For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' 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:

Empresa Brasileira De Aeronautica S.A. (EMBRAER): Docket 2003–NM–02–AD.

Applicability: Model EMB–120 series airplanes as listed in EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002; 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 the unavailability of supplemental oxygen to the flight attendant in the event of cabin decompression, which could result in loss of consciousness of the flight attendant, accomplish the following:

(a) Within 100 flight hours after the effective date of this AD, accomplish either paragraph (a)(1) or (a)(2) of this AD.

Airplane Flight Manual (AFM) Revision

(1) Revise the Limitations Section of EMBRAER EMB120 Brasilia Airplane Flight Manual AFM–120/794 to include the following information, and operate the airplane per those limitations (this may be accomplished by inserting a copy of this AD into the AFM):

''Maximum operating altitude is limited to 25,000 feet.''

(2) Accomplish either paragraph (a)(2)(i) or (a)(2)(ii) of this AD, as applicable.

Modification

(i) For airplanes listed in paragraph 1.1.1., Part I, of the effectivity of EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002: Replace the shock absorber of the flight attendant's seat with a new part, and install an oxygen bottle kit under the seat (including installing placards); per paragraph 2.1 of the Accomplishment Instructions of that service bulletin.

Rework

(ii) For airplanes listed in paragraph 1.1.2., Part II, of the effectivity of EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002: Rework the oxygen bottle kit (including installing placards and attaching the oxygen mask hose to the oxygen bottle), per paragraph 2.2 of the Accomplishment Instructions of that service bulletin.

AFM Revision

(b) Before further flight following the accomplishment of paragraph (a)(2) of this AD: Revise the Limitations Section of EMBRAER EMB120 Brasilia Airplane Flight Manual AFM–120/794 to include the following information, and operate the airplane per those limitations (this may be accomplished by inserting a copy of this AD into the AFM):

''Maximum operating altitude is limited to 30,000 feet.''

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, Transport Airplane Directorate, FAA. 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 §§ sections 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 Brazilian airworthiness directive 2001–11–03 R1, dated September 13, 2002.

Issued in Renton, Washington, on February 27, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–5122 Filed 3–4–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 95N–0304]

RIN 0910–AC51

Dietary Supplements Containing Ephedrine Alkaloids; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 30 days the comment period for a proposed rule entitled ''Dietary Supplements Containing Ephedrine Alkaloids'' that published in the **Federal Register** of June 4, 1997 (62 FR 30678) (the June 1997 proposal). In that document, FDA proposed a number of requirements relating to dietary supplements containing ephedrine alkaloids, including a requirement for a warning statement on the product label. Since publication of the June 1997 proposal, new scientific evidence has come to light concerning health risks associated with the use of dietary supplements containing ephedrine alkaloids. FDA is reopening the comment period to receive comment on this new evidence, as well as on the warning statement it is now considering for dietary supplements containing ephedrine alkaloids. FDA also intends to consider, to the extent possible, whether in light of current information FDA should determine that dietary supplements containing ephedrine alkaloids present a ''significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.''

DATES: Submit written or electronic comments April 4, 2003.

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: Anthony Curry, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2071.

SUPPLEMENTARY INFORMATION:

I. Reopening of Comment Period

In the **Federal Register** of June 4, 1997 (62 FR 30678) (the June 1997 proposal), FDA (''we'' or ''the agency'') proposed to amend our regulations to require the label of dietary supplements containing ephedrine alkaloids to bear a warning statement. The proposed warning statement contained several elements, including cautions that consumers not use the product if they have certain diseases or health conditions or are using certain drugs, and that they stop using the product if they develop certain signs or symptoms. FDA also proposed restrictions on the potency and composition of dietary supplements containing ephedrine alkaloids, including a prohibition on the use of ephedrine alkaloids in dietary supplements with ingredients, or with ingredients that contain substances that have a known stimulant effect, such as caffeine. In addition, the agency proposed several requirements and restrictions relating to labeling claims and directions for use.

We proposed these actions in response to reports of serious illnesses and injuries, including a number of deaths, associated with the use of dietary supplements containing ephedrine alkaloids and the agency's investigations and assessment of these illnesses and injuries.

The comment period for the proposed rule closed on August 18, 1997. On September 18, 1997, FDA reopened the comment period for 75 days until December 2, 1997 (62 FR 48968).

