

engines installed on aircraft of U.S. registry would be affected by this proposed AD, that it would take approximately 0.25 work hour per engine to accomplish the proposed calculations, and that the average labor rate is \$60 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$1,950.

Regulatory Impact

This proposed rule does not have federalism implications, as defined in Executive Order (EO) No. 13132, because it would not have a substantial direct effect 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under EO No. 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 removing Amendment 39-1086 (34 FR 18296, October 15, 1970) and Amendment 39-3610 (44 FR 72103, December 13, 1979), and by adding a new airworthiness directive,

GE Aircraft Engines: Docket No. 99-NE-13-AD.

Applicability: GE Aircraft Engines CT58 series turboshaft engine installed on, but not limited to Boeing -Vertol V-107 series, Kaman UH-1F series; and Sikorsky CH/HH-3E series, S-61 A/L/N/R series, and S-62 series rotorcraft.

Note 1: This airworthiness directive (AD) applies to each engine 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 engines 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 low-cycle fatigue failure of rotating parts that could result in uncontained engine failure and damage to the helicopter, accomplish the following:

Calculating New Life Limits for Rotating Parts

(a) Within 50 hours time-in-service (TIS) after the effective date of this AD, calculate the new cycles-since-new (CSN) for life-limited rotating parts in accordance with the Accomplishment Instructions, 2.A. through 2.G. of GEAE service bulletin (CT58)72-162 CEB-258, revision 9, dated October 6, 1998.

(b) Remove any part from service that exceeds the new calculated life limit and replace it with a serviceable part.

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, Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

(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 helicopter to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on March 28, 2000.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.
[FR Doc. 00-8134 Filed 3-31-00; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 134

RIN 1515-AC32

Country of Origin Marking

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document provides an additional 30 days for interested members of the public to submit comments on the proposal to restructure and clarify the country of origin marking rules set forth in Part 134 of the Customs Regulations. The proposal was published in the **Federal Register** on January 26, 2000, and the comment period was scheduled to expire on March 27, 2000.

DATES: Comments on the proposal must be received on or before April 26, 2000.

ADDRESSES: Comments may be submitted to and inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., Washington, D.C. 20229. All comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)) between 9:00 a.m. and 4:30 p.m. on normal business days at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., 3rd Floor, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Questions with regard to the following subject areas may be directed to the following staff attorneys of the Special Classification and Marking Branch, (202) 927-2310: Definitions of "country," "country of origin" and "ultimate purchaser"—Kristen VerSteege; Marking of containers—Monika Brenner; and Marking and certification requirements for processed and repackaged articles—Burton Schlissel.

SUPPLEMENTARY INFORMATION:

Background

Customs published a document in the **Federal Register** (65 FR 4193) on January 26, 2000, proposing to restructure and clarify the country of origin marking rules set forth in Part 134 of the Customs Regulations.

The document invited the public to comment on the proposal. Comments on the proposed rule were requested on or before March 27, 2000.

Customs has received a request to extend the comment period for an additional 30 days from the Alliance of Automobile Manufacturers to enable the organization to coordinate its comment with its member companies.

Customs has determined to grant the request for the extension. Accordingly, the period of time for the submission of comments is being extended 30 days. Comments are now due on or before April 26, 2000.

Dated: March 29, 2000.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 00-8141 Filed 3-31-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 95N-0304]

Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal in part.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is withdrawing certain provisions of a proposed rule that published in the **Federal Register** of June 4, 1997 (62 FR 30678), relating to dietary supplements containing ephedrine alkaloids. FDA is taking this action because of concerns regarding the agency's basis for proposing a certain dietary ingredient level and a duration of use limit for these products. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of new adverse event reports and related information associated with these products and its plans to participate in a public forum to discuss this new information at some future date. In addition, FDA is announcing elsewhere in this issue of the **Federal Register** the availability of additional documentation associated with certain adverse events referenced in the 1997 proposed rule.

DATES: The proposed rule that published on June 4, 1997 (62 FR 30678)

is withdrawn in part for § 111.100(a), (b), (c), (e), and (f) as of April 3, 2000.

ADDRESSES: Copies of the proposed rule and related comments are available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301-827-6733.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 4, 1997 (62 FR 30678), FDA published a proposed rule (hereinafter referred to as the "ephedrine alkaloids proposal") to establish that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in an intake of 8 mg or more within a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids (hereinafter referred to as "dosing level" or "dietary ingredient level"), and to require that the label of such supplement state that the product is not to be used for more than 7 days (hereinafter referred to as "duration of use limit"). The agency also proposed to prohibit 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, which may interact with ephedrine alkaloids; and to prohibit labeling claims, such as weight loss or body building, that require long-term intake to achieve the purported effect. In addition, the agency proposed to require a statement to accompany claims that encourage short-term excessive intake to enhance a purported effect, such as an increase in energy, that taking more than the recommended serving may result in serious adverse health effects; and to require specific warning statements to appear on product labels.

The agency proposed these actions in response to reports of serious illnesses and injuries, including a number of deaths, associated with the use of dietary supplement products containing ephedrine alkaloids and the agency's investigations and assessment of these illnesses and injuries. This action was also supported by many of the recommendations made during the October 1995 meeting of an ad hoc Working Group of the FDA Advisory Committee (Working Group) and the

August 1996 meeting of the Food Advisory Committee (FAC) and the Working Group concerning the potential public health problems associated with the use of dietary supplements containing ephedrine alkaloids and the recommended steps FDA should take to address the serious health concerns associated with their use (see Refs. 25 and 27 of the ephedrine alkaloids proposal (Docket No. 95N-0304)).

The comment period for the June 4, 1997 (62 FR 30678), proposed rule closed on August 18, 1997. In a notice in the **Federal Register** of August 20, 1997 (62 FR 44247), FDA announced its intent to reopen the comment period after the agency corrected a number of inadvertent omissions in the administrative record. Subsequently on September 18, 1997 (62 FR 48968), the agency reopened the comment period for an additional 75 days until December 2, 1997.

The agency received approximately 350 letters regarding the use of ephedrine alkaloid-containing dietary supplements prior to publication of the ephedrine alkaloids proposal. These comments have been considered by the agency along with those commenting in response to the proposal. The agency received approximately 14,775 comments on the ephedrine alkaloids proposal. Individual consumers who use ephedrine alkaloid-containing dietary supplements and independent distributors of these products submitted most of the comments. Other comments were received from persons who had, or who knew persons who had, suffered adverse events or who were reporting adverse events associated with the use of an ephedrine alkaloid-containing dietary supplement. The remaining comments included those submitted by medical professionals, scientists, a scientific association, State and local health departments, medical associations, government agencies, dietary supplement manufacturers, Chinese medicine practitioners and associations, dietary supplement industry trade associations, public health associations, and consumer groups.

The House Committee on Science requested that the Government Accounting Office (GAO) examine the scientific bases for the ephedrine alkaloids proposal and the agency's adherence to the regulatory flexibility analysis requirements for Federal rulemaking. On August 4, 1999, GAO released its report entitled "Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids." A copy of this