(b) If the locking mechanism does not seat properly, replace the buckle with an airworthy buckle.

(c) The requirements of this AD may be performed by an owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with sections 43.11 and 91.417(a)(2)(v) of the Federal Aviation Regulations (14 CFR sections 43.11 and 91.417(a)(2)(v)).

Note 3: If the seat restraint systems' locking mechanisms are found to be functioning properly after the visual check described in paragraph (a) of this AD, the following is an example of a maintenance record entry that may be used:

''AD (number), paragraph (a) complied with by visual check. Seat belt buckle locking mechanism(s) found serviceable. (Date) (Aircraft total time-in-service). (Signature) (Certificate number and type of certificate held)''

If any of the seat restraint systems' locking mechanisms are found to malfunction after the visual check described in paragraph (a), the following is an example of a maintenance record entry that may be used:

''AD (number), paragraphs (a) and (b) complied with by visual check and replacement of seat belt buckle locking mechanism(s) on (seat location(s)) with airworthy buckle(s). (Date) (Aircraft total time-in-service). (Signature) (Certificate number and type of certificate held)''

(d) 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, Airplane Certification Office, FAA. Operators shall submit their requests through a FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Airplane Certification Office.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Airplane Certification Office.

(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 aircraft to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective on January 14, 2000.

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

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–32083 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing 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 new animal drug applications (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. Elsewhere in this issue of the **Federal Register**, FDA is issuing a companion proposed rule. If significant adverse comments are received about this direct final rule, it will be withdrawn and FDA will follow its usual procedures for notice-and-comment rulemaking based on the companion proposed rule.

DATES: This regulation is effective April 24, 2000. Submit written comments on this direct final rule by February 23, 2000. If FDA receives no significant adverse comments within the specified comment period, 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. If timely significant adverse comments are received, the agency will publish in the **Federal Register** a document withdrawing this direct final rule before its effective date.

ADDRESSES: Submit written comments 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 is amending the animal drug regulations 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. 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 the 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, since it does not refer to designated journals.

The direct final rule amends 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 Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA will publish a notice of significant adverse comment and withdraw this direct final rule within 30 days after the comment period ends if it receives any

significant adverse comments. If this 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 the companion proposed rule published elsewhere in this issue of the **Federal Register**. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a period of 75 days for comment on this direct final rule, to run concurrently with the comment period for the companion proposed rule. This comment period begins on December 10, 1999, and ends on February 23, 2000. If FDA receives any significant adverse comment, FDA intends to publish in the **Federal Register** a document to withdraw this direct final rule within 30 days after the comment period ends. If FDA receives no significant adverse comment during the specified comment period, FDA will publish in the **Federal Register** a document within 30 days after the comment period ends to confirm the effective date of this direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment suggesting a change in addition to that proposed by the rule would not be considered a significant adverse comment, unless, as explained by the comment, the rule would be ineffective without change.

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 direct final 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 direct final rule and has determined that the rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA finds that the direct final rule will not be an economically significant rule under the Executive Order.

The direct final rule deletes 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 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 direct final rule will have on small entities, including small businesses, and certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities. FDA has also analyzed this direct final rule in accordance with the Unfunded Mandates Reform Act and determined that the direct final 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

This direct final 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 Docket Management Branch (address above) written comments regarding this direct final 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, 21 CFR parts 10, 12, and 510 are 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. 99–31907 Filed 12–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 94F–0455]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of X-radiation, produced by operation of X-ray tubes at energy levels of 500 kilovolt peak or lower, to inspect food. This action is in response to a petition filed by American Science and Engineering, Inc.

DATES: This regulation is effective December 10, 1999; written objections and request for a hearing by January 10, 2000.

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

FOR FURTHER INFORMATION CONTACT: Felicia Binion Williams, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3122.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 13, 1995 (60 FR 3249), FDA announced that a food additive petition (FAP 5M4438) had been filed by American Science and Engineering, Inc., 829 Middlesex Turnpike, Billerica, MA 01821, formerly 40 Erie St., Cambridge, MA 02139–4286. The petitioner proposed that the food additive regulations in § 179.21 *Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing* (21 CFR 179.21), be amended to provide for the safe use of X-radiation, produced by operation of X-ray tubes at energy levels of 500,000 electron volts (500 keV) or lower, to inspect cargo containers that may contain food. The current regulation limits the operation of X-ray tubes to energy levels of 300,000 electron volts (300 keV) peak or lower.

FDA has evaluated the data and information in the petition and other relevant material, and notes that information in the petition establishes that an extension of the upper limit on the energy level is necessary in order to be able to inspect large cargo containers using X-ray tubes. The data and information available to the agency establish that the maximum absorbed dose expected as a result of the petitioned use of X-radiation is 50 micrograys. This level of absorption is well below 10 grays, a level established as safe, by prior agency reviews.

The agency concludes that the proposed use of X-radiation, produced by operation of X-ray tubes at energy levels of 500 keV or lower, to inspect food, is safe and that the conditions listed in § 179.21 should be amended as set forth below. In addition, FDA is making a minor editorial change in the wording of the regulation to reflect the fact that operating voltage of the X-ray source should be described as a voltage, rather than an energy level. This change is more technically accurate and does not change the requirements of the current regulation.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final 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.

Any person who will be adversely affected by this regulation may at any time on or before January 10, 2000, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any