

Figure 1 to paragraph (g) of this AD – *Service bulletins*

Airplane Model	Bombardier Service Bulletin	Issue Date
BD-700-1A10	700-53-051	May 17, 2017
BD-700-1A10	700-53-6009	May 17, 2017
BD-700-1A11	700-1A11-53-026	May 17, 2017
BD-700-1A11	700-53-5010	May 17, 2017

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York ACO Branch, 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 your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO Branch, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7300; fax 516-794-5531. 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.

(2) *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, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF-2018-14, dated May 1, 2018, for related information. This MCAI may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0796.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7323; fax 516-794-5531; email 9-avs-nyacos@faa.gov.

(j) 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.

(i) Bombardier Service Bulletin 700-1A11-53-026, dated May 17, 2017.

(ii) Bombardier Service Bulletin 700-53-051, dated May 17, 2017.

(iii) Bombardier Service Bulletin 700-53-5010, dated May 17, 2017.

(iv) Bombardier Service Bulletin 700-53-6009, dated May 17, 2017.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514-855-5000; fax 514-855-7401; email thd.crj@aero.bombardier.com; internet <http://www.bombardier.com>.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(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/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on November 23, 2018.

John P. Piccola,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018-26534 Filed 12-10-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2018-1013; Airspace Docket No. 18-ANE-7]

RIN 2120-AA66

Amendment of VOR Federal Airways V-318 and V-352; Northeastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the descriptions of VHF Omnidirectional Range (VOR) Federal airways V-318 and V-352 to reflect the removal of certain route segments within Canadian airspace that were deleted by NAV CANADA. This rule modifies the above airway descriptions to match the current configuration of the routes.

DATES: Effective date 0901 UTC, February 28, 2019. 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 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy 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 7400.11C at NARA, call (202)

741–6030, or go to <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, 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 modifies the descriptions of VOR Federal airways V–318 and V–352 to maintain the accuracy of navigation publications.

Background

NAV CANADA is the company that operates Canada's civil air navigation service. As part of Canada's efforts to expand the availability of area navigation (RNAV) routing, NAV CANADA has amended certain routes that traverse both Canadian and United States airspace. In this case, the descriptions of VOR Federal airways V–318 and V–352, as published in FAA Order 7400.11C, originate in Canadian airspace, then traverse through United States airspace (in the State of Maine) then reenter Canadian airspace.

The current route description of V–318 extends between the Quebec, PQ, Canada, VORTAC and the St John, NB, Canada, VOR/DME. NAV CANADA has deleted that segment at the western end of V–318 that runs between the Quebec VORTAC and the United States/Canadian border, at the PINTE, Canada, navigation fix. Therefore, the FAA is removing that segment from the V–318 description. The remainder of the route from the PINTE fix to the Houlton, ME, VOR/DME, and on to the St John, Canada VOR/DME remains in effect as currently charted.

The current route description of V–352 extends between the Beauce, PQ,

Canada VORTAC and the Fredericton, NB, Canada, VOR/DME. NAV CANADA has deleted the segment on the western end of the route between the Beauce VORTAC and the DEPRI, ME, waypoint (WP) at the United States/Canadian border. Additionally, NAV CANADA has deleted the route segment on the eastern end of the route between the Houlton, ME, VOR/DME and the Fredericton, NB, VOR/DME. FAA is amending the description of V–352 to remove the segments deleted by NAV CANADA. The amended V–352 lies totally within United States airspace and extends between PATTA, ME, navigation fix (defined by the intersection of the Beauce, PQ, Canada VOR/DME 085°(T)/100°(M) and the Bangor, ME, VORTAC 336°(T)/355°(M) radials) and the Houlton, ME, VOR/DME.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document will be subsequently amended in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying the descriptions of VOR Federal airways V–318 and V–352 to remove certain route segments in Canadian airspace.

