rotor system, and subsequent loss of control of the helicopter.

The FAA has reviewed MD Helicopters Inc. Service Bulletin SB600N–033, dated December 13, 2001 (ASB), which specifies reducing the life limit of the drive shaft at the next scheduled maintenance or within 1 year, whichever occurs first.

This unsafe condition created by this reduced fatigue life limit to a critical component is likely to exist or develop on other helicopters of the same type design. Therefore, the proposed AD would require within 100 hours TIS reducing the life limit for the drive shaft from 16,000 hours TIS to 14,000 hours TIS and reflecting the reduced life limit on the component history card or an equivalent record.

The FAA estimates that this proposed AD would affect 46 helicopters of U.S. registry, that it would take approximately .5 work hour per helicopter to update the records, 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 $1,380.

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 a new airworthiness directive to read as follows:

MD Helicopters Inc.: Docket No. 2003–SW–04–AD.

Applicability: Model 600N, with main rotor drive shaft assembly (drive shaft), part number (P/N) 600N5510–1, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters 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 within 100 hours time-in-service (TIS), unless accomplished previously.

To prevent failure of the drive shaft, loss of drive to the main rotor hub, and subsequent loss of control of the helicopter, accomplish the following:

(a) Revise the component history card or equivalent record for drive shaft, P/N 600N5510–1, by changing the life limit from 16,000 to 14,000 hours TIS. Before further flight, replace any drive shaft that has 14,000 or more hours TIS with an airworthy drive shaft.

(b) This AD revises the Limitations section of the maintenance manual by reducing the life limit of the drive shaft, P/N 600N5510–1, to 14,000 hours TIS.

(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, Los Angeles Aircraft Certification Office (LAACO), FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, LAACO.

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

(d) Special flight permits may be issued in accordance with 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 Fort Worth, Texas, on May 12, 2003.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 03–12401 Filed 5–16–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2003–14656; Airspace Docket No. 03–ACE–25]

Proposed Establishment of Class E Airspace; Brookfield, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This action corrects a notice of proposed rulemaking that was published in the **Federal Register** on Monday, May 5, 2003, (68 FR 23622) (FR Doc. 03–11031). It corrects an error in the legal description of the proposed Brookfield, MO Class E airspace.

DATES: Comments for inclusion in the Rules Docket must be received on or before June 10, 2003.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 03–11031 published on Monday, May 5, 2003, (68 FR 23622) proposed to establish Class E airspace at Brookfield, MO. The proposed airspace was to protect aircraft executing newly established instrument approach procedures at North Central Missouri Regional Airport, Brookfield, MO. The format of the legal description of the Brookfield, MO Class E airspace area was not in accordance with FAA Order 74000.2E, PROCEDURES FOR HANDLING AIRSPACE MATTERS and was published incorrently.

Accordingly, pursuant to the authority delegated to me, the Brookfield, MO Class E airspace, as published in the **Federal Register** on Monday, May 5, 2003, (68 FR 23622), [FR Doc. 03–11031], is corrected as follows:

§ 71.1 [Corrected]

On page 23623, Column 3, second paragraph from the bottom, change ''North Central Missouri Regional Airport, MO'' to read ''Brookfield, North Central Missouri Regional Airport, MO.''

Issued in Kansas City, MO, on May 8, 2003.

David W. Hope,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 03–12378 Filed 5–16–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 111 and 112

[Docket No. 96N–0417]

RIN 0910–AB88

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 11, 2003, the comment period for a proposed rule published in the **Federal Register** of March 13, 2003. The proposed rule would establish the minimum current good manufacturing practices (CGMPs) necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. This action is being taken in response to requests for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by August 11, 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: Karen Strauss, Center for Food Safety and Applied Nutrition (HFS–821), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 02740–3835, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 13, 2003 (68 FR 12158), FDA published a proposed rule that, if finalized, would establish the minimum CGMPs necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The proposed provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of the dietary ingredients and dietary supplements.

In the March 13, 2003, proposed rule, FDA announced that the time period for public comment would be 90 days from the date of the publication in the **Federal Register**. On April 21, 2003, FDA received a request to allow an additional 60 days for interested persons to comment. In addition, on April 25, 2003, FDA received a request to allow an additional 90 days for interested persons to comment. The requesters assert that the time period of 90 days is insufficient to respond fully to FDA's multiple requests for comments and analyses and to enable all potential respondents adequate time to conduct the research necessary to provide complete scientific responses to questions posed in the proposed rule.

FDA believes that an extension of the comment period is appropriate, given the variety of issues raised by the proposed rule. However, because the agency wants to move forward on finalizing the rule as quickly as possible, FDA is extending the comment period only for an additional 60 days, until August 11, 2003. This extension will provide the public with a total of 150 days to submit comments. FDA does not intend to grant any additional time for extensions of the comment period.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12366 Filed 5–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D–0785]

Draft Guidances for Industry on Medical Imaging Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three draft guidances for industry on ''Developing Medical Imaging Drug and Biological Products.'' These draft guidances are intended to assist developers of medical imaging drug and biological products (medical imaging agents) in planning and coordinating their clinical investigations and preparing and submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to NDAs or BLAs. The draft guidances provide information on how FDA will interpret and apply certain provisions in the agency's regulations on in vivo radiopharmaceuticals used for diagnosis and monitoring of diseases and conditions.

DATES: Submit written or electronic comments on the draft guidances by June 18, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your request. Submit written comments on the draft guidances to the Dockets Management Branch (HFA–305), Food and Drug