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

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

807. A manufacturer or an initial distributor of an imported blood culturing device that has already begun commercial distribution under the existing exemption from premarket notification is required to submit a premarket notification on or before October 25, 1995 and must have a premarket notification cleared by FDA by April 22, 1996.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, Ext. 157.

SUPPLEMENTARY INFORMATION:

I. Background

Blood culturing system devices are diagnostic devices used in clinical settings to detect the presence or growth of bacteria, fungi, or other microorganisms from blood samples or from samples of other body fluids that are normally sterile. The process involves testing for these microorganisms by inoculating the patient's sample directly into broth media or by inoculating a processed sample concentrate onto agar media. Microbial growth is monitored either by traditional manual methods (visual inspection, microscopic evaluation, and/or subculturing) or by instrument-assisted (automated) monitoring of microbial metabolic activities, such as the detection of increased presence of carbon dioxide or changes in fluorescence, bioluminescence, or ATPase activities.

In the **Federal Register** of November 9, 1982 (47 FR 50814 at 50826), FDA classified blood culturing system devices into class I (21 CFR 866.2560). In the **Federal Register** of June 12, 1989 (54 FR 25042 at 25046), FDA published a final rule exempting microbial growth monitors, subject to certain limitations, from the requirement of premarket notification. In the **Federal Register** of April 26, 1991 (56 FR 19333), FDA proposed to revoke this exemption for blood culturing system devices because of safety and effectiveness considerations. FDA determined, on reconsideration, that blood culturing system devices do not meet the criteria for exemption identified in the regulation published in the **Federal Register** of June 12, 1989.

Although current efforts have been directed toward streamlining the regulation of in vitro diagnostic devices, FDA's revocation of the blood culturing system devices exemption is necessary because it is based on significant safety and effectiveness considerations.

Subsequent to June 12, 1989, through the medical/scientific literature, FDA became aware of a significant number of problems related to these devices. These problems include: (1) Failure of media to support growth of certain organisms; (2) false negative and false positive results; and (3) cross contamination of cultures. Also, in the early 1990's, the use of instrument assisted microbial growth monitors, originally intended for blood culturing, started to be commonly used to detect, recover, and provide a complete panel of susceptibility results for *Mycobacterium tuberculosis*.

Since these devices are relied upon for rapid diagnosis of bacterial or fungal infection, and are commonly used to detect, recover, and determine susceptibility of *Mycobacterium tuberculosis*, the reported failure of these devices raises significant questions of safety and effectiveness. Bacterial or fungal infections of the bloodstream may be life-threatening. Tuberculosis is a disease of serious health consequences for the patient and its potential for quick dissemination is a very significant public health concern. Malfunction of these devices, therefore, could result in misdiagnosis and mistreatment, thus endangering patients, health care professionals, and the public at large.

Because of safety and effectiveness concerns presented by the device, FDA believes it is necessary to revoke the exemption from the premarket notification procedures to enable FDA to monitor the introduction into commerce, by manufacturers and importers, of automated blood culturing system devices, and to determine whether the devices are as safe and effective as legally marketed devices. Devices using traditional manual methods employing visual turbidity measurement or direct counts are not affected by this final regulation.

FDA provided interested persons 60 days to submit written comments on the proposal. FDA received two comments. A summary of these comments and FDA's responses follows:

1. One comment requested clarification of the continued exemption for traditional culture media used with manual blood culture methods. The comment suggested that the amended section contain language that makes it clear that traditional manual blood culture bottles in which microbial growth is detected by visual reading and conventional subculturing techniques are not affected by the revocation of the exemption.

FDA agrees with this suggestion. Conventional media dispensed in blood culture bottles (20 to 100 milliliter volume) with limited entry seals that are used only with conventional manual blood culture procedures (visual observation for signs of microbial growth and routine subcultures and/or microscopic screening for presence of bacteria and fungi) are not dependent on instrument-based monitoring for detection of signs of microbial growth. However, media bottles used with the automated system are an integral part of the system; therefore, any new or modified media to be used with an automated blood culturing system are also subject to the revocation.

2. A second comment objected to the continued exemption for blood culture systems not using automated instrumentation.

FDA disagrees with the comment. Current traditional manual blood culturing methods use media formulations and techniques that have been in use for many years. The types of media used are often commercialized for blood culturing by manual procedures developed and controlled by individual laboratories. In contrast, devices or systems that specify incubation and observation procedures based on a combination of different media or for use with a monitoring component (other than visual inspection for evidence of microbial growth and routine subculture to solid media and microscopic examination) are not exempt from premarket notification.

