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 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 Airspace Docket No. 97–ASO–26.'' 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 notice may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Assistant Chief 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 notice 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 amend the Class E airspace area at New Bern, NC. The required weather observation information is available on a continuous basis to the air traffic control facility providing service to New Bern, Craven County, NC, Airport. Therefore, the Class E surface area airspace at New Bern, NC, meets the requirement for modification from part time to continuous. Class E airspace areas designated as a surface area for an airport are published in Paragraph 6002 of FAA Order 7400.9E dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations 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. 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 14 CFR 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 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

ASO NC E2—New Bern, NC [Revised]

New Bern, Craven County Regional Airport, NC
(Lat 35°04′21″ N, long. 77°02′37″ W)
New Bern VOR/DME
(Lat 35°04′23″ N, long 77°02′42″ W)

Within a 4-mile radius of Craven County Regional Airport and within 2.4 miles each side of New Bern VOR/DME 038° and 210° radials, extending from the 4-mile radius northeast and southwest of the VOR/DME.

* * * * *

Issued in College Park, Georgia, on November 24, 1997.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–32035 Filed 12–5–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 173P]

Schedules of Controlled Substances: Proposed Placement of Sibutramine Into Schedule IV

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Acting Deputy Administrator of the DEA to place the substance, sibutramine, including its salts and optical isomers into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) that sibutramine be added to Schedule IV and on an evaluation of the relevant data by the DEA. If finalized, this action will impose the regulatory controls and criminal sanctions of Schedule IV on those who handle sibutramine and products containing sibutramine.

DATES: Comments, objections, and requests for a hearing must be received on or before January 7, 1998.

ADDRESSES: Comments, objections and requests for a hearing should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537, Attn.: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Sibutramine is an amphetamine analogue pharmacologically similar to other anorectic agents that produce central nervous system stimulation and amphetamine-like effects in humans and animals. Sibutramine hydrochloride will be marketed under the trade name of MERIDA as an oral anorectic for the long term management of obesity.

The Acting Deputy Administrator of the DEA received a letter dated November 12, 1997 from the Acting Assistant Secretary for Health, on behalf of the Secretary of the DHHS, recommending that the substance, sibutramine, and salts and isomers thereof, be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the letter from the Assistant Secretary was a document prepared by the Food and Drug Administration (FDA) entitled ''Basis for the Recommendation for Control of Sibutramine and its Salts in Schedule IV of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811(b)] and the summarized recommendations regarding the placement of sibutramine into Schedule IV of the CSA.

The factors considered by the Assistant Secretary for Health with respect to the drug sibutramine were:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under the CSA.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary of Health, the FDA New Drug Application (NDA) approval on November 22, 1997, and a DEA review, the Acting Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Sibutramine has a low potential for abuse relative to the drugs or other substances in Schedule III.

(2) Sibutramine has a currently accepted medical use in treatment in the United States.

(3) Abuse of sibutramine may lead to limited physical dependence and psychological dependence relative to the drugs or other substances in Schedule III.

Interested persons are invited to submit their comments, objections or requests for a hearing, in writing, with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537. Attention: DEA Federal Register Representative/CCR. In the event that comments, objections or requests for a hearing raise one or more issues which the Acting Deputy Administrator finds warrants a hearing, the Acting Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking on the record after opportunity for a hearing. Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1).

The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Sibutramine is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marked once it is placed into Schedule IV of the CSA. This proposed rule, if finalized, will allow these entities to have access to a new pharmaceutical product.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, drug traffic control, narcotics, prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

§ 1308.14 [Amended]

2. Section 1308.14 is proposed to be amended by redesignating the existing paragraph (e)(10) as (e)(11) and adding a new paragraph (e)(10) to read as follows:

§ 1308.14 Schedule IV

* * * * *

(10) Sibutramine 1675

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Dated: December 2, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–31951 Filed 12–5–97; 8:45 am]

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