to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Except for editorial changes this amendment is the same as that proposed in the notice.

The Rule

This action amends part 71 by lowering the floor of a portion of V–465 from 12,400 MSL to 1,200 feet above the surface. This action supports the instrument approach procedure requirements into the Jackson Hole Airport, Jackson, WY.

This action also establishes a new segment of V–465 between Billings, MT, and Miles City, MT. When V–465 was established, the FAA intended that the airway include a segment between Billings, MT, and Miles City, MT; however, the airway segment was omitted due to a typographical error. This action properly defines that portion of V–465 between Billings, MT, and Miles City, MT, that was omitted in previous publications. This new segment does not result in any additional controlled airspace because the segment is co-located with a segment of V–2.

The FAA is taking this action to enhance the management of air traffic operations in the Jackson Hole, WY, area.

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. Therefore, this regulation: (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.

Domestic VOR Federal airways are published in paragraph 6010(a) 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 airways listed in this document will be published subsequently in the Order.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 [Revised]

2. The incorporation by reference in 14 CFR 71.1 of the 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 6010(a)—Domestic VOR Federal Airways

* * * * *

V–465 [Revised]

From Bullion, NV, Wells, NV; 12 miles; 30 miles, 115 MSL, 20 miles, 90 MSL, 36 miles, 115 MSL, 24 miles, 95 MSL, Malad City, ID; Jackson, WY; Dunoir, WY; 14 miles, 45 miles, 137 MSL, Billings, MT; Miles City, MT; Williston, ND.

* * * * *

Issued in Washington, DC, on July 24, 1998.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 98–20341 Filed 7–29–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 341

[Docket No. 76N–052N]

RIN 0910–AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion caused by acute or chronic rhinitis) to add the ingredient levmetamfetamine (formerly l-desoxyephedrine) and to classify this ingredient as generally recognized as safe and effective for OTC use. The agency is also removing l-desoxyephedrine from the list of nonmonograph active ingredients. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: July 30, 1999.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin, 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 August 23, 1994 (59 FR 43386), the agency published a final rule in the form of a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective. The final monograph did not include l-desoxyephedrine as a nasal decongestant active ingredient because it was not currently standardized and characterized for quality and purity in an official compendium, i.e., the United States Pharmacopeia (USP)/National Formulary (59 FR 43386 at 43408). Instead, the final rule listed l-desoxyephedrine in § 310.545(a)(6)(ii)(B) (21 CFR 310.545(a)(6)(ii)(B)) as not generally recognized as safe and effective. The agency stated in the final rule that OTC drug products containing l-desoxyephedrine as a topical nasal decongestant active ingredient were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)). The effective date of the final rule was August 23, 1995.

In the **Federal Register** of March 8, 1996 (61 FR 9570), the agency stayed the entry for ''l-desoxyephedrine (topical)'' in § 310.545(a)(6)(ii)(B) until further notice. The agency explained that a citizen petition submitted in response to the OTC nasal decongestant final rule requested that the agency defer the effective date of § 310.545(a)(6)(ii)(B) as it applies to l-desoxyephedrine (topical) until December 31, 1996. The petitioner stated that it had forwarded a draft compendial monograph for l-desoxyephedrine to the USP in late July 1995. The agency added that when l-desoxyephedrine becomes official in the

USP, the final monograph for OTC nasal decongestant drug products would be amended to include the active ingredient and § 310.545(a)(6)(ii)(B) would be revised accordingly. The agency provided certain labeling requirements that would be in effect for topical nasal decongestant drug products containing l-desoxyephedrine during the stay (61 FR 9570).

II. Recent Developments

In the *Pharmacopeial Forum* of January/February 1997 (Ref. 1), USP proposed a monograph for l-desoxyephedrine. Based on the United States Adopted Names (USAN) Council's recommendation, the proposal included levmetamfetamine as the new name for l-desoxyephedrine. The USAN Council and USP used the International Nomenclature Name (INN), levmetamfetamine, in place of l-desoxyephedrine. Levmetamfetamine is the title of the monograph adopted in the 6th Supplement of USP 23 (Ref. 2).