Closed systems that exclude routine microscopic examination and subcultures would also be considered a microbial growth monitor and would be subject to the revocation. Similarly, any media bottle designed to be used with a microbial growth monitor (blood culture instrument or detection mechanism other than direct observation/subculture/microscopic inspection) for detection of microorganisms from patient specimens would be considered a component of the microbial growth monitor and also subject to the revocation.

II. References

The following information has been placed on display in the Dockets management Branch (HFA–350), Food and Drug Administration, rm. 1–24, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Aronson, M. D., and D. H. Bor, ''Blood Cultures,'' *Annals of Internal Medicine*, 106:246–253, 1987.

2. Thorpe, T. C., et al., ''BacT/Alert: An Automated Calorimetric Microbial Detection System,'' *Journal of Clinical Microbiology*, 28:1608–1612, 1990.

3. Wallis, C., and J. L. Melnick, ''Rapid, Calorimetric Method for the Detection of Microorganisms in Blood Culture,'' *Journal of Clinical Microbiology*, 21:505–508, 1985.

4. Washington, II, J. A., and D. M. Ilstrue, ''Blood Cultures: Issues and Controversies,'' *Reviews of Infectious Diseases*, 8:792–802, 1986.

5. Welch, W. D., et al., ''Variability in CO_2, O_2, and pH levels in Blood Culture Bottles from Five Different Manufacturers,'' *Journal of Clinical Microbiology*, 20:881–883, 1984.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (a)(10) 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.

IV. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule revokes an exemption and places manufacturers of these devices on a level with manufacturers of other devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required on small entities.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 866.2560 is amended by revising paragraph (b) to read as follows:

§ 866.2560 Microbial growth monitor.

* * * * *

(b) *Classification*. Class I. With the exception of automated blood culturing system devices that are used in testing for bacteria, fungi, and other microorganisms in blood and other normally sterile body fluids, this device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18446 Filed 7–26–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 902, 926, 934, and 950

Alaska, Montana, North Dakota, and Wyoming Regulatory Programs

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of decision.

SUMMARY: OSM is announcing its decision on initial enforcement of underground coal mine subsidence control and water replacement requirements in Alaska, Montana, North Dakota, and Wyoming. Amendments to the Surface Mining Control and Reclamation Act of 1977 (SMCRA) and the implementing Federal regulations require that underground coal mining operations conducted after October 24, 1992: promptly repair or compensate for subsidence-caused material damage to noncommercial buildings and to occupied residential dwellings and related structures and promptly replace drinking, domestic, and residential water supplies that have been adversely affected by underground coal mining. After consultation with Alaska, Montana, North Dakota, and Wyoming and consideration of public comments, OSM has decided that initial enforcement in Alaska and North Dakota will be accomplished through the State program amendment process; in Montana through State enforcement and, if necessary, direct Federal enforcement; and in Wyoming through State enforcement and the State program amendment process.

EFFECTIVE DATE: July 27, 1995.

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Director, Casper Field Office, Telephone: (307) 261–5776.

SUPPLEMENTARY INFORMATION:

A. The Energy Policy Act

Section 2504 of the Energy Policy Act of 1992, Pub. L. 102–486, 106 Stat. 2776 (1992) added new section 720 to SMCRA. Section 720(a)(1) requires that all underground coal mining operations promptly repair or compensate for subsidence-caused material damage to noncommercial buildings and to occupied residential dwellings and related structures.

Repair of damage includes rehabilitation, restoration, or replacement of the structures identified in section 720(a)(1), and compensation must be provided to the owner in the full amount of the reduction in value of the damaged structures as a result of subsidence. Section 720(a)(2) requires prompt replacement of certain identified water supplies if those supplies have been adversely affected by underground coal mining operations.

These provisions requiring prompt repair or compensation for damage to structures, and prompt replacement of water supplies, went into effect upon passage of the Energy Policy Act on October 24, 1992. As a result, underground coal mine permittees in States with OSM-approved regulatory programs are required to comply with these provisions for operations conducted after October 24, 1992.

B. The Federal Regulations Implementing the Energy Policy Act

On March 31, 1995, OSM promulgated regulations at 30 CFR Part 817 (60 FR 16722) to implement the performance standards of sections 720(a)(1) and (2) of SMCRA.

30 CFR 817.121(c)(2) requires in part that:

> The permittee must promptly repair, or compensate the owner for, material damage resulting from subsidence caused to any non-commercial building or occupied residential dwelling or structure related thereto that existed at the time of mining. * * * The requirements of this paragraph apply only to subsidence-related damage caused by underground mining activities conducted after October 24, 1992.