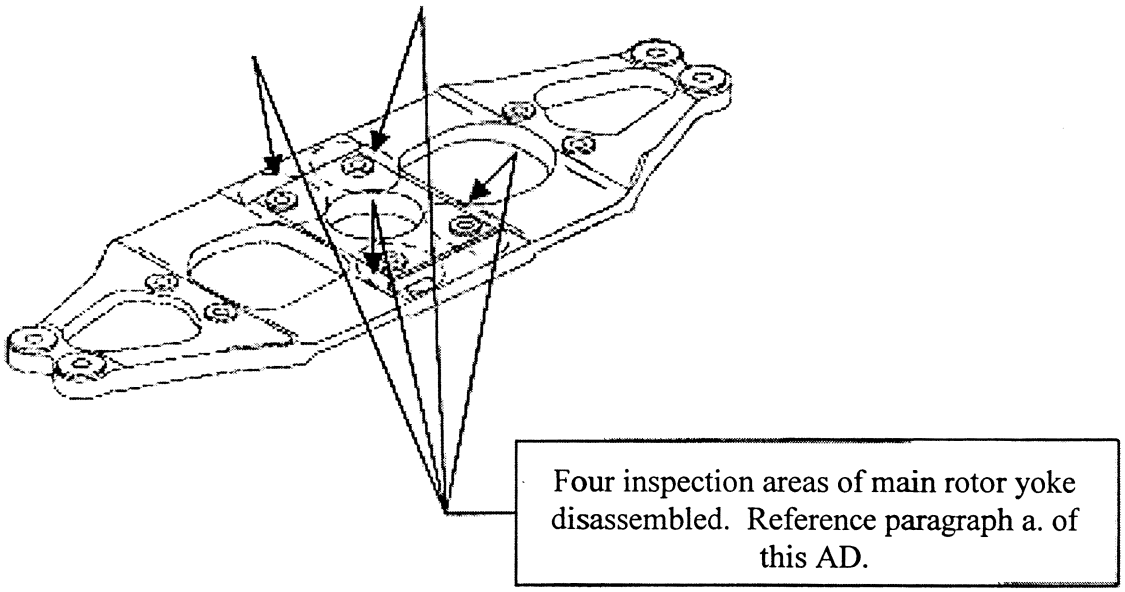

Figure 3. Main Rotor Yoke Inspection Areas

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(b) Within 50 hours TIS or by the next scheduled inspection for each hub assembly, whichever occurs first, and thereafter at intervals not to exceed 50 hours TIS, determine the torque of the four main rotor flapping bearing retaining bolts or nuts. While holding the bolt head, apply 100 foot-pounds (135Nm) of torque to the nut in the tightening direction.

(1) If 100 foot-pounds (135Nm) of torque is reached without movement of the nut, before further flight, torque the nut to 125 foot-pounds.

(2) If any nut moves before reaching 100 foot-pounds (135Nm) of torque, before further flight, remove both flapping bearings from the hub assembly. Inspect the yoke, the bolt and nut, and the trunnion supports with a 10X or higher magnifying glass, for a crack, fretting, or buffer deterioration.

(i) If a crack is found on any part, before further flight, replace the part with an airworthy part.

(ii) If fretting or buffer deterioration is found on any part, before further flight, repair any unairworthy part or replace the part with an airworthy part.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, FAA, for information about previously approved alternative methods of compliance.

Note 2: The subject of this AD is addressed in Transport Canada (Canada) AD CF–2003–27, dated November 17, 2003.

Issued in Fort Worth, Texas, on June 16, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04–14315 Filed 6–23–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 2004N–0194]

Definition of Primary Mode of Action of a Combination Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending until August 20, 2004, the comment period on the primary mode of action proposed rule that appeared in the **Federal Register** of May 7, 2004 (69 FR 25527). In the primary mode of action proposed rule, the agency states its intentions to amend the product jurisdiction regulations to define ''mode of action'' and ''primary mode of action'' (PMOA). Along with these definitions, the proposed rule sets forth an algorithm the agency would use to assign combination products to an agency component for regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product. Finally, the proposed rule would also require a sponsor to base its recommendation of the agency component with primary jurisdiction for regulatory oversight of its combination product on the PMOA definition and, if appropriate, the assignment algorithm. The proposed rule is intended to promote the public health by codifying the agency's criteria for the assignment of combination products in transparent, consistent, and predictable terms.

DATES: Submit written or electronic comments no later than August 20, 2004.

ADDRESSES: You may submit comments, identified by Docket 2004N–0194, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*.

Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0194 in the subject line of your e-mail message.

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. 2004N–0194 or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leigh Hayes, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION: FDA issued this proposed rule with an opportunity for public comment during a 60-day time period beginning May 7, 2004. On May 18, 2004, FDA received a request from the Advanced Medical Technology Association (AdvaMed) to extend the comment period for an additional 60 days for Docket No. 2004N–0194. According to AdvaMed, the Association needs additional time to advise their members about the proposed rule, and to collect and organize their members' input regarding the proposed rule.

Comments

In response to the request from AdvaMed, FDA is extending the comment period an additional 45 days to close on August 20, 2004. This extension will provide the public with a total of 105 days to submit comments. To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposed rule by August 20, 2004. 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 number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14265 Filed 6–23–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[VA150–5079b; FRL–7777–6]

Approval and Promulgation of Air Quality Implementation Plans; Commonwealth of Virginia; Emission Standards for Mobile Equipment Repair and Refinishing Operations in the Northern Virginia Volatile Organic Compound Emission Control Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia establishing regulations for the control of volatile organic compound (VOC) emissions from mobile equipment repair and refinishing operations in the northern Virginia portion of the Metropolitan Washington, DC ozone nonattainment area (northern Virginia Area). In the final rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by July 26, 2004.

ADDRESSES: Submit your comments, identified by VA150–5079 by one of the following methods:

A. Federal Rulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. E-mail: *morris.makeba@epa.gov.*

C. Mail: Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. VA150–5079. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103, and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Janice Lewis, (215) 814–2185, or by e-mail at *lewis.janice@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the