

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. Persons 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-2007-29361/Airspace Docket No. 07-AEA-5." 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. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at <http://www.faa.gov> or the Federal Register's web page at <http://www.gpoaccess.gov/fr/index.html>. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace at Factoryville, PA. A new Runway 4 Standard Instrument Approach Procedure (SIAP) has been developed for Seamans Field. As a result, controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain the SIAP and for Instrument Flight Rules

(IFR) operations at Seamans Field. This proposal would increase current Class E airspace from a 6.2-mile radius to an 8.2-mile radius of Seamans Field and including the airspace within 5.3 miles each side of the Lake Henry VORTAC 299° radial extending from the 8.2-mile radius of Seamans Field to the VORTAC. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9R, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation 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.

The FAA's authority to issue rules regarding aviation safety is found in the 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 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 amends Class E Airspace at Factoryville, PA.

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 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA PA E5 Factoryville, PA [Amended]

Seamans Field, PA

(Lat. 41°35'22" N., long. 75°45'22" W.)

Lake Henry VORTAC

(Lat. 41°28'33" N., long. 75°28'57" W.)

That airspace extending upward from 700 feet above the surface within an 8.2-mile radius of Seamans Field and including the airspace within 5.3 miles each side of the Lake Henry VORTAC 299° radial extending from the 8.2-mile radius of Seamans Field to the VORTAC.

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Issued in College Park, Georgia, on December 17, 2007.

Mark D. Ward,

Manager, System Support Group, Eastern Service Center.

[FR Doc. 08–350 Filed 1–30–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–283P]

Schedules of Controlled Substances: Placement of Indiplon Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance indiplon (N-methyl-N-[3-[3-(2-thienylcarbonyl)-pyrazolo[1,5-a]pyrimidin-7-

yl]phenyl]acetamide), including its salts, and all products containing indiplon 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) and an evaluation of the relevant data by DEA. This scheduling of indiplon in schedule IV will not be finalized until a New Drug Application (NDA) for an indiplon product is approved by the Food and Drug Administration (FDA). If finalized, this action will impose the regulatory controls and criminal sanctions applicable to schedule IV non-narcotics on those who handle indiplon and products containing indiplon.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before March 3, 2008.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-283" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. However, persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. DEA will accept electronic comments containing MS Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Note Regarding This Proposed Scheduling Action

In accordance with the provisions of the Controlled Substances Act (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 the Administrative Procedure Act (5 U.S.C. 556 and 557). Interested persons are invited to submit their comments, objections or requests for a hearing with regard to this proposal. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. Requests for a hearing should be made in accordance with 21 CFR 1308.44 and

should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Background

Indiplon acts as an agonist at benzodiazepine sites of the GABA_A receptor-channel complex. It has comparable sedative/hypnotic action to that of the benzodiazepines, diazepam and triazolam, and non-benzodiazepines that bind to the GABA_A complex, such as zolpidem, zaleplon and zopiclone, all of which are controlled as depressants in schedule IV of the CSA. Indiplon has a similar pharmacological profile as these substances in addition to a short plasma half-life and short duration of action. In a human abuse-liability study in individuals with known histories of sedative abuse, oral administration of indiplon (30 mg, 50 mg and 80 mg) produced dose-dependent increases in drug-liking and decreases in psychomotor and cognitive functioning comparable to those produced by the schedule IV benzodiazepine, triazolam. Indiplon is likely to be diverted and abused in the same manner as other schedule IV depressants.

The FDA has received two NDAs for indiplon products, Somposure® and Somposure® MR. These products are currently under review for the treatment of insomnia, as characterized by difficulty in sleep onset or sleep maintenance. Indiplon is a new chemical entity and has not been marketed in the United States or in other countries.

On January 23, 2006, the Assistant Secretary for Health of the DHHS sent the Administrator of the DEA a scientific and medical evaluation and a letter recommending that indiplon be placed into schedule IV of the CSA. Enclosed with the January 23, 2006, letter was a document prepared by the FDA entitled, "Basis for the Recommendation for Control of Indiplon 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)).

The factors considered by the Assistant Secretary of Health and DEA with respect to Indiplon were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effects;
- (3) The state of current scientific knowledge regarding the drug;
- (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; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter (21 U.S.C. 811(c)).

