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:

Eurocopter Deutschland: Docket No. 98–SW–77–AD.

Applicability: Model MBB–BK 117 helicopters, serial numbers 7001 through 7250 and 7500 through 7509, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopter that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue failure of the tail rotor (output) drive bevel gear (bevel gear), loss of tail rotor drive, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 100 hours time-in-service (TIS):

(1) Record in the accessory replacement record and historical record ''Main Transmission'' section the retirement life of 18,500 hours TIS for the bevel gear.

(2) Determine the total hours TIS of the bevel gear. If the total hours TIS cannot be determined, use the operating time of the main transmission.

(b) If the bevel gear's total hours TIS is equal to or greater than 18,400 hours TIS, remove the bevel gear within the next 100 hours TIS and replace it with an airworthy bevel gear. If the bevel gear's total hours TIS is less than 18,400 hours TIS, remove the bevel gear on or before 18,500 hours TIS and replace it with an airworthy bevel gear.

(c) This AD revises the helicopter Airworthiness Limitations section of the maintenance manual by establishing a new retirement life for the bevel gear of 18,500 hours TIS.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through a FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

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

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

Note 3: The subject of this AD is addressed in Luftfahrt-Bundesamt (Federal Republic of Germany) AD No. 97–350, dated December 18, 1997.

Issued in Fort Worth, Texas, on December 3, 1999.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–32085 Filed 12–9–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, and 510

[Docket No. 99N–4957]

Removal of Designated Journals; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove its regulation that lists the veterinary and scientific journals available in FDA's library. The purpose of the list is to allow individuals to reference articles from listed journals in the new animal drug application (NADA) documents submitted to the Dockets Management Branch, and objections and requests for a hearing on a regulation or order instead of submitting a copy or reprint of the article. FDA is taking this action because this list of journals is outdated and because individuals rarely use the regulation. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. If FDA receives significant adverse comments about the direct final rule, it will be withdrawn, and the comments will be considered in the development of a final rule using usual notice-and-comment rulemaking based on this proposed rule.

DATES: Submit written comments on or before February 23, 2000. If FDA receives any significant adverse comment regarding this rule, FDA will publish in the **Federal Register** a document withdrawing the companion direct final rule within 30 days after the comment period ends. If FDA does not receive any significant adverse comment, the agency intends to publish in the **Federal Register** a document confirming the effective date of the final rule within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective April 24, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0205.

SUPPLEMENTARY INFORMATION:

I. Background

FDA proposes to remove 21 CFR 510.95 *Designated journals*. This regulation lists veterinary and scientific journals available in FDA's library. It permits waiving submission of reprints and summaries of articles from listed journals. FDA is taking this action because the regulation has rarely been used, the list of journals is outdated, and FDA does not believe it to be a wise expenditure of its resources to update the list and to have reviewers retrieve copies of referenced journals from its library, given the minimal burden on individuals to submit copies. Because

providing a copy of the reference article facilitates the review process with given the minimal burden, individuals routinely submit copies in their submissions. FDA notes that the change is more likely to expedite rather than delay review of applications and other documents. For example, if the sponsor provides a copy of the article in full, it permits prompt and efficient review of the application.

Prior to the bifurcation of human and animal drug regulations under the Animal Drug Amendments of 1968, the designated journal rule was found at 21 CFR 130.38. At that time, 21 CFR 130.4, the rule covering new drug applications (human and animal) stated that, ''[r]eprints are not required of reports in designated journals''. When NADA rule (presently § 514.1 (21 CFR 514.1)) was separated from the new human drug applications rule, this reference to the designated journals rule was dropped. The agency continued to consider the designated journals provision cited above to be part of the NADA rule, however, and allowed sponsors to omit from their NADA's copies of articles from designated journals. The agency is not amending the NADA rule (§ 514.1) because it does not refer to designated journals.

The proposed rule would amend 21 CFR 10.20 *Submission of documents to the Dockets Management Branch; computation of time; availability for public disclosure* and 21 CFR 12.22 *Filing objections and requests for a hearing on a regulation or order* by eliminating the designated journals exception to the requirement that copies of cited articles be provided.

II. Rulemaking Procedures

In the final rules section of this **Federal Register**, FDA is announcing the adoption of this amendment through direct final rulemaking procedures. FDA described its procedures for direct final rulemaking in the **Federal Register** of November 21, 1997 (62 FR 62466). This action is appropriate for direct final rulemaking because it is a noncontroversial amendment to FDA's regulations. Furthermore, FDA anticipates no significant adverse comments. Consistent with FDA's procedures for direct final rulemaking, FDA will publish a document of significant adverse comment and withdraw the direct final rule within 30 days after the comment period ends if it receives any significant adverse comments. If the direct final rule is withdrawn, FDA will consider all comments received in developing a final rule using the usual notice-and-comment rulemaking procedures based on this proposed rule. FDA is providing a 75-day comment period on this proposed rule, to run concurrently with the comment period for the companion direct final rule. This comment period begins on December 10, 1999, and it ends on February 23, 2000. If FDA receives any significant adverse comment, the agency intends to publish in the **Federal Register** a document to withdraw the companion direct final rule within 30 days after the comment period ends. If FDA does not receive any significant adverse comment in response to the direct final rule, the agency will not take action on this proposed rule. Instead, FDA will publish a document in the **Federal Register** within 30 days after the comment period on the direct final rule ends confirming that the direct final rule will be effective April 24, 2000. For additional information, see the companion direct final rule published in the final rules section of this **Federal Register**.