In the **Federal Register** of April 3, 2000 (65 FR 17474), we withdrew the proposed requirements and restrictions concerning potency, labeling claims, and directions for use, but not the proposed warning statement or the proposed prohibition on dietary supplements that combine ephedrine alkaloids with other stimulant ingredients. In the same issue of the **Federal Register** (65 FR 17510), we also announced the availability of adverse event reports and related information that had become available since the June 1997 proposal; we reopened the comment period until May 18, 2000, to receive comments on this new information (Docket No. 00N–1200).

Recently, more scientific evidence has come to light concerning the risks posed by ephedrine alkaloids, including approximately 17,000 adverse event reports received overall by FDA. For example, one study compared the risks of adverse events attributable to ephedra and other herbal products through a comparative case series investigation based upon poison control center reporting (Ref. 1). Another study, a case-controlled investigation, examined the association between the use of ephedra and the risk for hemorrhagic stroke (Ref. 2). One study evaluated the adverse cardiovascular events from the FDA database that were temporally associated with the use of ephedra (Ref. 3). Another study evaluated the pharmacology of ephedrine alkaloids and caffeine after a single dose in humans (Ref. 4). Two studies were double-blind controlled clinical trials that evaluated the efficacy of ephedra in combination with caffeine for weight loss, with treatment durations of 6 weeks (Ref. 5) or 6 months (Ref. 6). Further, the RAND Corporation, under contract with the U.S. Department of Health and Human Services, has conducted an evidence based review of all available sources of information on ephedrine alkaloid containing dietary supplements (Ref. 7).

Comments to the June 1997 proposal stressed the importance of ensuring that consumers were aware of the risks of consuming dietary supplements containing ephedrine alkaloids. Therefore, in light of the new scientific evidence as well as the comments received in response to the June 1997 proposal, FDA is considering the following warning statement for dietary supplements containing ephedrine alkaloids. This statement is consistent with the recent scientific reports referenced in this document.

The following warning statement would appear on the principal display panel of the product:

WARNING: ***Contains ephedrine alkaloids. Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids***. Not for pregnant or breast-feeding women or persons under 18. Risk of injury can increase with dose or if used during strenuous exercise or with other products containing stimulants (including caffeine). Do not use with certain medications or if you have certain health conditions. Stop use and contact a doctor if side effects occur. See more information [...].

The following additional information would appear on the outer product label or in product labeling that is an integral part of the outer product packaging such that this information may be read at point of purchase (For example, this information could be contained in the outer information panel, riser backing, panel extension, outsert, etc.):

This product contains ephedrine alkaloids, which can have potentially dangerous effects on the heart and central nervous system.

☛ **Do not use with**

- ✓ a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping a MAOI drug;
- ✓ certain drugs for depression, psychiatric, or emotional conditions;
- ✓ drugs for Parkinson's disease;
- ✓ drugs for obesity or weight control;
- ✓ methyldopa.

☛ **Contact a doctor before using this product if you have or ever had**

- ✓ heart disease, high blood pressure, thyroid disease, seizure, diabetes, depression, other mental, emotional or behavioral conditions, glaucoma, or difficulty urinating due to prostate enlargement.

☛ **Stop use and contact a doctor immediately if these side-effects occur**

- ✓ dizziness, severe headache, rapid and/or irregular heartbeat, chest pain, shortness of breath, nausea, loss of consciousness, or changes in emotions or behavior (such as depression, hallucinations or severe mood swings).

☛ **Your risks of serious side-effects from this product can increase**

- ✓ with increased dose, frequency, or duration of use;
- ✓ if you take it with other dietary supplements containing ephedrine alkaloids (such as ephedra, ma huang, Sida cordifolia);
- ✓ if you take it with additional products containing stimulants, such as caffeinated beverages and foods (including dietary supplements containing guarana, kola nut, mate, yohimbine/yohimbe, Citrus aurantium);
- ✓ if you take it with medications containing synephrine, phenylephrine, ephedrine, pseudoephedrine, or phenylpropanolamine;
- ✓ if you use it before or during strenuous exercise.

FDA also intends to consider, to the extent possible, whether in light of current information FDA should determine that dietary supplements containing ephedrine alkaloids present a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use" (see 21 U.S.C. 342(f)(1)(A)). Furthermore, FDA

seeks comment on what additional legislative authorities, if any, would be necessary or appropriate to enable FDA to address this issue most effectively.

For interested parties who would like to submit comments on these issues or additional data from any well-conducted scientific studies, we are reopening the comment period of the June 1997 proposal for 30 days. If, after evaluating the comments received on this document, FDA believes that a warning statement on the labels of dietary supplements containing ephedrine alkaloids is necessary to protect the health of individuals consuming such products, the agency will move quickly to publish a final rule requiring the appropriate warning statement and to take any other action we determine to be appropriate.

