FOR FURTHER INFORMATION CONTACT: Mark R. Winter, Tennessee Valley Authority, 1101 Market Street (CST 13B), Chattanooga, TN 37402–2801, telephone number: (615) 751–2523.

SUPPLEMENTARY INFORMATION: This rule was not published in proposed form since it relates to internal agency organization and administration. Since this rule is nonsubstantive, it is being made effective immediately, July 27, 1995.

List of Subjects in 18 CFR Part 1301

Administrative practice and procedure, Freedom of information, Privacy Act, Sunshine Act.

For the reasons set forth in the preamble, title 18, chapter XIII, part 1301 of the Code of Federal Regulations is amended as follows:

PART 1301—PROCEDURES

1. The authority citation for part 1301 continues to read as follows:

Authority: 16 U.S.C. 831–831dd, 5 U.S.C. 552.

2. Section 1301.1 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1301.1 Records.

* * * * *

(b) *Requests.* Requests to inspect and copy TVA records shall be directed to the Tennessee Valley Authority, TVA FOIA Officer, Records and Information Management (RIM), 1101 Market Street, Chattanooga, TN 37402–2801. A request shall:

* * * * *

3. Section 1301.1 is amended by revising the text of paragraph (c)(1)(i) to read as follows:

§ 1301.1 Records.

* * * * *

(c) *Processing of requests*—(1) *Initial determination.* (i) Within 10 days (excluding Saturdays, Sundays, and legal public holidays) after a request is received by TVA, and subject to paragraph (c)(3) of this section, TVA shall make an initial determination as to whether to comply with the request, and shall immediately give written notice of the determination to the person making the request. Initial determinations shall be made by the TVA FOIA Officer or the TVA FOIA Officer's designee. If the initial determination is not to comply with the request, the notice to the person making the request shall include a statement of the reasons for the denial of the request; a notice of the right of the person making the request to appeal the denial to the TVA FOIA Appeal Official designated in paragraph (c)(2)(iii) of this section, and the time limits therefor; and the name and job title of the person responsible for the initial determination.

* * * * *

4. Section 1301.1 is amended by revising the text of paragraph (c)(2)(i) to read as follows:

§ 1301.1 Records.

* * * * *

(c) *Processing of requests*—* * *

(2) *Appeal.* (i) If the initial determination is to deny the request, the person making the request may appeal such action to the TVA FOIA Appeal Official. Such an appeal must be taken within 30 days after the person's receipt of the initial determination and is taken by delivering a written notice of appeal to the TVA FOIA Appeal Official designated in paragraph (c)(2)(iii) of this section. Such notice shall include a statement that it is an appeal from a denial of a request under the Freedom of Information Act and shall indicate:

(A) The date on which the denial was issued; and

(B) The date on which the denial was received by the person making the request.

* * * * *

5. Section 1301.1 is amended by revising the text of paragraph (c)(2)(ii) to read as follows:

§ 1301.1 Records.

* * * * *

(c) * * *

(2) * * *

(ii) Within 20 days (excluding Saturdays, Sundays, and legal public holidays) after an appeal is received, and subject to paragraph (c)(3) of this section, TVA shall make a final determination on the appeal. In making such a determination, TVA will consider whether or not to waive the provisions of any exemption contained in paragraph (a) of this section, except that without the written permission of the person involved, TVA will not waive the exemptions contained in paragraphs (a) (4), (6) and (7) of this section. Determinations of appeals under this section shall be made by the TVA FOIA Appeal Official or the FOIA Appeal Official's designee. If the determination on the appeal is to deny the request for records, TVA shall notify the person making the request of such determination, including the reason for the denial; a notice of the person's right to judicial review of the denial; and the name and job title of the TVA official responsible for the determination of the appeal.

* * * * *

6. Section 1301.1 is amended by adding a new paragraph (c)(2)(iii) to read as follows:

§ 1301.1 Records.

* * * * *

(c) * * *

(2) * * *

(iii) TVA has designated its Senior Manager, Administrative Services, TVA, 400 Summit Hill Drive, Knoxville, TN 37902–1499 as the TVA FOIA Appeal Official and appeals should be directed accordingly.

* * * * *

7. Section 1301.1 is amended by revising the text of paragraph (c)(3)(ii) to read as follows:

§ 1301.1 Records.

* * * * *

(c) * * *

(3) * * *

(ii) The 20-day time limit provided in paragraph (c)(2) of this section may be extended by TVA for unusual circumstances as set forth in this paragraph upon written notice to the person appealing a denial of a request for records. The notice shall specify the reasons for the extension and the date on which a determination of the appeal is expected to be dispatched. The aggregate length of an extension under this paragraph when combined with any extension provided under paragraph (c)(3)(i) of this section shall not exceed 10 working days. A decision to make an extension under this paragraph shall be made by the TVA FOIA Appeal Official or the FOIA Appeal Official's designee.