III. Analysis of Impacts

A. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

B. Economic Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to examine the economic impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The agency has reviewed this proposed rule and has determined that the proposed rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA finds that the proposed rule will not be an economically significant rule under the Executive Order.

The proposed rule would delete the regulations regarding designated journals that could be referenced by a sponsor in its application and by anyone who submits a document to the Dockets Management Branch or files an objection and request for a hearing on a regulation or order. FDA is taking this action because the list is outdated, is not being used, and is not an efficient use of agency resources. The customary practice in industry is for those preparing NADA's to include a copy of all referenced material. This is preferred because it ensures the application is complete at submission and will not result in a delay in the review process. FDA estimates that the additional copying cost to those few applicants that would have relied on the rule would be insignificant, as well as offset by the savings to the agency from not copying the same material. The agency also estimates that the additional copying costs to those few individuals that relied on the rule for documents submitted to the Dockets Management Branch and for objections and requests for hearings on a regulation or order would be insignificant.

In accordance with the Regulatory Flexibility Act, FDA has considered the effect that this proposed rule will have on small entities, including small businesses, and certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. FDA has also analyzed this proposed rule in accordance with the Unfunded Mandates Reform Act and determined that the proposed rule will not result in the expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million. Therefore, no further analysis is required.

IV. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Request for Comments

Interested persons may, on or before February 23, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except

that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday. All received comments will be considered comments regarding the proposed rule and this direct final rule.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 12

Administrative practice and procedure.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 10, 12, and 510 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.20 [Amended]

2. Section 10.20 *Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure* is amended by adding in paragraph (c)(1)(iii) the word ''or'' after the word ''available;'', by removing in paragraph (c)(1)(iv) the words ''agency; or'' and adding in its place the word ''agency.'', and by removing paragraph (c)(1)(v).

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

3. The authority citation for 21 CFR part 12 continues to read as follows:

Authority: 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

§ 12.22 [Amended]

4. Section 12.22 *Filing objections and requests for a hearing on a regulation or order* is amended by adding in paragraph (a)(5)(i)(*a*) the word ''or'' after the word ''available;'', by removing in paragraph (a)(5)(i)(*b*) the words ''agency; or'' and adding in its place the word ''agency.'', and by removing paragraph (a)(5)(i)(*c*).

PART 510—NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.3 [Amended]

6. Section 510.3 *Definitions and interpretations* is amended by removing paragraph (l).

§ 510.95 [Removed and Reserved]

7. Section 510.95 *Designated journals* is removed and reserved.

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31908 Filed 12–9–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA–222–0198; FRL–6506–7]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to disapprove revisions to the California State Implementation Plan (SIP). The revisions provide for the exemption of sources from visible emission limits in the South Coast Air Quality Management District. EPA has evaluated these revisions and is proposing to disapprove these revisions to the California SIP because the revisions are not consistent with applicable Clean Air Act (Act) requirements.

DATES: Comments must be received on or before December 27, 1999.

ADDRESSES: Comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rule and EPA's evaluation report for the rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are available for inspection at the following locations:

Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765

FOR FURTHER INFORMATION CONTACT: Patricia Bowlin, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1188.

SUPPLEMENTARY INFORMATION:

I. Applicability of EPA's Proposed Action

This document addresses EPA's proposed disapproval of South Coast Air Quality Management District (SCAQMD) Rule 401, Visible Emissions, as adopted by SCAQMD on September 11, 1998. SCAQMD Rule 401 was submitted by the California Air Resources Board to EPA on January 12, 1999.

This **Federal Register** action for the SCAQMD excludes the Los Angeles County portion of the Southeast Desert AQMA, otherwise known as the Antelope Valley Region in Los Angeles County, which is now under the jurisdiction of the Antelope Valley Air Pollution Control District as of July 1, 1997.[1]

II. Background of the State Submittal

On January 29, 1985 EPA approved into the SIP a version of SCAQMD Rule 401, Visible Emissions, that had been adopted by SCAQMD on March 2, 1984. Revisions to this rule were subsequently adopted on April 7, 1989 and submitted to EPA on March 26, 1990. EPA did not act on the 1990 submittal of Rule 401, which is now superseded by the January 12, 1999 submittal.

EPA found the January 12, 1999 submittal of SCAQMD Rule 401, Visible

[1] The State has recently changed the names and boundaries of the air basins located within the Southeast Desert Modified AQMA. Pursuant to State regulation the Coachella-San Jacinto Planning Area is now part of the Salton Sea Air Basin (17 Cal. Code. Reg. § 60114); the Victor Valley/Barstow Region in San Bernardino County and the Antelope Valley Region in Los Angeles County are a part of the Mojave Desert Air Basin (17 Cal. Code. Reg. § 60109). In addition, in 1996 the California Legislature established a new local air agency, the Antelope Valley Air Pollution Control District, to have the responsibility for local air pollution planning and measures in the Antelope Valley Region (California Health & Safety Code § 40106).