Based on the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by the DEA, the Deputy Administrator of the DEA, pursuant to section 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Based on information now available, indiplon has a low potential for abuse relative to the drugs or other substances in schedule III;

(2) Once approved for marketing, indiplon will have a currently accepted medical use in treatment in the United States; and

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

Based on these findings, the Deputy Administrator of the DEA concludes that indiplon, including its salts, and all products containing indiplon, warrant control in schedule IV of the CSA, if and when a NDA for indiplon is approved.

Interested persons are invited to submit their comments, objections or requests for a hearing 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 Drug Enforcement Administration using the address information provided above. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. In the event that comments, objections, or requests for a hearing raise one or more issues which the Deputy Administrator finds warrant a hearing, the 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.

Requirements for Handling Indiplon

If this rule is finalized as proposed, indiplon and all products containing indiplon would be subject to the Controlled Substances Act and the Controlled Substances Import and Export Act regulatory controls and

administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with indiplon, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with indiplon, would need to register with the DEA to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

Security. Indiplon would be subject to schedule III-V security requirements and must be manufactured, distributed and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77.

Labeling and Packaging. All labels and labeling for commercial containers of indiplon which are distributed on or after finalization of this rule would need to comply with requirements of 21 CFR 1302.03–1302.07.

Inventory. Every registrant required to keep records and who possesses any quantity of indiplon would be required to keep an inventory of all stocks of indiplon on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who desires registration in schedule IV for indiplon would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to 21 CFR 1304.03, 1304.04, 1304.05, 1304.21, 1304.22, and 1304.23.

Prescriptions. All prescriptions for indiplon or prescriptions for products containing indiplon would be required to be issued pursuant to 21 CFR 1306.03–1306.06, 1306.21–1306.27.

Importation and Exportation. All importation and exportation of indiplon would need to be in compliance with 21 CFR Part 1312.

Criminal Liability. Any activity with indiplon not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after finalization of this proposed rule would be unlawful.

Regulatory Certifications

Executive Order 12866

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 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 entities. Indiplon products will be prescription drugs used for the treatment of insomnia. Handlers of indiplon often handle other controlled substances which are already subject to the regulatory requirements of the CSA.

Executive Order 12988

This regulation meets the applicable standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 United States-based companies to compete with foreign based companies in domestic and export markets.

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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.

2. Section 1308.14 is amended by redesignating paragraphs (c)(25) through (c)(51) as (c)(26) through (c)(52) and adding a new paragraph (c)(25) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(25) indiplon (N-methyl-N-[3-[3-(2-thienylcarbonyl)-pyrazolo[1,5-
a]pyrimidin-7-yl]phenyl]-acetamide)—
2726

* * * * *

Dated: January 22, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8-1692 Filed 1-30-08; 8:45 am]

BILLING CODE 4410-09-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R03-OAR-2007-1139; FRL-8523-4]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Control of Volatile Organic Compound (VOCs) Emissions From the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, VA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia on October 29, 2007. This revision pertains to a federally enforceable state operating permit containing terms and conditions for the control of emissions of volatile

organic compounds (VOCs) from the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, Virginia. The submittal is for the purpose of meeting the requirements for reasonably available control technology (RACT) in order to implement the maintenance plan for the Richmond 8-hour ozone maintenance area. EPA is proposing to approve the revision to the Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: Written comments must be received on or before March 3, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2007-1139, by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *E-mail:*

fernandez.cristina@epa.gov.

C. *Mail:* EPA-R03-OAR-2007-1139, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2007-10139. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM

you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814-2166, or by e-mail at *shandruk.irene@epa.gov*.

SUPPLEMENTARY INFORMATION: On October 29, 2007, the Commonwealth of Virginia submitted a revision to its State Implementation Plan (SIP) for the control of emissions of VOCs from the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, Virginia. The submittal is for the purpose of meeting the requirements for Reasonably Available Control Technology (RACT) in order to implement the maintenance plan for the Richmond 8-hour ozone maintenance area.

I. Background

RACT is the lowest emission limit that a particular source is capable of meeting by the application of control technology that is reasonably available with the consideration of technological and economic feasibility. When the Richmond area was originally designated as an ozone nonattainment area under the 1-hour standard, it was classified as moderate and thereby had to meet the non-CTG RACT requirements of section 182 of the CAA. As part of the 1-hour ozone attainment plan, one of the sources located in the area identified as being subject to non-CTG RACT was Nabisco Brands (now Kraft Foods). Cookies, crackers, and pretzels are produced at this plant. The sources of VOC emissions at this plant