

(1) Incorporate a passenger seat, ERDA Vendor Part Number (VPN) 403008-1 or 403008-2 (also identified as Pilatus Part Number (P/N) 959.30.01.601, 959.30.01.602, 959.30.01.613, or 959.30.01.614) (or FAA-approved equivalent part number), with a serial number as specified in Decrane Aircraft, ERDA, Inc., Service Bulletin SB02010, Revision A, June 3, 2002; and

(2) Are certificated in any category.
 (b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.
 (c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct pedestal leg assemblies on aft facing passenger seats that are in

nonconformance with manufacturing standards. Nonconforming passenger seats could result in passenger injury in an emergency situation.
 (d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following, unless already accomplished:

Actions	Compliance	Procedures
(1) Inspect the forward pedestal legs on the aircraft aft facing passenger seat for correct configuration.	Within the next 90 days after the effective date of this AD.	In accordance with Decrane Aircraft, ERDA, Inc., Service Bulletin SB02010, Revision A, June 3, 2002; as specified in Pilatus PC12 Service Bulletin No. 25-025, dated September 27, 2002.
(2) If the legs are incorrectly configured, modify to the correct configuration.	Prior to further flight after the inspection required in paragraph (d)(1) of this AD.	In accordance with Decrane Aircraft, ERDA, Inc., Service Bulletin SB02010, Revision A, June 3, 2002; as specified in Pilatus PC12 Service Bulletin No. 25-025, dated September 27, 2002.
(3) Do not install any affected seat specified in paragraph (a) of this AD unless it has been inspected as specified in paragraph (d)(1) of this AD and configured in accordance with Decrane Aircraft, ERDA, Inc., Service Bulletin SB02010, Revision A, June 3, 2002; as specified in Pilatus PC12 Service Bulletin No. 25-025, dated September 27, 2002.	As of the the effective date of this AD	In accordance with Decrane Aircraft, ERDA, Inc., Service Bulletin SB02010, Revision A, June 3, 2002; as specified in Pilatus PC12 Service Bulletin No. 25-025, dated September 27, 2002

Note 1: Although not required by this AD, we recommend that you verify that the Pilatus part number correctly corresponds with the ERDA vendor part number on certain passenger seats. The procedures for accomplishing this action are contained in Decrane Aircraft, ERDA, Inc., Service Bulletin SB02011, Revision A, June 3, 2002.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:
 (1) Your alternative method of compliance provides an equivalent level of safety; and
 (2) The Manager, Standards Office, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standards Office.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas

City, Missouri 64106; telephone: (816) 329-4059; facsimile: (816) 329-4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Pilatus Aircraft Ltd., Customer Liaison Manager, CH-6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 619 6224; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021; telephone: (303) 465-9099; facsimile: (303) 465-6040. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in Swiss AD Number HB 2002-658, dated November 30, 2002.

Issued in Kansas City, Missouri, on February 10, 2003.

Michael Gallagher,
 Manager, Small Airplane Directorate, Aircraft Certification Service.
 [FR Doc. 03-3871 Filed 2-18-03; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA 2003-14368; Airspace Docket No. ASD 02-ASW-4]

RIN 2120-AA66

Proposed Revision of Jet Route; Baton Rouge, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to revise segments of Jet Route 2 (J-2), J-138, and J-590 by realigning the routes to the north over the Baton Rouge, LA, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC). The FAA is proposing this action to enhance the management of the aircraft operations over the Baton Rouge, LA, area.

DATES: Comments must be received on or before April 17, 2003.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify the docket number FAA-2003-14368/ Airspace Docket No. 02-ASW-4, at the beginning of your comments.

You may also submit comments on the Internet at <http://dms.dot.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, 2601 Meacham Blvd.; Fort Worth, TX 76193-0500.

FOR FURTHER INFORMATION CONTACT: Steve Rohring, Airspace and Rules Division, ATA-400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA 2003-14368/Airspace Docket No. 02-ASW-4." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the Internet at <http://dms.dot.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov> or the Superintendent of Document's Web page at <http://www.access.gpo.gov/nara>.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should call the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

The FAA is conducting a comprehensive revision of the Houston terminal airspace area. As part of this effort, the FAA plans to revise certain segments of J-2, J-138, and J-590 over the new Baton Rouge, LA, VORTAC to promote the expeditious movement of aircraft through the Baton Rouge, LA, airspace area. The FAA believes that this action would enhance the management of air traffic operations in the area.

The Proposal

The FAA is proposing to amend Title 14 Code of Federal Regulations (14 CFR) part 71 (part 71) to revise segments of J-2 and J-138 between the Lake Charles, LA, VORTAC and the Semmes, AL, VORTAC; and J-590 between the Lake Charles, LA, VORTAC and the Greene County, MS, VORTAC, by realigning the routes to the north over the Baton Rouge, LA, VORTAC. This action is necessary to support the planned revision of the Houston terminal airspace area.

Jet routes are published in paragraph 2004 of FAA Order 7400.9K dated August 30, 2002, and effective September 16, 2002, which is incorporated by reference in 14 CFR 71.1. The jet route listed in this document would be published subsequently in the order.