* * * * *

William S. Moore,

Senior Manager, Administrative Services.

[FR Doc. 95–18430 Filed 7–26–95; 8:45 am]

BILLING CODE 8120–08–W

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 202, 500, 501, and 510

Animal Drugs, Feeds, and Related Products; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration is amending the animal drug regulations to reflect a change in several cross-references to the Federal Food, Drug, and Cosmetic Act (the act). These changes resulted from enactment

of the Nutritional Labeling and Education Act of 1993 (NLEA). By making these changes to the animal drug regulations those who rely on these regulations will be better able to understand and adhere to the requirements of the regulations.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

EFFECTIVE DATE: July 27, 1995.

SUPPLEMENTARY INFORMATION: As a result of enactment of the NLEA, certain cross-references to the act in 21 CFR Chapter I are incorrect. Under section 3 of the NLEA, entitled ''Technical Amendments to the Federal Food, Drug, and Cosmetic Act,'' paragraph (r) provides for several amendments to section 512 of the act (21 U.S.C. 360b). The amendments changed the cites for two definitions under section 201 of the act (21 U.S.C. 321), specifically the cites for ''new animal drug'' and ''animal feeds'' were changed from ''201(w)'' to ''201(v)'' and from ''201(x)'' to ''201(w),'' respectively. This document amends §§ 202.1, 500.26, 501.4, and 510.413 (21 CFR 202.1, 500.26, 501.4, and 510.413) of the animal drug regulations to conform to those changes.

Publication of this document constitutes final action on these changes. Under the Administrative Procedure Act (5 U.S.C. 553(b)), FDA finds for good cause that due notice and public procedure is unnecessary. This document only corrects various technical errors introduced by enactment of the NLEA. By making these changes to the animal drug regulations, those who rely on these regulations, including regulated industry, will be better able to understand and adhere to the requirements of the regulations. Therefore, FDA concludes that good cause exists for proceeding directly to a final rule.

The agency has determined under 21 CFR 25.24(a)(9) 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.

List of Subjects

21 CFR Part 202

Advertising, Prescription drugs.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

21 CFR Part 501

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 202, 500, 501, and 510 are amended as follows:

PART 202—PRESCRIPTION DRUG ADVERTISING

1. The authority citation for 21 CFR part 202 continues to read as follows:

Authority: Secs. 201, 301, 502, 505, 507, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 355, 357, 360b, 371).

§ 202.1 [Amended]

2. Section 202.1 *Prescription-drug advertisements* is amended in paragraph (e)(4)(i)(*b*)(*3*) by removing ''201(w)'' and adding in its place ''201(v)''.

PART 500—GENERAL

3. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

§ 500.26 [Amended]

4. Section 500.26 *Timed-release dosage form drugs* is amended in paragraph (a) by removing ''201(w)'' and adding in its place ''201(v)''.

§ 500.27 [Amended]

5. Section 500.27 *Methylene blue-containing drugs for use in animals* is amended in paragraph (a)(3) by removing ''201(w)'' and adding in its place ''201(v)''.

PART 501—ANIMAL FOOD LABELING

6. The authority citation for 21 CFR part 501 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

§ 501.4 [Amended]

7. Section 501.4 *Animal food; designation of ingredients* is amended in paragraph (b)(13) by removing ''201(x)'' and adding in its place ''201(w)''.

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.413 [Amended]

9. Section 510.413 *Chloroform used as an ingredient (active or inactive) in animal drug products* is amended in paragraph (b) by removing ''201(w)'' and adding in its place ''201(v)''.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18447 Filed 7–26–95; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 866

[Docket No. 91N–0063]

Immunology and Microbiology Devices; Revocation of the Exemption From Premarket Notification; Blood Culturing System Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the microbial growth monitor classification regulation by revoking the exemption from the premarket notification requirements for automated blood culturing system devices used in testing blood and other normally sterile body fluids for bacteria, fungi, and other microorganisms. Revocation of the exemption is necessary because of the importance of these devices in providing rapid diagnosis of potentially life-threatening conditions. Devices using traditional manual methods employing turbidity measurements or direct counts, included under this classification regulation, will continue to be exempt from the requirement of premarket notification.

DATES: The final rule is effective October 25, 1995. A premarket notification submission is required for any automated blood culturing system intended to be introduced or delivered for introduction into commerce on or after October 25, 1995, under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), and the procedures in subpart E of 21 CFR part