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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.

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**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 FDA is taking this action because this list of journals is outdated and because individuals rarely use the regulation.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 If FDA receives significant adverse comments about the direct final rule, it will be withdrawn, and the comments will be considered in the development of a final rule using usual notice-and-comment rulemaking based on this proposed rule.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 (*insert date 75 days after date of publication in the Federal Register*). 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 (*insert date 13.5 days after date of publication in the Federal Register*).

**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 (*insert date of publication in the **Federal Register***), and it ends on (*insert date 7.5 days after date **of** publication in the **Federal Register***). 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 (*insert date 135 days after date **of** publication **of** the*

*direct final rule in the **Federal Register***). 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 (*insert date 7.5 days after date of publication in the Federal Register*), 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 Q-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).

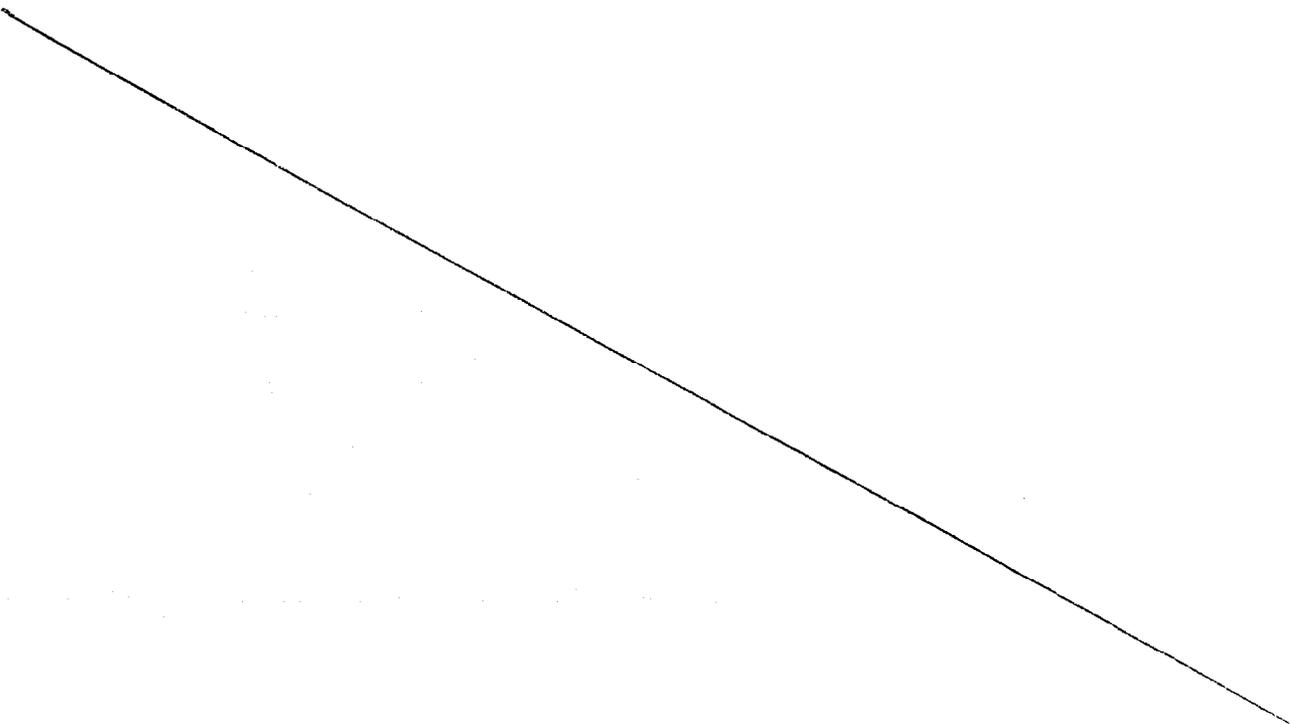
## PART 510—NEW ANIMAL DRUGS

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 5 10.3 *Definitions and interpretations* is amended by removing paragraph (1).

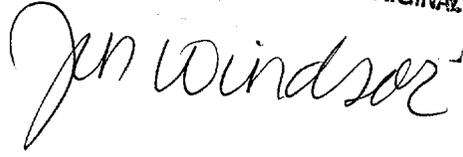


§ 510.95 [Removed and Reserved]

7. Section 5 10.95 *Designated journals* is removed and reserved.

Dated: 11-30-99  
November 30, 1999

  
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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL  


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