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, certified 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.
§ 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.

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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 Practice (CGMP) 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 proposal. 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.