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. Therefore, this proposed regulation: (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 will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

Authority: 49 U.S.C. 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 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 2004—Jet Routes

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J-2 [Revised]

From Mission Bay, CA, via Imperial, CA; Bard, AZ; INT of the Bard 089° and Gila Bend, AZ, 261° radials; Gila Bend; Cochise, AZ; El Paso, TX; Fort Stockton, TX; Junction, TX; San Antonio, TX; Humble, TX; Lake Charles, LA; Baton Rouge, LA; Semmes, AL; Crestview, FL; INT of the Crestview 091° and the Seminole, FL, 290° radials; Seminole to Taylor, FL.

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J-138 [Revised]

From Fort Stockton, TX, via Center Point, TX; San Antonio, TX; Hobby, TX; Lake Charles, LA; Baton Rouge, LA; to Semmes, AL.

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J-590 [Revised]

From Lake Charles, LA, via Baton Rouge, LA; Greene County, MS; to Montgomery, AL.
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Issued in Washington, DC, on February 12, 2003.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 03-3965 Filed 2-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 349

[Docket No. 80N-145B]

RIN 0910-AA01

Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Proposed Amendment of Final Monograph for Over-the-Counter Ophthalmic Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) ophthalmic drug products to include OTC emergency first aid eyewash drug products. These products are used to flush or irrigate the eye to remove acid and alkali chemicals or particulate contamination. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by May 20, 2003. Submit written or electronic comments on the agency's economic impact determination by May 20, 2003. Please see section IX of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Marina Y. Chang, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 1988 (53 FR 7076), FDA published a final monograph for OTC ophthalmic drug products in part 349 (21 CFR part 349). The monograph provides for eyewash drug products in § 349.20, but does not include emergency first aid eyewash drug products because there were no submissions or comments on these products during the rulemaking process.

After the final monograph was published, the agency received a request for an advisory opinion (Ref. 1) concerning the status of a product used for emergency first aid treatment of chemical burns of the eyes and skin. This product was described as a sterile phosphate buffered solution containing sodium phosphate, USP and monobasic potassium phosphate, NF, preserved with edetate disodium, USP 1:2,000 and benzalkonium chloride, USP 1:5,000, for use immediately following a chemical burn to thoroughly flush the eyes and skin for the express purpose of removing the chemical irritant, and to relieve the discomfort and burning caused by the irritating chemical prior to seeking medical treatment.

As a result, the agency published a request for data and information on this category of drugs in the **Federal Register** of December 5, 1989 (54 FR 50240). The agency stated that it was unaware of sufficient data to make a determination as to the safety, effectiveness, and proper labeling of these ophthalmic drug products. Specifically, the agency noted that the majority of these products: (1) Are not intended to be marketed directly to individual consumers; (2) are often packaged in large volume containers not normally found at the retail level of distribution, especially for OTC ophthalmic drug products; (3) may be stored for long periods of time under different environmental conditions; (4) may be marketed in different types of containers and closure systems; and (5) may be used with plumbed, nonplumbed, self-contained emergency eyewash, or shower equipment/stations. The agency noted it was not aware of all of the various labeling formats, labeling statements, and formulations of all the various emergency first aid eyewash products.

In response to the request for data and information, three manufacturers and one manufacturer's association provided submissions (Refs. 2 through 7) that included several journal articles in support of the safety and effectiveness of products that provide immediate emergency care by neutralization and

dilution to the most serious burns due to strong acids and alkalis. The submitted literature explained that acid burns cause instantaneous coagulation of protein and result in limited damage, whereas strong alkalis penetrate the ocular tissues rapidly and produce damage that is widespread, uncontrolled, and progressive (Ref. 8). The literature (Ref. 2) included a quote from the National Institute of Occupational Safety and Health occupational health guidelines which states: "If (chemical) gets into the eyes, wash eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately." The comment included an excerpt from the regulations of the Occupational Safety and Health Administration (OSHA) entitled "Requirements for Medical and First Aid" (42 CFR 1910.151). This portion of the OSHA regulations assures that workers exposed to injurious corrosive materials be provided with "suitable facilities for quick drenching or flushing of the eye." One manufacturer also provided sample labeling of several marketed products (Ref. 5).

II. Comments Received and the Agency's Responses

A. Neutralization

Three comments addressed the term "neutralization." One comment stated that it removed this term from the principal display panel of its product's labeling and replaced it with "Wash/Flush" because the latter term better expressed the action of the product. Another comment considered the term "neutralization" to be relative and not absolute. The third comment believed that neutralizing was part of the action of the product and provided a chart demonstrating the buffering capacity of a neutralizer solution towards strong acids and bases versus purified water (Ref. 7).

The agency reviewed available medical literature (Refs. 8 through 15) and found the treatment of choice for acid and alkali burns listed in this literature to be copious and continuous irrigation of the area with water or a pH balanced solution for at least 20 to 30 minutes. According to the American Academy of Ophthalmology (Ref. 8), "Specific neutralizing agents are not useful; simple dilution (with water or saline solution) is the most effective and practical way of neutralizing strong chemicals." *Casarett and Doull's Toxicology: The Basic Science of Poisons* (Ref. 9) states: "Attempts to obtain some special buffered solution or