In response to the USP proposed monograph for levmetamfetamine (Ref. 1), the agency at that time expressed its strong objection and the objection of the U.S. Department of Justice, Drug Enforcement Administration (DEA) concerning the USAN Council's recommendation to adopt ''levmetamfetamine'' as the nonproprietary name for l-desoxyephedrine (Ref. 3). The agency indicated to the Council that both FDA and DEA shared concerns about an increased use of methamphetamine in the United States and with the large-scale diversion of some OTC drug products for illicit use in the manufacture of the controlled substances methamphetamine and methcathinone. Both agencies had concerns that the new name, levmetamfetamine, might draw the attention of potential drug abusers to these OTC nasal decongestant drug products if they contain ''metamfetamine'' in their name. The agency pointed out that although l-desoxyephedrine is a nonnarcotic substance (21 CFR 1308.22), an OTC drug product label containing a sound-alike name, such as ''levmetamfetamine'' may encourage intentional misuse. For these concerns, the agency asked the USAN Council to reconsider the proposed name change.

At its January 27, 1997, meeting, the USAN Council considered the agency's request regarding the name change of l-desoxyephedrine to ''levmetamfetamine'' and voted to retain the name for the following reasons (Ref. 4): (1) Levmetamfetamine is nonaddictive, (2) the new name is consistent with INN policy, and (3) any other name for l-desoxyephedrine may also be confusing. At this time, the agency accepts the USAN Council's decision and is using levmetamfetamine as the new name for l-desoxyephedrine in the OTC nasal decongestant final monograph.

III. The Agency's Final Conclusions

Based on the new USP monograph for levmetamfetamine, the agency is amending the final monograph for OTC nasal decongestant drug products to include levmetamfetamine in § 341.20(b)(1) (21 CFR 341.20(b)(1)) as a safe and effective OTC nasal decongestant active ingredient. The agency is also adding labeling for products containing this ingredient to the OTC nasal decongestant final monograph as follows:

1. In § 341.80(c)(2)(ii) (21 CFR 341.80(c)(2)(ii): *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for adults.* ''Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.''

2. In § 341.80(c)(2)(vii): *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for children under 12 years of age.* ''Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.''

3. In § 341.80(d)(2)(i): *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form.* ''The product delivers in each 800 milliliters of air 0.04 to 0.150 milligrams of levmetamfetamine. Adults: 2 inhalations in each nostril not more often than every 2 hours. Children 6 to under 12 years of age (with adult supervision): 1 inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: ask a doctor.''

4. In § 341.80(d)(2)(viii), the agency is expanding the header to read: ''Other required statements—For products containing levmetamfetamine or propylhexedrine identified in § 341.20(b)(1) or (b)(9) when used in an inhalant dosage form.''

The agency is also amending § 310.545(a)(6)(ii)(B) by removing the entry for ''l-desoxyephedrine (topical).''

IV. Labeling Guidance

In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA proposed to establish a standardized format for the labeling of OTC drug products. The labeling in this final rule does not follow the new format because the proposal has not been finalized to date. However, the agency is providing manufacturers guidance on how labeling in this final rule would be converted into the format proposed in § 201.66 (62 FR 9024 at 9050 and 9051). The purpose and use of the products are already listed in and would follow § 341.80(a) and (b) of the final monograph for OTC nasal decongestant drug products. The directions would appear as stated in this final rule and in § 341.80(d)(2)(viii). The warnings in § 341.80(c)(2)(ii) and (c)(2)(vii) would meet the requirements of proposed § 201.66(c)(4) as follows:

TABLE 1.—CONVERSION OF MONOGRAPH WARNINGS TO PROPOSED NEW FORMAT

Nasal Decongestant Final Monograph	February 27, 1997, Proposal
Do not use this product for more than 7 days.	DO NOT USE: for more than 7 days
If symptoms persist, ask a doctor.	STOP USING THIS PRODUCT IF: symptoms persist ASK A DOCTOR. THESE MAY BE SIGNS OF A SERIOUS CONDITION.
Use only as directed.	WHEN USING THIS PRODUCT: use only as directed
Frequent or prolonged use may cause nasal congestion to recur or worsen.	frequent or prolonged use may cause nasal congestion to recur or worsen

Until the final rule for the labeling format proposal is published, manufacturers, distributors, and packagers must comply with the final rule published in this document. The final rule for the new labeling format will provide a date by which the labeling of all OTC nasal decongestant drug products covered by the monograph will need to be converted to the new labeling format.

V. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts, and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities.

Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The proposed rule that has led to the development of this final rule was published on January 15, 1985 (50 FR 2220), before the Unfunded Mandates Reform Act was enacted. The agency explains in this final rule that the final rule will not result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

The agency believes that this final rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this final rule is to establish conditions under which OTC nasal decongestant drug products containing levmetamfetamine (formerly l-desoxyephedrine) are generally recognized as safe and effective. This includes establishing the allowable monograph labeling.

