• The total number of flight cycles accumulated on the airplane;

• A description of the area of the wiring where the sleeving was missing; and

• A description of the damage found.

Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

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

(f) The actions shall be done in accordance with Boeing Message M–7200–98–01080, dated March 18, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on May 27, 1998.

Issued in Renton, Washington, on May 5, 1998.

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–12512 Filed 5–11–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 430, 431, 432, 433, 436, 440, 441, 442, 443, 444, 446, 448, 449, 450, 452, 453, 455, and 460

[Docket No. 98N–0211]

Removal of Regulations Regarding Certification of Antibiotic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is repealing its regulations governing certification of antibiotic drugs. The agency is taking this action in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA repealed the statutory provision in the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs. FDAMA also made conforming amendments to the act.

DATES: The direct final rule is effective September 24, 1998. Submit written comments on or before July 27, 1998. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before August 25, 1998, confirming the effective date of the direct final rule. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule before August 25, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell or Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. FDAMA

On November 21, 1997, the President signed FDAMA (Pub. L. 105–115). Section 125(b) of FDAMA repealed section 507 of the act (21 U.S.C. 357). Section 507 of the act was the section under which the agency certified antibiotic drugs. Section 125(b) of FDAMA also made conforming amendments to the act.

FDA has determined that it will be most efficient to make changes in its regulations to reflect the repeal of section 507 of the act in phases. In this first phase, this direct final rule removes parts 430 through 460 (21 CFR parts 430 through 460). These regulations provide the procedures and standards used to certify antibiotic drugs, including FDA's antibiotic drug monographs. FDA plans to initiate a second phase direct final rulemaking procedure to make various, noncontroversial conforming amendments to the balance of Title 21 of the Code of Federal Regulations (CFR), such as removing citations to section 507 of the act and references to the certification of antibiotics. The agency recognizes that as it implements the transition from regulating the premarket review and approval of antibiotic drugs under section 507 of the act to section 505 of the act (21 U.S.C. 355), other issues may arise that could require additional rulemaking. These issues will be addressed in the third phase of implementation.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. The repeal of section 507 of the act eliminates the statutory provision on which the agency relied to certify antibiotic drugs. FDA will, therefore, remove all provisions of Title 21 of the CFR that were issued primarily to carry out the agency's program for the certification of antibiotic drugs under former section 507 of the act. The actions taken should be noncontroversial and the agency does not anticipate receiving any significant adverse comments on this rule.

If FDA does not receive significant adverse comment on or before July 27, 1998, the agency will publish a document in the **Federal Register** before August 25, 1998, confirming the effective date of the direct final rule. A significant adverse comment is one 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. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule before August 25, 1998.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, which is identical to the direct final rule, that provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not

provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to part of this rule and that part may be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Description of the Rule

This rule eliminates Part 430—Antibiotic Drugs; General, in its entirety. Part 430 provided definitions used in the certification of antibiotic drugs and contains § 430.10, which carried out former section 507(h) of the act and was intended to address the certification or release of antibiotic drugs affected by the Drug Amendments of 1962 (Pub. L. 87–781).

This rule also eliminates Part 431—Certification of Antibiotic Drugs, which provided various administrative and procedural requirements for the antibiotic certification program, established conditions on the effectiveness of a certification issued by the agency, and set the fees needed to maintain the agency's antibiotic certification program (see former section 507(b) of the act). Subpart D of Part 431—Confidentiality of Information, is also being eliminated because it is duplicative of the provisions in 21 CFR 312.130 governing the disclosure of information in or about an investigational new drug application.

Part 433—Exemptions from Antibiotic Certification and Labeling Requirements is removed by this rule. Part 433 set the conditions for exempting antibiotic drugs from the general requirement of certification as well as from other, more specific, regulatory requirements (see former section 507(c) and (d) of the act).

This rule eliminates Part 436—Tests and Methods of Assay of Antibiotic and Antibiotic-Containing Drugs. Part 436 contained sterility test methods, biological test methods, microbiological assay methods, and chemical tests for antibiotic drugs generally and for specific antibiotic drugs and antibiotic drug dosage forms. These tests and methods of assay established the means by which the agency would certify that a given batch of antibiotic drug was in compliance with applicable standards of identity, strength, quality, and purity (see former section 507(a) and (b) of the act).

This rule also repeals the following parts: Part 440—Penicillin Antibiotic Drugs; Part 441—Penem Antibiotic Drugs; Part 442—Cepha Antibiotic Drugs; Part 443—Carbacephem Antibiotic Drugs; Part 444—Oligosaccharide Antibiotic Drugs; Part 446—Tetracycline Antibiotic Drugs; Part 448—Peptide Antibiotic Drugs; Part 449—Antifungal Antibiotic Drugs; Part 450—Antitumor Antibiotic Drugs; Part 452—Macrolide Antibiotic Drugs; Part 453—Lincomycin Antibiotic Drugs; Part 455—Certain Other Antibiotic Drugs; and Part 460—Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease. These parts contain the standards of identity, strength, quality, and purity that served as the agency's basis for batch certifying or otherwise authorizing the marketing of drugs that were subject to former section 507 of the act, including the classes of penicillin; penem; cepha; carbacephem; oligosaccharide; tetracycline; peptide; antifungal; antitumor; macrolide; and lincomycin antibiotic drugs; several antibiotic drugs not included in the parts listed above; and antibiotic susceptibility discs, powders, and test panels, respectively (see former section 507(a) and (b) of the act).

With the repeal of part 436 and parts 440 *et seq*., the test methods and assays contained in the approved marketing application and, when applicable, the United States Pharmacopeia (USP) will be used to determine if antibiotic drugs meet the standards of identity, strength, quality, and purity found in the approved marketing application for the drug and, when applicable, the USP.

Finally, the agency is eliminating Part 432—Packaging and Labeling of Antibiotic Drugs, which sets forth special packaging requirements and additional labeling requirements (in addition to the requirements prescribed by 21 CFR 201.100) for drugs that were subject to batch certification or release under former section 507 of the act. With the repeal of section 507 of the act, there is no need to maintain separate or additional labeling and packaging requirements for antibiotic drug products. As with other drug products, labeling of antibiotic drugs will be governed by the agency's general labeling provisions found in 21 CFR part 201 and by applicable over-the-counter drug monographs and approved marketing applications.

Part 432 also included § 432.9, which conditionally authorized the batch certification of antibiotic drugs intended for export, even if the drug failed to meet certain labeling requirements, and provided additional guidance on the labeling of antibiotic drugs for export. In light of the repeal of the batch certification requirement, § 432.9 may also be eliminated without affecting the export of antibiotic drug products.

It should be noted, however, that differences remain between the application of the export provisions in sections 801 and 802 of the act (21 U.S.C. 381 and 382) to antibiotic drugs and the application of those provisions to other new drugs. Prior to the repeal of section 507 of the act, these differences were based on the fact that antibiotic drugs were not subject to premarket approval under section 505 and, therefore, could be exported under section 801(e)(1) of the act. Antibiotic drugs did not have to meet the export requirements in section 802 that apply to unapproved new drugs. Thus, manufacturers could export antibiotic drugs that had not been certified, released, or exempted from certification, subject only to the provisions of section 801(e)(1) of the act. Section 125(c) of FDAMA preserved the export status of antibiotic drugs (which are now subject to approval under section 505 of the act) by expressly exempting them from section 802. (Section 125(c) of FDAMA included the same exemption for insulin products.) In the second phase of the implementation of section 125 of FDAMA, the agency will consider making appropriate amendments to its regulations to reflect this difference between the application of the export provisions of the act to antibiotic drugs (and insulin products) as opposed to all other new drugs.

The removal of parts 430 *et seq*. is not expected to result in any immediate, significant changes in the manufacturing, packaging, labeling, or marketing of antibiotic drug products. Since 1982, the agency has conditionally exempted all antibiotic drugs from batch certification (47 FR 39155, September 7, 1982). With limited exceptions, such as in the areas of export and generic drug approvals, the agency has imposed much the same regulatory requirements on exempted antibiotic drug products as it has on all other drug products.

IV. 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.

V. Analysis of Impacts

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 of 1995 (Pub. L. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. As discussed below, the agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the direct 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 that if a rule has a significant impact on a substantial number of small entities, the agency must analyze regulatory options to minimize the economic impact on small entities. The agency certifies, for the reasons discussed below, that the direct final rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Reform Act requires an agency to prepare a budgetary impact statement before issuing any rule likely to result in a Federal mandate that may result in expenditures by State, local, and tribal governments or the private sector of $100 million (adjusted annually for inflation) in any 1 year. The elimination of the regulations governing the certification of antibiotic drugs will not result in any increased expenditures by State, local, and tribal governments or the private sector. Because this rule will not result in an expenditure of $100 million or more on any governmental entity or the private sector, no budgetary impact statement is required.

This rule is intended to eliminate regulatory procedures and standards that the agency, as a result of the repeal of section 507 of the act, is no longer required to maintain. The elimination of the above listed parts is expected to streamline the regulation of antibiotic drugs by making these products subject to the same regulatory standards as all other drugs for human use. Many of the provisions that are being eliminated by this rulemaking have not had a material impact on the marketing of antibiotic drugs since 1982, when all antibiotic drugs were conditionally exempted from the batch certification requirement. Other provisions, such as the standards of identity, strength, quality, and purity, have in some instances not been kept up-to-date, are duplicative of USP standards, or have been incorporated into approved marketing applications for specific antibiotic drug products. For these reasons, the agency believes that this rule is necessary and that it is consistent with the principles of Executive Order 12866; that it is not a significant regulatory action under that Order; that it will not have a significant impact on a substantial number of small entities; and that it is not likely to result in an annual expenditure in excess of $100 million.

VI. Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (Pub. L. 104–13) is not required.

VII. Request for Comments

Interested persons may, on or before July 27, 1998, submit to the Dockets Management Branch (address above) written comments regarding this 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.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Part 431

Administrative practice and procedure, Antibiotics, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 432

Antibiotics, Labeling, Packaging and containers.

21 CFR Part 433

Antibiotics, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 436, 440, 441, 442, 443, 444, 446, 448, 449, 450, 452, 453, 455, and 460

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration Modernization Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. Part 430 is removed.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

2. Part 431 is removed.

PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

3. Part 432 is removed.

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

4. Part 433 is removed.

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

5. Part 436 is removed.

PART 440—PENICILLIN ANTIBIOTIC DRUGS

6. Part 440 is removed.

PART 441—PENEM ANTIBIOTIC DRUGS

7. Part 441 is removed.

PART 442—CEPHA ANTIBIOTIC DRUGS

8. Part 442 is removed.

PART 443—CARBACEPHEM ANTIBIOTIC DRUGS

9. Part 443 is removed.

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

10. Part 444 is removed.

PART 446—TETRACYCLINE ANTIBIOTIC DRUGS

11. Part 446 is removed.

PART 448—PEPTIDE ANTIBIOTIC DRUGS

12. Part 448 is removed.

PART 449—ANTIFUNGAL ANTIBIOTIC DRUGS

13. Part 449 is removed.

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

14. Part 450 is removed.

PART 452—MACROLIDE ANTIBIOTIC DRUGS

15. Part 452 is removed.

PART 453—LINCOMYCIN ANTIBIOTIC DRUGS

16. Part 453 is removed.

PART 455—CERTAIN OTHER ANTIBIOTIC DRUGS

17. Part 455 is removed.

PART 460—ANTIBIOTIC DRUGS INTENDED FOR USE IN LABORATORY DIAGNOSIS OF DISEASE

18. Part 460 is removed.

Dated: May 1, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12543 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803 and 804

[Docket No. 98N–0170]

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing reporting by manufacturers, importers, distributors, and health care (user) facilities of adverse events related to medical devices. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA is publishing these amendments in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and withdraws this direct final rule.

DATES: This rule is effective September 24, 1998. Submit written comments on or before July 27, 1998. Submit written comments on the information collection requirements on or before July 13, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Spitzig, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2812.

SUPPLEMENTARY INFORMATION:

I. Background

Under the act and the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), FDA issued medical device reporting regulations for manufacturers on September 14, 1984 (49 FR 36326). To correct weaknesses noted in the 1976 amendments, and to better protect the public health by increasing reports of device-related adverse events, Congress enacted the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) that required medical device user facilities and distributors to report certain device-related adverse events.

Distributor reporting requirements became effective on May 28, 1992, following the November 26, 1991 (56 FR 60024), publication of those provisions in a tentative final rule. In the **Federal Register** of September 1, 1993 (58 FR 46514), FDA published a notice announcing that the proposed distributor reporting regulations had become final by operation of law and were now codified in part 804 (21 CFR part 804).

On June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (the 1992 amendments) (Pub. L. 102–112) amending certain provisions of section 519 of the act (21 U.S.C. 360i) relating to reporting of adverse device events. Prior to the 1992 amendments, distributors and manufacturers reported adverse events by using a ''reasonable probability'' standard. Importers may be manufacturers or distributors, depending on their activities. Among other things, the 1992 amendments amended section 519 of the act to change the reporting standard for manufacturers and importers; however, the reporting standard for distributors who are not importers remained the same.

On November 21, 1997, the President signed FDAMA into law. FDAMA made several changes regarding the reporting of adverse events related to devices, including the elimination of reporting requirements for certain distributors, which became effective on February 19, 1998, that are reflected in this direct final rule. However, section 422 of FDAMA states that FDA's regulatory authority under the act, relating to tobacco products, tobacco ingredients, and tobacco additives shall be exercised under the act as in effect on the day before the date of enactment of FDAMA. Because the authority relating to tobacco products remains the same, the reporting requirements for manufacturers and distributors (including distributors who are importers) of cigarettes or smokeless tobacco remain unchanged.

Under part 897, the regulations pertaining to tobacco products, and parts 803 (21 CFR part 803) and 804, the regulations pertaining to device adverse event reporting, importers may be either manufacturers or distributors, depending on their activities. Under parts 897, 803, and 804, importers who repackage or relabel are manufacturers. Similarly, under those sections, importers whose sole activity is distribution of devices are defined as distributors.

As previously stated, the 1992 amendments created a bifurcated reporting standard for distributors, depending on whether they are domestic distributors or importers. When the agency asserted jurisdiction over tobacco products and issued regulations under part 897, tobacco distributors also became subject to this bifurcated reporting standard. Accordingly, the reporting standard applicable to tobacco products distributors has depended on whether the distributor is domestic or an importer. Consistent with section 422 of FDAMA, the direct final rule states that tobacco distributors will continue to use the appropriate reporting standard as described in § 804.25.

Changes made by FDAMA relating to reporting requirements for all medical devices other than tobacco products are as follows:

1. Section 213(a) of FDAMA revised section 519(a) of the act to eliminate distributors as an entity required to report adverse device events. Importers are still required to report under section 519(a) of the act.

2. Section 213(a) also amended section 519(a) of the act to clarify that existing requirements continue to apply for distributors to keep records concerning adverse device events and make them available to FDA upon request.

3. Section 213(a)(2) revoked section 519(d) of the act, which required manufacturers, importers, and distributors to submit to FDA an annual certification concerning the number of