DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. 93P–0174]

Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to change the regulations for liquid medicated feed and free-choice medicated feed. By changing the regulations for liquid medicated feed, FDA wants to clarify: What data are required to demonstrate chemical and physical stability of a drug in liquid feed; how such data may be submitted for use in the new animal drug approval process; and which liquid medicated feeds may be manufactured in a feed manufacturing facility that has not obtained a medicated feed mill license from FDA. By changing the regulations for free-choice medicated feed, FDA wants to ensure that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medicated feed and liquid medicated feed comply with the terms of the Animal Drug Availability Act (ADAA) of 1996.

DATES: We invite you to comment on this proposed rule. We will consider all comments that we receive by August 26, 2003. Send comments on the information collection provisions by July 28, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974. Comments must be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: dmomcilo@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Section I of the preamble addresses the proposed changes in the regulation for liquid medicated feeds. Section II addresses the proposed changes for free-choice medicated feeds.

I. Liquid Medicated Feed

A. Current Regulations

According to the new animal drugs for use in animal feeds regulations under part 558 (21 CFR part 558), provided specifically in § 558.3(b) are three types of medicated products for use in feed; a Type A medicated article and two types of medicated feed, Type B and Type C. A Type A medicated article is a new animal drug that is used for the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Under the current rule, the use of a drug in the manufacture of a liquid Type B medicated feed requires that the feed mill obtain an approved new animal drug application (NADA) (§ 558.5(a)) and an approved medicated feed mill license (§ 558.5(b)). A Type B medicated feed is used solely for the manufacture of other medicated feeds, Type B or Type C (§ 558.3(b)(3)). A Type C medicated feed can be either fed as the complete feed, ''top dressed'' (added on top of usual ration), offered ''free-choice'' in conjunction with other animal feed, or further diluted to produce another Type C medicated feed (§ 558.3(b)(4)).

B. Chronology of the American Feed Industry Association (AFIA) Citizen Petitions on Liquid Feed Regulations, FDA Responses, and ADAA

On April 30, 1993, the AFIA filed a citizen petition (docket number 93P–0174/CP1), requesting that FDA:

1. Amend § 558.5 to clarify the information and data needed to demonstrate chemical and positional (physical) stability in liquid medicated feeds, and

2. Describe the circumstances under which a medicated feed application (MFA) (Form FDA 1900) will or will not be required.

In our November 10, 1993, tentative response to AFIA, we stated that we agreed ''in principle'' to modify § 558.5 to include appropriate directions on submission of chemical and positional (physical) stability data. We stated, however, that we disagreed with the request to eliminate the requirement for an approved MFA for the manufacture of Type B or Type C liquid medicated feeds from a Type A medicated article, Category I drug. Finally, we stated that we were preparing to propose a change to § 558.5 and would provide a final response to the citizen petition once the notice of proposed rulemaking was published in the **Federal Register**.

AFIA modified the requested actions in letters of March 3, 1994, and January 6, 1995, to ask that no MFA be required where a specific formula or the specifications for the finished liquid Type B product is published in a regulation for a Category I drug.

On April 19, 1995, we sent a second tentative response to AFIA that modified some of what was explained in our letter of November 10, 1993. We stated, in the April 19, 1995, letter that we agreed ''in principle that an MFA (Form FDA–1900) should not be required if a specific formula or the specifications for the finished liquid Type B product is published in the regulations and the drug is a Category I product.'' We explained that our position is based on the text of 21 CFR 558.5(a), ''which addresses the concern for drug stability in liquid feeds, except where specific approval has been granted for such use'' and that ''We interpret this exception to be the basis for not requiring MFA approval for these Category I Type B liquid feeds 21 CFR 558.5(b).'' We continued to believe, however, that the manufacture of a liquid Type B medicated feed from an approved Category I drug will require an approved MFA if a formula or the specifications for the liquid Type B product were not published in the regulation. Also stated in the letter, we considered that since ''the formula or specifications are not published and are privileged information, the MFA is needed to ensure that only the manufacturer is authorized to utilize the intended formula or specifications.'' We also noted that an approved MFA was required to manufacture all Category II Type B liquid feeds.