V–318: NAV CANADA has deleted the route segment that extends between the Quebec VORTAC and the PINTE navigation fix (located on the United States/Canadian border). The FAA is amending the description of V–318 by removing the words “From Quebec, Province of Quebec, Canada, 81 miles 65 MSL, 26 miles 85 MSL,” and replacing them with the words “From INT Beauce, PQ, Canada 103°(T)/119°(M) and Quebec, PQ, Canada 047°(T)/062°(M) radials.” The new wording defines the PINTE fix. The remainder the route description to St John, NB, Canada, is unchanged.

The amended V–318 description reads:

“From INT Beauce, PQ, Canada 103° and Quebec, PQ, Canada 047° radials; Houlton, ME; INT Houlton 128° and St John, NB, Canada 267° radials; to St John. The airspace in Canada is excluded.”

V–352: NAV CANADA has deleted the route segments between the Beauce, PQ, Canada, VOR/DME and the United States/Canadian border; and the segments between the Houlton, ME, VOR/DME and the Fredericton, NB, Canada, VOR/DME.

The FAA is amending the description of V–352 by removing the words “From Beauce, Quebec, Canada, via” and replacing them with the words “From INT Beauce, PQ, Canada 085°(T)/100°(M) and Bangor, ME 336°(T)/355°(M) radials; to” and removing the words “to Fredericton, NB, Canada, excluding the airspace in Canada.” The amended route is entirely within United States airspace.

The amended V–352 description reads:

“From INT Beauce, PQ, Canada 085° and Bangor, ME, 336° radials; to Houlton, ME.”

Note: For reference, both True and Magnetic degrees are shown where new navigation aid radials are added in the above descriptions. Per standard practice, only True degrees are stated in the amended route descriptions as listed in “The Amendment” section, below.

Because this amendment is necessary to update the descriptions of V–318 and V–352 by removing airway segments in Canadian airspace that have been deleted by NAV CANADA, I find that notice and public procedure under 5 U.S.C. 553(b) are impractical and contrary to the public interest. This action is necessary to ensure agreement between navigation databases and accurate depiction of the routes on aeronautical charts.

Regulatory Notices and Analyses

The FAA has determined that this 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 action, of modifying the descriptions of VOR Federal airways V-318 and V-352 to reflect the removal of certain route segments within Canadian airspace deleted by NAV CANADA, qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, 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). This action is not expected to result in any potentially significant environmental impacts. 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 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018 and effective September 15, 2018, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V-318 [Amended]

From INT Beauce, PQ, Canada 103° and Quebec, PQ, Canada, 047° radials; Houlton, ME; INT Houlton 128° and St John, NB, Canada, 267° radials; to St John. The airspace within Canada is excluded.

V-352 [Amended]

From INT Beauce, PQ, Canada 085° and Bangor, ME 336° radials; to Houlton, ME.

* * * * *

Issued in Washington, DC, on December 3, 2018.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–26678 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2016–N–2462]

RIN 0910–AH35

List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations to revise the list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. Drug products appearing on this list may not be compounded under the exemptions provided by sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, the final rule adds two entries to this list of drug products.

DATES: This rule is effective January 10, 2019.

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:

Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993–0002, 301–796–3110.

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I. Executive Summary

A. Purpose of the Regulatory Action

FDA is amending its regulations to revise the list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (referred to as “the withdrawn or removed list” or “the list”) (§ 216.24 (21 CFR 216.24)). Drug products appearing on the withdrawn or removed list may not be compounded under the exemptions provided by sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b). In this final rule, the Agency is finalizing in part the proposed amendments to § 216.24 set forth in the proposed rule published in the **Federal Register** of October 18, 2016 (81 FR 71648).

B. Summary of the Major Provisions of the Regulatory Action

After soliciting public comments and consulting with the FDA Pharmacy Compounding Advisory Committee (the Committee), we are adding the following entries to the list in § 216.24 of drug products that have been withdrawn or removed from the market because such drug products or