

number of small entities, the agency must analyze regulatory options that would minimize the impact on small entities. FDA certifies in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) that this proposed rule would not have a significant economic impact on a substantial number of small entities, and therefore, a regulatory flexibility analysis is not required.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any regulation 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 (adjusted annually for inflation) in any 1 year. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the proposed 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 approximately \$110 million.

The proposed rule is intended to clarify, simplify, and elaborate on the current regulations concerning liquid medicated feeds and free-choice medicated feeds. This rule, which offers more precise and detailed language than do the current regulations, responds to requests submitted in citizen petitions and comments by an industry association. It would also make changes to the current regulatory language for free-choice medicated feeds in order to be consistent with the ADAA provision that replaced the medicated feed application system with the medicated feed mill licensing system.

A. Liquid Medicated Feeds

The proposal for liquid medicated feeds would clarify the types of liquid medicated feeds for which a separate new animal drug approval is necessary and for which a feed mill license is necessary. In particular, it elaborates more fully on the procedures and requirements for demonstrating the chemical and physical stability of a drug in liquid feeds, as well as how the data from such a demonstration can be submitted to the agency.

The proposed rule references requirements under § 514.1 that are currently required for the approval of all new animal drugs. As these requirements do not represent a new burden, there is no cost associated with this aspect of the proposed rule. Likewise, the proposed rule adds to the current labeling provisions for certain drugs that are approved for use in

animal feed or drinking water but not approved for use in certain liquid feeds. The proposed rule describes the waiver process for the exclusion of certain products from these labeling requirements. Because this waiver process already exists under the current rule, it would not impose any additional cost to industry.

B. Free-Choice Medicated Feed

The proposed revisions to § 510.455 concern free-choice medicated feed and very closely follow the liquid medicated feed proposal. Proposed § 510.455 would clarify and elaborate on the NADA requirements for drugs intended for use in free-choice medicated feeds. In addition, it would replace the language that provided for the medicated feed application with language for the medicated feed mill system that was created by the ADAA. Since the estimated costs and benefits of the feed mill system were prepared for the proposed and final regulations implementing that system, these costs and benefits would not be considered to be effects of this proposed rule. In total, the proposed rule would not be expected to impose any new compliance burdens on the industry and are not associated with any costs.

It is possible that the proposed rule would, in fact, result in some cost savings due to the proposed provision that would eliminate the requirement for a medicated feed mill license for the manufacture of some liquid and free-choice medicated feeds that contain a Category I drug. In recent years, we have received an average of 128 medicated feed mill license applications annually. Since the applications do not explicitly specify the types of medicated feed that would be manufactured, we are not able to estimate the size of the decrease in applications that would be expected as a result of the proposed rule. However, we would expect there to be some decrease in applications as some feed mills would be exempted from this requirement in the future. We believe this could lead to a modest cost savings for these feed mills. Further, the increased clarity and simplification of §§ 510.455 and 558.5 would be expected to result in additional cost savings to industry in the preparation of new animal drug applications to the agency. We cannot precisely quantify such savings, but believe the impact to be modest.

V. Federalism

We have analyzed this proposed rule in accordance with the principles in Executive Order 13132. We have determined that the proposed rule does

not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement has not been prepared.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Waivers from Labeling Requirements for New Animal Drugs Intended for Use in Liquid Medicated Animal Feed

Description: Proposed § 558.5 specifies procedures for obtaining a waiver from labeling requirements for certain drugs intended for use in animal feed or drinking water but not approved for use in liquid medicated feed. The request for waiver must include: (1) A copy of the product label; (2) a description of the formulation; and (3) information to establish that the physical, chemical, or other properties of the product are such that diversion to use in liquid medicated feeds is unlikely. This information would be collected if the manufacturer or sponsor chose not to include the required warning "FOR USE IN ____ ONLY, NOT