In a letter of May 19, 1995, AFIA requested that we convert the process for development of an amendment to § 558.5 into a negotiated rulemaking. However, in a letter of June 15, 1995, AFIA asked that its request for negotiated rulemaking be held ''in abeyance.'' The letter stated that AFIA anticipated that its concerns would be addressed in the proposed rule and that ''If further rulemaking is necessary, then we believe negotiated rulemaking would be in order.''

On October 9, 1996, the ADAA became a law. The ADAA provided for

a system of medicated feed mill licensing that replaces the provisions for the MFA. Therefore, the requirements specified in the current regulation for liquid medicated feeds, including those in part 558 that provide for the use of specific animal drugs in liquid medicated feeds, must be amended to be consistent with the ADAA provisions for feed mill licensing.

On December 6, 1996, in response to the passage of the ADAA, AFIA filed another amendment to its citizen petition from April 30, 1993. The amended petition revised AFIA's suggested regulation for liquid medicated feeds so that the terms of the regulation are consistent with the provisions for feed mill licensing. Both petitions, the amended and the original, suggested revised language for § 558.5 that would clarify the procedures and requirements for demonstrating chemical and positional (physical) stability for liquid Type B medicated feeds. The suggested language on chemical and positional (physical) stability specifies that the submitted data should describe the relevant ranges of conditions under which the drug would be chemically stable and the conditions under which the drug would be positionally (physically) stable if labeling requiring agitation is not proposed.

The suggested language also stated that the stability data might be submitted by either the sponsor of the new animal drug in an NADA or abbreviated NADA (ANADA) or by a feed manufacturer in a master file (MF), which could be referenced in the NADA or the ANADA. The suggested language also provided that FDA would notify the feed manufacturer by letter that the liquid feed addressed in the MF could be manufactured.

As we have preliminarily stated in correspondence with AFIA, we agree with its request for modification of § 558.5 and inclusion of appropriate directions on chemical and positional (physical) stability. We agree that the clarification of these requirements will enhance the approval process for liquid feeds. We also agree to permit submission of stability data through an MF that can be referenced by a subsequent applicant. This is consistent with the current free-choice medicated feed rule in § 510.455 (21 CFR 510.455).

Where feed manufacturers would like to use Type A medicated articles in the manufacture of liquid medicated feeds with formulas or specifications differing from those in approvals codified in the CFR, there must be a separate NADA approved under part 514 (21 CFR part 514) for such use containing the safety and effectiveness data required by § 514.1, and the stability data required by §§ 514.1 and 558.5. In such circumstances, under this proposed rule, the drug sponsor could submit an NADA containing the safety and effectiveness data required by § 514.1, the feed manufacturer (or any other third party) could submit the stability data for the liquid feed in an MF, and the sponsor could reference the MF in its NADA rather than including its own stability data. On request of the owner of the formula (i.e. ingredient list, product composition) and/or specifications (i.e. other product specific parameters, such as pH data, viscosity, etc.), the formula and/or specifications for the liquid medicated feed will be included in the published approval. We otherwise will not publish the formula and/or specifications because they generally are trade secret information entitled to protection under section 301(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 331(j)). Where we do not publish the formula and/or specifications, we will include a statement that the liquid medicated feed has been approved under procedures outlined in proposed § 558.5(f)(2). Because the formula and/or specifications are generally protected information, we expect that such liquid medicated feeds will be manufactured only by the NADA holder, the MF holder, or someone authorized by them. We intend to provide the NADA holder and the MF holder with a certified letter citing the approved formula and/or specifications of the liquid feed where that information is not published. The letter will demonstrate to FDA inspectors that the liquid medicated feed is manufactured using an approved formula and/or specifications.

