regulated.

DATES: This rule is effective March 23, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993, 301–796–6650, *daniel.gottlieb@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

This final rule amends FDA's regulation that defines ''biological product'' by making a technical revision and conforming to the statutory definition enacted in the BPCI Act, as further amended by section 605 of the FCA Act (Pub. L. 116–94). The BPCI Act amended the definition of ''biological product'' in section 351(i) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(i)) to include a ''protein (except any chemically synthesized polypeptide).'' After publication of the proposed rule, section 605 of the FCA Act further amended the definition of ''biological product'' in section 351(i) of the PHS Act to remove the parenthetical ''(except any chemically synthesized polypeptide)'' from the statutory category of ''protein.'' The final rule makes conforming changes to § 600.3 (21 CFR 600.3) to add FDA's interpretation of the statutory term ''protein.''

B. Summary of the Major Provisions of the Final Rule

Under the final rule, the term *protein* means any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size. This is consistent with the interpretation of this term that FDA previously described in the notice of proposed rulemaking published in the **Federal Register** on December 12, 2018 (83 FR 63817) and in a final guidance document issued on April 30, 2015 (see 80 FR 24259 (announcing the availability of a guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,'' available at *https://www.regulations.gov* (Docket No. FDA–2011–D–0611) (2015 Biosimilars Q&A Guidance); see also ''New and Revised Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation Act (Revision 2)'' (December 2018; 83 FR 63898)).

C. Legal Authority

This final rule amends FDA's regulations to implement certain aspects of the BPCI Act and the FCA Act. FDA's authority for this rule derives from the biological product provisions in section 351 of the PHS Act and the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, *et seq.*) applicable to drugs, as well as section 701 of the FD&C Act (21 U.S.C. 371). The rule is necessary to clarify the statutory authority under which biological products are regulated, to prevent inconsistent regulation of such products, and for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

This final rule codifies FDA's interpretation of the statutory term ''protein'' in a manner that is consistent with the interpretation of this term that FDA previously described in guidance (see 2015 Biosimilars Q&A Guidance) and the proposed rule. Formalizing this interpretation will reduce regulatory uncertainty over whether certain products are regulated as drugs or biological products. This reduced uncertainty, under the ''bright-line'' approach described in the proposed rule, will allow both FDA and private industry to avoid spending time and resources on case-by-case determinations for each product. The primary estimate of the benefits in 2018 dollars annualized over 10 years is $394,562 using a 7 percent discount rate and $348,436 using a 3 percent discount rate. We also calculate ranges of benefits of $356,775 to $411,345 and $316,116 to $362,792, respectively. The estimated annualized costs range from $13,511 to $16,889, with a primary estimate of $15,012 using a 7 percent discount rate over a 10-year horizon. For a 3 percent discount rate, we estimate a range of $12,471 to $15,589, with a primary estimate of $13,857.

II. Table of Abbreviations/Commonly Used Acronyms in This Document