The March 8, 1996, notice of partial stay of the OTC nasal decongestant final monograph included labeling that manufacturers of OTC topical nasal decongestant drug products containing levmetamfetamine (l-desoxyephedrine) had to have in effect by September 9, 1996. Therefore, all such currently marketed drug products should have this labeling in effect. The only labeling change that is necessary at this time is to change the established name from l-desoxyephedrine to levmetamfetamine as a result of the 6th Supplement to USP 23 (Ref. 2). A number of manufacturers of these products have already made this change as new labeling needed to be prepared. The agency believes that an effective date of 1 year from the date of this publication will provide manufacturers of the remaining products sufficient time to incorporate the name change during a future manufacturing cycle. The agency estimates that there are less than 100 stock keeping units (SKU) (individual products, packages, and sizes) of products containing this ingredient currently in the OTC marketplace. Other manufacturers who now wish to market a product containing this ingredient may enter the marketplace at any time.

The agency considered but rejected several labeling alternatives: (1) A longer implementation period, and (2) an exemption for small entities. The agency does not consider either of these approaches acceptable because only a single labeling change (in the product's established name) is needed at this time. Further, the agency is aware that manufacturers of products containing this ingredient already started to change product labeling after the name change became official in USP 23.

The analysis shows that this final rule is not economically significant under Executive Order 12866 and that the agency has considered the burden to small entities. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Act does not apply to the final rule because it would not result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

VI. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VIII. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) *Pharmacopeial Forum,* The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 3429, January through February, 1997.

(2) *Sixth Supplement to USP 23 and to NF 18,* United States Pharmacopeial Convention, Inc., Rockville, MD, p. 3631, 1997.

(3) Memorandum from D. Bowen, FDA, to R. Wolters, FDA representative to USAN Council, dated January 22, 1997, Docket No. 76N–052N, Dockets Management Branch.

(4) Memorandum from R. Wolters, FDA representative to USAN Council, to D. Bowen *et al.*, FDA, dated February 6, 1997, Docket No. 76N–052N, Dockets Management Branch.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 341

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310 and 341 are amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 *Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses* is amended in paragraph (a)(6)(ii)(B) by removing the entry for ''l-desoxyephedrine (topical).''

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

3. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. Section 341.20 is amended by revising paragraph (b)(1) to read as follows:

§ 341.20 Nasal decongestant active ingredients.

* * * * *

(b) * * *

(1) Levmetamfetamine.

* * * * *

5. Section 341.80 is amended by revising paragraphs (c)(2)(ii), (c)(2)(vii), and (d)(2)(i), and the heading of paragraph (d)(2)(viii) to read as follows:

§ 341.80 Labeling of nasal decongestant drug products.

* * * * *

(c) * * *

(2) * * *

(ii) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for adults.* ''Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.''

* * * * *

(vii) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for children under 12 years of age.* ''Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.''

* * * * *

(d) * * *

(2) * * *

(i) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form.* The product delivers in each 800 milliliters of air 0.04 to 0.150 milligrams of levmetamfetamine. Adults: 2 inhalations in each nostril not more often than every 2 hours. Children 6 to under 12 years of age (with adult supervision): 1 inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: ask a doctor.

* * * * *

(viii) *Other required statements—For products containing levmetamfetamine or propylhexedrine identified in § 341.20(b)(1) or (b)(9) when used in an inhalant dosage form.* * * *

* * * * *

Dated: July 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20303 Filed 7–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 98N–0513]

Medical Devices; Neurological Devices; Classification of Cranial Orthosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the cranial orthosis into class II (special controls). The special controls that will apply to the cranial orthosis are restriction to prescription use, biocompatibility testing, and certain labeling requirements. The agency is taking this action in response to a petition submitted under the Federal, Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying cranial orthosis into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

EFFECTIVE DATE: August 31, 1998.

FOR FURTHER INFORMATION CONTACT: James E. Dillard, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the FDA regulations (21 CFR part 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on March 12, 1998, classifying the Dynamic Orthotic Cranioplasty (DOC™ Band) in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On March 31, 1998, Cranial Technologies, Inc., submitted a petition requesting classification of the DOC™ Band under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and the medical literature, FDA determined that the DOC™ Band can be