Since the term ''positional stability,'' as suggested in the citizen petition, is not appropriate in relation to the state of matter, which is either chemical or physical, we are using the term ''physical stability'' instead of ''positional stability.'' Also, our chemists will determine during the NADA approval process what specifications are required for approval a particular liquid medicated feed.

Finally, we agree with AFIA's request to eliminate the requirement for an approved medicated feed mill license for the manufacture of some liquid medicated feeds that contain a Category I drug. Under this proposed rule an approved feed mill license is required for the manufacture of a liquid medicated feed that contains either any Category II drug or a Category I drug that is manufactured with a formula and/or specifications that are not published (i.e., proprietary).

Where the formula and/or specifications are published, FDA has an assurance that all medicated feed mills have access to the information necessary to manufacture the approved liquid medicated feed. Where the formula and/or specifications are proprietary, medicated feed mills might attempt to manufacture the liquid medicated feed knowing only that the drug is approved for use in liquid feed, but not knowing the formula and/or specifications. Manufacture of a liquid medicated feed without such crucial information could endanger animal health and public health due to unsafe drug residues. Section 510(h) of the act (21 U.S.C. 360(h)) requires that FDA inspect licensed medicated feed mills at least once every 2 years. During such inspections, we can ensure that medicated feed mills manufacturing liquid medicated feeds with proprietary formulas and/or specifications have the approved formula and/or specifications. For this reason, we tentatively conclude that it is necessary for FDA to maintain greater regulatory oversight over facilities manufacturing liquid medicated feeds with proprietary formulas and/or specifications, and we are proposing that they must have an approved medicated feed mill license. The proposed rule also requires that facilities manufacturing liquid medicated feeds containing Category II drugs have an approved feed mill license because of the potential for unsafe residues associated with Category II drugs (§ 558.3(b)(1)(ii)).

We are proposing to exempt from the feed mill license requirement facilities manufacturing liquid feeds containing a Category I drug with a published formula and/or specifications. Given the reduced risk of unsafe residues from a Category I drug and the assurance that medicated feed mills have the information necessary to manufacture the liquid medicated feed where the formula and/or specifications are published, we believe this exemption is consistent with public health, as required by section 512(m)(6) of the act (21 U.S.C. 360b(m)(6)).

C. Description of the Proposed § 558.5

The proposed rule: (1) Replaces the references to ''medicated feed application'' in the current rule with the term ''medicated feed mill license''; (2) defines the types of liquid medicated feed covered by this regulation; (3) clarifies the types of approvals required for liquid medicated feed; (4) explains that an approval is required for a drug intended for use in a liquid feed and

clarifies the procedures and requirements for demonstrating chemical and physical stability of a drug in liquid feed; (5) permits submission of the stability data through a MF for reference by a subsequent applicant; (6) explains what information will be included in the published approval of a drug for use in liquid feed; (7) identifies the conditions under which an approved medicated feed mill license will be required for the manufacture of a liquid medicated feed; and (8) describes the labeling provisions for several drugs approved for use in water but not in liquid feed.

D. Discussion of Proposed § 558.5

Proposed § 558.5(a) and (b) describe the types of liquid medicated feed covered by the proposed rule.

Proposed § 558.5(c) states that an approved NADA, a supplemental NADA, or an abbreviated NADA is required for new animal drugs intended for use in liquid feed.

An approved, supplemental, or abbreviated NADA for new animal drugs intended for use in liquid feed is required for the same reasons we described when § 558.5 was proposed in 1973. First, some reports had demonstrated the instability of certain drugs (bacitracin, oxytetracyclin, and chlortetracycline) in liquid feed (37 FR 27634, December 19, 1972). Second, liquid animal feed differs substantially from dry feeds or dry feed supplements in that small variations in some of the components of liquid feed have a marked effect on the stability of added drugs that may compromise the safety and efficacy of such drugs (38 FR 21178, August 6, 1973). We concluded that the manufacture of liquid feed is inherently more difficult to control than the manufacture of dry feed; and therefore, it should be more closely regulated (38 FR 21178).

