

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 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.

FDA is proposing to revoke §§ 510.515 and 558.15 because they are obsolete. The purpose of § 510.515 was to provide exemption from certification and labeling requirements of certain drugs used in animal feeds. FDA has discontinued the practice of certifying antibiotic animal drugs, thereby rendering the regulation obsolete relative to its intended purpose. The original purpose of § 558.15, requiring the submission of the results of studies on the effects of long-term administration of then-marketed antimicrobial drugs in animal feed on the occurrence of multiple drug-resistant bacteria associated with these animals, is also obsolete as FDA has a new strategy and concept for assessing the safety of antimicrobial new animal drugs, including subtherapeutic use of antimicrobials in animal feed, with regard to their microbiological effects on bacteria of human health concern.

Almost all of the drug product listings contained in §§ 510.515 and/or 558.15 are already reflected in approval regulations published elsewhere in part 558 subpart B. In two documents published in this issue of the **Federal Register**, the agency is addressing the drug product listings whose approvals are not currently reflected in the approval regulations in part 558 subpart B.

A. Benefits

This proposal is expected to provide clarity and equity in the regulations for new animal drugs for use in animal feeds by deleting the obsolete provisions at §§ 510.515 and 558.15. We do not expect this proposed rule to result in a direct human or animal health benefit. Rather, this proposal would remove unnecessary regulations that both provided exemptions for certifications that no longer occur, or required the submission of safety data for approved subtherapeutic uses of antibiotics, nitrofurans and sulfonamides in the 1970s.

B. Compliance Costs

FDA expects this proposal to result in the loss of marketing ability for five combination uses listed in § 558.15 as described in III.B of this document. In an attempt to certify the approval status, FDA contacted, or attempted to contact, the three sponsors of these five drug combinations. Attempts with one sponsor indicated that they did not wish to certify the transitional approvals, and no response was received from the other sponsors concerning these transitional approvals. Accordingly, we believe that these products were erroneously listed in § 558.15 and that these sponsors no longer market these combination uses as provided for under § 558.15. The revocation of § 558.15 is not expected to have a substantive effect on any approved new animal drugs, or to cause any approved new animal drug to lose its marketing ability. Therefore, we do not expect any loss of sales to result from this provision. We request public comment on the loss of sales or other effects to any products or drug combinations that will lose marketing ability due to this proposed rule.

C. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact on a substantial number of small entities. FDA has determined in section V.B of this document that this proposed rule would not impose compliance costs on the sponsors of any products that are currently marketed. Further, it is not expected to cause any drugs that are currently marketed to lose their marketing ability. We therefore certify that the proposed rule would not have a significant economic effect on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (as amended).

D. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The

current inflation-adjusted statutory threshold is about \$110 million.

VI. 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 is not required.

VII. References

The following references have been placed on display in the Division of Dockets Management (*see ADDRESSES*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. National Academy of Sciences/National Research Council, "The Effects on Human Health of Subtherapeutic Use of Antimicrobials in Animal Feeds," 1980.
2. Petition of the Natural Resources Defense Council, Inc., to Secretary of Health and Human Services, New York, NY, November 20, 1984.
3. Decision of the Secretary Denying Petition, Docket No. 84P-0399, November 13, 1985.
4. National Academy of Sciences/Institute of Medicine, "Human Health Risks With the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed," 1989.
5. Report of the American Society for Microbiology Task Force on Antibiotic Resistance; the American Society for Microbiology, Public and Scientific Affairs Board; Washington, DC, March 16, 1995.
6. World Health Organization (WHO), "The Medical Impact of the Use of Antimicrobials in Food Animals," Report of a WHO meeting, WHO/EMC/ZOO/97.4, Berlin, Germany, October 13 to 17, 1997.
7. WHO, "Use of Quinolones in Food Animals and Potential Impact on Human Health," Report of a WHO meeting, WHO/EMC/ZDI/98.12, Geneva, Switzerland, June 2 to 5, 1998.
8. Discussion paper: "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals," Center for Veterinary Medicine, Food and Drug Administration, 1999; Docket 98D-1146 (http://www.fda.gov/cvm/antimicrobial/ar_framework.htm).

VIII. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper 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 Division