II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Identify all comments with the docket numbers found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bent, S., T. N. Tiedt, M. C. Odden, and M. G. Shlipak, ''The Relative Safety of Ephedra Compared with Other Herbal Products,'' published in the *Annals of Internal Medicine*, March 2003, vol. 138, number 6.

2. Morgenstern, L. B., C. M. Viscoli, W. N. Kernan, L. M. Brass, J. P. Broderick, E. Feldmann, J. L. Wilterdink, T. Brott, and R. I. Horwitz, ''Use of Ephedra-Containing Products and Risk for Hemorrhagic Stroke,'' published in the *Journal of Neurology*, 2003; vol. 60: pp. 132–135.

3. Samenuk, D., M. S. Link, M. K. Homoud, R. Contreras, T. C. Theohardes, P. J. Wang, Estes NA 3d., ''Adverse Cardiovascular Events Temporally Associated With ma huang, an Herbal Source of Ephedrine,'' *Mayo Clinic Proceedings*, 2002, vol. 77(1):12–6.

4. C. A., Haller, P. Jacob 3rd, N. L. Benowitz, ''Pharmacology of Ephedra Alkaloids and Caffeine After Single-dose Dietary Supplement Use,'' *Clinical Pharmacology and Therapeutics*, 2002, June, vol. 71(6), pp. 421–432.

5. Boozer, C. N., J. A. Nasser, S. B. Heymsfield, V. Wang, G. Chen, J. L. Solomon, ''An Herbal Supplement Containing Ma Huang-Guarana for Weight Loss: A Randomized, Double-blind Trial,'' *International Journal of Obesity and Related Metabolic Disorders*, 2001;25(3):316–24.

6. Boozer, C. N., P. A. Daly, P. Homel, J. L. Solomon, D. Blanchard, J. A. Nasser, et. al. ''Herbal Ephedra/Caffeine for Weight Loss: a 6-month Randomized Safety and Efficacy Trial,'' *International Journal of Obesity Related and Metabolic Disorders*, 2002, vol. 26(5): pp. 593–604.

7. Shekelle, P. G, M. L. Hardy, M. Maglione, S. C. Morton, ''Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects,'' Agency for Healthcare Research and Quality (in press).

Dated: February 27, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–5072 Filed 2–28–03; 3:30 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 219

RIN 0596–AB86

National Forest Service Land and Resource Management Planning

AGENCY: Forest Service, USDA.

ACTION: Notice; extension of public comment period.

SUMMARY: Notice is hereby given that the public comment period for the proposed rule for National Forest System Land and Resource Management Planning, published in the **Federal Register** on December 6, 2002 (67 FR 72770), is being extended. The original comment period end date was March 6, 2003.

DATES: Comments on the proposed rule must be received in writing, on or before the new deadline of April 7, 2003.

ADDRESSES: Comments may be sent to USDA FS Planning Rule, Content Analysis Team, PO Box 8359, Missoula, MT 59807; via email to *planning_rule@fs.fed.us;* or by facsimile to Planning Rule Comments at (406) 329–3556. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying.

FOR FURTHER INFORMATION CONTACT: Jody Sutton, Content Analysis Team Program Coordinator, Forest Service, (801) 517–1023.

SUPPLEMENTARY INFORMATION: The Diversity Options Workshop was held February 18–20, 2003, to discuss the approaches to implementing the National Forest Management Act (NFMA) diversity requirement in the proposed rule; address strengths and weaknesses of the two diversity options in the proposed rule; and to discuss any additional options for implementing the NFMA diversity requirement. Proceedings from the Diversity Options Workshop are expected to be posted on World Wide Web at *www.fs.fed.us/emc/nfma* by March 17, 2003.

Dated: February 26, 2003.

Bov B. Eav,

Acting Chief.

[FR Doc. 03–5116 Filed 3–4–03; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1243–P]

RIN 0938–AM41

Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: In this proposed rule, we are proposing to change the methodology for determining payments for extraordinarily high-cost cases (cost outliers) made to Medicare-participating hospitals under the acute care hospital inpatient prospective payment system.

Under the existing outlier methodology, the cost-to-charge ratios from hospitals' latest settled cost reports are used in determining a fixed-loss amount cost outlier threshold. We have become aware that, in some cases, hospitals' recent rates of charge