Proposed § 558.5(d) clarifies approval requirements for new animal drugs intended for use in liquid feed including the specific stability data necessary for liquid medicated feed to meet the requirements of § 514.1(b)(5)(x). Chemical stability data must be submitted for all drugs intended for use in liquid medicated feed. Because of the potential for the uneven distribution of an animal drug in a liquid feed, the physical stability for liquid medicated feeds must also be demonstrated for an appropriate period of time under field conditions. If not demonstrated, labeling must include instructions for agitation or recirculation before use of the liquid medicated feed.

Proposed § 558.5(e) specifies that the stability data may be submitted either directly as part of the NADA by the sponsor or to an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

Proposed § 558.5(f) explains that the formulas and/or specifications for the liquid medicated feed will be codified in the CFR if requested by the sponsor or MF holder. Otherwise, the approval codified in the CFR will not include the formula and/or specifications, but instead will state that the approval has been granted for a proprietary formula and/or specifications.

Proposed § 558.5(g) states that an approved medicated feed mill license is required for the manufacture of a liquid feed that contains any Category II drug, or a Category I drug that is manufactured with a proprietary formula and/or specifications.

Proposed § 558.5(h) spells out labeling requirements for certain drugs that are intended for use in animal feed and/or drinking water. As previously noted, we are concerned about these drugs because of their demonstrated instability in liquid feed. The purpose of this paragraph is to prevent use of such drugs in liquid medicated feeds.

Proposed § 558.5(i) explains conditions and procedures for obtaining a waiver from labeling provisions outlined in § 558.5(h). We are considering removing this waiver option because since its inception in 1973 it has never been utilized. We are seeking comments on this issue.

Proposed § 558.5(j) includes additional information on the labeling provisions of § 558.5(h).

II. Free-Choice Medicated Feed

A. Current Regulation in § 510.455

The current regulation explains that free-choice medicated feed products such as medicated blocks (agglomerated feed compressed or rendered into a solid mass cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements containing one or more animal drugs, are placed in feeding or grazing areas for consumption and are not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. This regulation reflects our concerns about the safety and effectiveness of animal drugs when administered free-choice by stating that an approved NADA is required for a drug intended for use in free-choice medicated feed, and that a medicated feed mill license is required for feed mills that manufacture free-choice medicated feeds.

Finally, as with all drugs intended for use in animal feeds, all applicants have to demonstrate that such drugs are stable and safe and effective when offered free-choice (§ 514.1(b)(5)(x) and (b)(8)).

B. The Advance Notice of Proposed Rulemaking (ANPR) and AFIA Response

On November 21, 1996 (61 FR 59209), we issued an ANPR seeking comments concerning various issues for the development of regulations implementing the provisions of the ADAA. In a comment in response to the ANPR, dated December 6, 1996, the AFIA suggested a revised version of § 510.455 that would adopt the terms of feed mill licensing in accordance with the ADAA and allow a feed manufacturer to submit an NADA for the approval of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. In this response, as well as in its other response from April 30, 1993, the AFIA suggested language for § 558.5 that would clarify that liquid medicated feeds intended for use free-choice are also subject to the requirements of § 510.455.

