under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

British Aerospace Regional Aircraft [Formerly Jetstream Aircraft Limited; British Aerospace (Commercial Aircraft) Limited]: Docket 2000–NM–152–AD.

Applicability: All Model Jetstream 4101 airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, 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 (c) 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 the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent restricted movement of the rudder pedals due to structural interference, which could result in reduced controllability of the airplane, accomplish the following:

Functional Check

(a) Within 60 days after the effective date of this AD, perform a functional check of the

left and right rudder pedals to ensure full and free movement at all rudder pedal positions, in accordance with Part 1 of the Accomplishment Instructions of Jetstream Alert Service Bulletin J41–A27–055, dated March 10, 2000. If any restriction in rudder pedal movement is found, prior to further flight, accomplish the modification required by paragraph (b) of this AD.

Modification

(b) Within 8 months after the effective date of this AD, modify the forward pedal boxes [including moving the rudder pedals and measuring clearances between the rod attachment bolt and the flange of the floor channel; correcting any incorrect clearances; and repeating the functional check of the rudder pedals specified in paragraph (a) of this AD] in accordance with Part 2 of the Accomplishment Instructions of Jetstream Alert Service Bulletin J41–A27–055, dated March 10, 2000.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in British airworthiness directive 002–03–2000.

Issued in Renton, Washington, on August 23, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. 00–21997 Filed 8–28–00; 8:45 am] BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00-ASO-29]

Proposed Establishment of Class D and Class E4 Airspace; New Bern, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Class D and Class E4 airspace at New Bern, NC. A Federal Contract Tower will become operational at Craven County Regional Airport, NC, by October 1, 2000. The air traffic controllers will be certificated as weather observers when the tower opens. Therefore, the airport will meet criteria for Class D and Class E4 airspace. Class D surface area airspace and Class E4 airspace designated as an extension to Class D airspace are required when the control tower is open to accommodate current Standard **Instrument Approach Procedures** (SIAPs) and for Instrument Flight Rules (IFR) operations at the airport. This action would establish Class D airspace extending upward from the surface to and including 2,500 feet MSL within a 4-mile radius of the airport.

DATES: Comments must be received on or before September 28, 2000.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 00–ASO–29, Manager, Airspace Branch, ASO–520, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5627.

FOR FURTHER INFORMATION CONTACT:

Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5586.

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 the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made:

"Comments to Airspace Docket No. 00-ASO-29." The postcard will be date/ time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, 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 NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class D airspace and Class E4 airspace at New Bern, NC. Class D airspace designations for airspace areas extending upward from the surface and Class E4 airspace designations for airspace areas designated as an extension to a Class D airspace area are published in Paragraphs 5000 and 6004 respectively, of FAA Order 7400.9G, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E4 airspace designations listed in this document would be published subsequently in the

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 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 Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 5000 Class D Airspace

ASO NC D New Bern, NC [New]

Craven County Regional Airport, NC (Lat. 35°04′23″ N, long. 77°02′35″ W)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4-mile radius of the Craven County Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E4 Airspace Areas Designated as an Extension to a Class D Airspace Area

ASO NC E4 New Bern, NC [New]

Craven County Regional Airport, NC (Lat. 35°04′23″ N, long. 77°02′35″ W)

New Bern VOR/DME, NC

(Lat. 35°04'23" N, long. 77°02'42" W)

That airspace extending upward from the surface within 2.4 miles each side of the New Bern VOR/DME 038° and 210° radials,

extending from the 4-mile radius to 7 miles northeast and southwest of the VOR/DME. This Class E4 airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in College Park, Georgia, on August 17, 2000.

Earl Newalu.

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–22043 Filed 8–28–00; 8:45 am] BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 822

[Docket No. 00N-1367]

Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement the postmarket surveillance (PS) provisions of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the FDA Modernization Act of 1997 (FDAMA). The purpose of this proposed rule is to provide for the collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information about devices.

DATES: Submit written comments on the proposed rule by November 27, 2000. See section III of this document for the proposed effective date of a final rule based on this document. Submit written comments regarding the information collection by September 28, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and other data to http://www.accessdata.fda.gov/ scripts/oc/dockets/comments/ commentdocket.cfm. For other information about filing comments electronically, see the SUPPLEMENTARY **INFORMATION** section for information on electronic access and filing address. Submit written comments on the information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington,