Commission requests comment on whether specific reporting requirements for participants in the OTC derivatives markets are needed and, if so, what reports should be made and by whom. If the Commission were to establish reporting requirements, it would coordinate with other regulatory agencies and, to the extent possible, accept reports provided to other regulatory agencies in satisfaction of the Commission's requirements. The Commission solicits comment concerning how these goals might best be accomplished.

Request for comment. 70. Should the Commission establish reporting requirements for participants in the OTC derivatives markets? If so, what information should be reported? By whom?

C. Self-Regulation

Having identified areas in which current exemptions might be modified, the Commission is also interested in the views of commenters concerning whether, and to what extent, any needed changes concerning the oversight of the OTC derivatives market could be accomplished through initiatives of industry bodies either voluntarily or through a self-regulatory organization empowered to establish rules and subject to Commission oversight. The Commission notes that several industry organizations already exist with an interest in maintaining and improving the integrity of the OTC derivatives marketplace. These organizations include, among others, the Derivatives Policy Group, the International Swaps and Derivatives Association, the Group of Thirty, and the End-Users of Derivatives Association. Industry groups have already issued a number of voluntary initiatives aimed at reducing risks and promoting stability and integrity in the OTC derivatives marketplace.[89] The Commission is interested in exploring the extent to which concerns described in this release might be addressed, and adequate oversight of the OTC derivatives marketplace might be attained, through industry bodies or through self-regulatory organizations.

Request for comment. 71. How effective are current self-regulatory efforts? What are their strengths and weaknesses?

72. Are there particular areas among those discussed above where self-regulation could obviate the need for government regulation?

73. Please discuss the costs and benefits of existing voluntary versus potential mandatory self-regulatory regimes.

74. If a self-regulatory regime were adopted, what mechanism would best assure effective oversight by the Commission?

75. How best can the Commission achieve effective coordination with other regulators in connection with the oversight of the OTC derivatives market?

IV. Summary of Request for Comment

Commenters are invited to discuss the broad range of concepts and approaches described in this release. The Commission specifically requests commenters to compare the advantages and disadvantages of the possible changes discussed above with those of the existing regulatory framework. In addition to responding to the specific questions presented, the Commission encourages commenters to submit any other relevant information or views.

Issued in Washington, D.C. this 6th day of May, 1998, by the Commodity Futures Trading Commission.

By the Commission (Chairperson BORN, Commissioners TULL and SPEARS; Commissioner HOLUM dissenting).

Jean A. Webb,

Secretary of the Commission.

Dissenting Remarks of Commissioner Barbara Pedersen Holum, Concept Release, Over-the-Counter Derivatives

In Section 4(c)(1) of the Commodity Exchange Act, Congress authorized the Commission to exempt certain transactions ''[i]n order to promote responsible economic or financial innovation and fair competition.'' Indeed, it appears that the dramatic growth in volume and the products offered in the OTC derivatives market may be attributed in part to the Commission's past exemptive action. In the spirit of the Commission's ongoing regulatory review program, it is appropriate to examine the continuing applicability of the existing exemptions, focusing on the expanding economic significance of the OTC market. However, in my judgement,the release goes beyond the scope of regulatory review by exploring regulatory areas that may be inapplicable to an OTC market. Accordingly, I am dissenting from the majority's decision to issue the Concept Release on OTC Derivatives in its current form.

Dated: May 6, 1998.

Barbara Pedersen Holum,

Commissioner.

[FR Doc. 98–12539 Filed 5–11–98; 8:45 am]

BILLING CODE 6351–01–M

listing, by credit rating category and industry segment, the current net exposure, net replacement value, and gross replacement values; (3) a Geographic Distribution listing, by country, the current net exposure, the net replacement value, and the gross replacement values; (4) a Net Revenues Report listing, by product category and month, the net revenue; and (5) a Consolidated Activity Report listing, by product category, the aggregate notional amount.

[89] See, e.g.: Framework for Voluntary Oversight, supra; Principles and Practices for Wholesale Financial Market Transactions, supra; and Global Derivatives Study Group, Group of Thirty, Derivatives: Practices and Principles, supra.

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; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which is intended to repeal FDA's 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: Comments must be received on or before July 27, 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. Background

As described more fully in the related direct final rule, section 125(b) of FDAMA (Pub. L. 105–115) repealed section 507 of the act (21 U.S.C. 357)

and made conforming amendments to the act and other provisions of Federal law. Section 507 of the act was the section under which the agency certified antibiotic drugs. FDA is proposing to remove all provisions of Title 21 of the Code of Federal Regulations that were issued primarily to carry out the agency's program for the certification of antibiotic drugs under former section 507 of the act.

II. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule.

The amendments contained in this rule are a direct result of the repeal of the statutory certification provision. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to the companion proposed rule. Instead, FDA will publish a confirmation notice within 30 days after the comment period ends, and FDA intends the direct final rule to become effective 30 days after publication of the confirmation notice. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule and, if appropriate, the rule will be finalized under this companion proposed rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**. All persons who may wish to comment should review the rationale for these amendments set out in the preamble discussion of the direct final rule. If FDA receives significant adverse comments, the agency will withdraw the companion final rule and will treat those comments as comments to this proposed rule. The agency will address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment. 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.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed 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 proposed 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 parts 430 *et seq.* 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 (47 FR 39155, September 7, 1982). 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 U.S.P. 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.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections 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.

VI. Request for Comments

Interested persons may, on or before July 27, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the 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.

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, it is proposed that 21 CFR chapter I be 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. 98–12542 Filed 5–11–98; 8:45 am]

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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; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain regulations governing reporting by manufacturers, importers, distributors, and health care (user) facilities of adverse events related to medical devices. This proposed rule is a companion document to the direct final rule, published elsewhere in this issue of the Federal Register. The amendments are intended to implement provisions of 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 this 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 the direct final rule.

DATES: 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 on the proposed rule 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: This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule is substantively identical to the direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and the direct final rule is withdrawn. FDA is publishing the direct final rule