We agree that the terms of feed mill licensing in accordance with the ADAA must be adopted in the provisions for free-choice feed. As we already stated for liquid feeds, where feed manufacturers would like to use Type A medicated articles in the manufacture of free-choice medicated feeds with formulas and/or specifications differing from those in approvals already codified in the CFR, there must be a separate NADA approved for such use containing the safety and consumption/effectiveness data required by § 514.1, and the stability data required by §§ 514.1 and 558.5. In such circumstances, under this proposed rule the drug sponsor could submit an NADA containing the safety and consumption/effectiveness data required by § 514.1, the feed manufacturer (or any other third party) could submit the stability data for the free-choice feed in an MF, and the sponsor could reference the MF in its NADA rather than including its own stability data. Under the proposed rule, on request of the owner of the formula and/or specifications for the free-choice feed, this information will be included in the published approval. Otherwise, we will not publish the formula and/or specifications because it is generally trade secret information entitled to protection under section 301(j) of the act. Where we do not publish the formula and/or specifications, we will include a statement that the free-choice

medicated feed has been approved under procedures outlined in § 510.455(e)(2). Because the formula and/or specifications are generally protected information we expect that these free-choice medicated feeds will be manufactured only by the NADA holder, the MF holder, or someone authorized by them.

We intend to provide the NADA holder and the MF holder with a certified letter citing the approved formula and/or specifications of the free-choice feed where that information is not published. The letter will demonstrate to FDA inspectors that the free-choice feed is manufactured using an approved formula and/or specifications.

C. Description of Proposed § 510.455

This proposal for free-choice medicated feed, in most respects, mirrors the liquid medicated feed proposal. Thus, the required chemical and physical stability data and consumption/effectiveness data may be submitted by the sponsor in the NADA, or to an MF that a sponsor may subsequently reference in its NADA with written consent of the MF holder. Likewise, the method of submission of stability data for the drug approval process, and the determination of whether product formulas are included in the approval codified in the CFR are similar to those discussed for liquid medicated feeds. It also incorporates the provisions of feed mill licensing in accordance with the ADAA.

The proposed rule: (1) Modifies the current rule by providing a definition of free-choice medicated feed; (2) explains that one of three types of NADAs is required for a drug intended for use in a free-choice feed; (3) specifies the data required for such applications and the procedures for their submission; (4) explains how such data must be submitted; (5) states what information will be included in the published approval of a new animal drug intended for use in free-choice feed; and (6) explains the situations that will require a medicated feed mill license for the manufacture of a free-choice medicated feed.

D. Discussion of Proposed § 510.455

Section 510.455(a) remains largely unchanged because the definitions appear adequate; however, the first statement is modified to define free-choice medicated feed. Proposed § 510.455(b) explains that new animal drugs intended for use in free-choice feed must be approved as an NADA, a supplemental NADA, or an abbreviated NADA.

Proposed § 510.455(c) explains that any new animal drug intended for use in free-choice feed must be approved under section 512 of the act (21 U.S.C. 360b) and that data showing that the target animal consumes the new animal drug in an amount that is safe and effective (consumption/effectiveness data) and chemical and physical stability data are required for approval of such drugs.

Proposed § 510.455(d) clarifies that the consumption/effectiveness and physical stability data must be submitted directly in the NADA and/or to an MF that a sponsor may then reference in an NADA with written consent of the MF holder. Therefore, the information in an MF can serve as a substitute for, or as an addition to, data submitted by the applicant.

Proposed § 558.455(e) explains that the formula and/or specifications for the free-choice medicated feed would be codified in the CFR on request of the NADA or MF holder. Otherwise, the approval codified in the CFR will not include the formula and/or specifications, but instead state that the approval has been granted for a proprietary formula and/or specifications.

Proposed § 558.455(f) clarifies that an approved feed mill license is required for the manufacture of free-choice medicated feeds that contain a Category II drug and those that contain a Category I drug with a proprietary formula and/or specifications.

As with liquid feeds, where the formula and/or specifications are published, FDA has an assurance that all medicated feed mills have access to the information necessary to manufacture an approved free-choice medicated feed. Where the formula and/or specifications are proprietary, medicated feed mills might attempt to manufacture the free-choice medicated feed knowing only that the drug is approved for use in free-choice feed, but not knowing the formula and/or specifications. Manufacture of a free-choice medicated feed without such crucial information could endanger animal health and public health due to unsafe drug residues. Section 510(h) of the act requires that FDA inspect licensed medicated feed mills at least once every 2 years. During such inspections, we can insure that medicated feed mills manufacturing free-choice medicated feeds with proprietary formulas and/or specifications have the approved formula. For this reason, we tentatively conclude that it is necessary for FDA to maintain greater regulatory oversight of facilities manufacturing free-choice medicated feeds with proprietary formulas and/or specifications, and we are proposing that they must have an approved medicated feed mill license. The proposed rule also requires that facilities manufacturing free-choice medicated feeds containing Category II drugs have an approved feed mill license because of the potential for unsafe residues associated with Category II drugs (§ 558.3(b)(1)(ii)).

We are proposing to exempt from the feed mill license requirement facilities manufacturing free-choice feeds containing a Category I drug with a published formula and/or specifications. Given the reduced risk of unsafe residues from a Category I drug and the assurance that medicated feed mills have the information necessary to manufacture the free-choice medicated feed where the formula and/or specifications are published, we believe this exemption is consistent with public health, as required under section 512(m)(6) of the act.

III. Environmental Impact

We have carefully considered the potential environmental impacts of this rule and 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.

The proposed action merely clarifies existing regulations concerning liquid medicated feeds and free-choice medicated feeds.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 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). We believe that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. We have also determined that 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. Under the Regulatory Flexibility Act, if a regulation has a significant impact on a substantial

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

FOR USE IN LIQUID MEDICATED FEEDS'' on its product label. The sponsor or manufacturers would then need to satisfy the requirements of the waiver section of the regulation. All other data collections are covered under OMB control number 0910–0032.

Description of Respondents: Medicated feed manufacturing facilities and sponsors of new animal drugs used in the manufacture of medicated feed.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
558.5(i)	1	1	1	5	5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived from data by FDA's Division of Animal Feeds in the Center for Veterinary Medicine. Only one respondent was used in these figures because although this particular waiver has been part of the regulations since 1973, it has never been utilized. We estimated it would take 5 hours to compile the required information because of the time necessary to explain why the drug would not be diverted to use in liquid feed.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB.

OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

VII. Conforming Changes

FDA is proposing conforming changes in its regulations in §§ 558.95, 558.305, 558.311, 558.342, 558.355, and 558.625 to remove reference to the term ''medicated feed application.'' These conforming changes will ensure the accuracy and consistency of the regulations.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

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, it is proposed that 21 CFR parts 510 and 558 be amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.455 is revised to read as follows:

§ 510.455 Requirements for free-choice medicated feeds.

(a) *What is free-choice medicated feed*? For the purpose of this part, free-choice medicated feed is medicated feed that is placed in feeding or grazing areas and is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Free-choice feeds include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements (''lick tank'' supplements) containing one or more animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations in part 225 of this chapter for medicated feeds.

(b) *What types of approvals are required for new animal drugs intended for use in free-choice feed*? New animal drugs intended for use in free-choice feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act), as:

(1) An original new animal drug application (NADA);

(2) A supplemental NADA; or

(3) An abbreviated NADA.

(c) *What are approval requirements for new animal drugs intended for use in free-choice feed*? (1) An approval under section 512 of the act is required for any new animal drug intended for use in a free-choice feed.

(2) An approved NADA for a Type A medicated article intended for use in free-choice feed must contain the following information:

(i) Data, or reference to data in a master file (MF), showing that the target animal consumes the new animal drug in the Type C free-choice feed in an amount that is safe and effective (consumption/effectiveness data); and

(ii) Data, or reference to data in an MF, showing the relevant ranges of conditions under which the drug will be chemically and physically stable in the Type C free-choice feed under field conditions.

