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