(d) *How are consumption/effectiveness and/or stability data to be submitted*? The data must be submitted:

(1) Directly in the NADA, by a sponsor; and/or

(2) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(e) *What will be stated in the published approval for a new animal drug intended for use in free-choice feed*? The approval of a new animal drug intended for use in free-choice feed, as published in this subchapter, will include:

(1) The formula and/or specifications of the free-choice medicated feed, where the owner of this information requests such publication; or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-choice medicated feed*? An approved medicated feed mill license is required for the manufacture of:

(1) All free-choice medicated feeds that contain a Category II drug; and

(2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

PART 558–NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.5 is revised to read as follows:

§ 558.5 Requirements for liquid medicated feed.

(a) *What types of liquid medicated feeds are covered by this section*? This section covers the following types of liquid medicated feed:

(1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3) of this chapter); or

(2) Type C feed that is intended for:

(i) Further manufacture of another Type C feed; or

(ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4) of this chapter).

(b) *How is liquid free-choice medicated feed regulated*? Liquid free-choice medicated feed is covered by this section and by § 510.455 of this chapter.

(c) *What types of approvals are required for new animal drugs intended for use in liquid feed*? New animal drugs intended for use in liquid feed must be approved for such use under section 512 of the act, as:

(1) An original NADA;

(2) A supplemental NADA; or

(3) An abbreviated NADA.

(d) *What are the approval requirements for new animal drugs intended for use in liquid feed*? (1) An approval under section 512 of the act is required for any new animal drug intended for use in a liquid feed; and

(2) An approved NADA for a drug intended for use in liquid feed must contain the following information:

(i) Data, or a reference to data in an MF, that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under actual field use conditions; and

(ii) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or

(iii) Feed labeling with recirculation or agitation directions as follows:

(A) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(B) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *How are chemical and physical stability data to be submitted*? The data must be submitted:

(1) Directly in the NADA;

(2) By a sponsor; or

(3) To a master file (MF) that a sponsor may then reference in its NADA with written consent of the MF holder.

(f) *What will be stated in the published approval for a new animal drug intended for use in liquid feed*? The approval of a new animal drug intended for use in liquid feed as published in this subchapter will include:

(1) The formula and/or specifications of the liquid medicated feed, where the owner of this information requests such publication; and/or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(g) *When is a medicated feed mill license required for the manufacture of a liquid medicated feed*? An approved medicated feed mill license is required for the manufacture of:

(1) All liquid medicated feeds that contain a Category II drug; and

(2) Liquid medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

(h) *What measures are in place to prevent certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, from being diverted to use in liquid feeds*? Any product containing any form of bacitracin, oxytetracycline, or chlortetracycline, intended for oral administration via animal feed and/or drinking water, and not approved for use in a liquid medicated feed must include in its labeling the following statement: ''FOR USE IN ____ ONLY. NOT FOR USE IN LIQUID MEDICATED FEEDS.'' The blank may be filled in with the words: ''DRY FEEDS'', ''DRINKING WATER'', or ''DRY FEEDS AND DRINKING WATER''.

(i) *Can the labeling provisions of paragraph (h) of this section be waived, and how can I apply for waiver*? (1) The labeling provisions of paragraph (h) may be waived if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

(2) To obtain a waiver, you must submit a letter requesting a waiver to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Office of New Animal Drug Evaluation (HFV–100), Rockville, MD 20855.

(3) The letter must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the new animal drug are such that diversion to use in liquid medicated feed is unlikely.

(j) *What else do I need to know about the labeling provisions of paragraph (h)*? The labeling provisions of paragraph (h) may be implemented without prior approval as provided for in § 514.8(d) and (e) of this chapter.

§ 558.95 [Amended]

5. Section 558.95 *Bambermycins* is amended in paragraph (d)(4)(iii)(*d*) by removing the last sentence.

§ 558.305 [Amended]

6. Section 558.305 *Laidlomycin* is amended in paragraphs (c)(1)(i) and (c)(1)(ii) by removing ''Type B'' whenever it appears.

§ 558.311 [Amended]

7. Section 558.311 *Lasalocid* is amended:

a. In paragraphs (d)(1)(i), (d)(1)(ii), (d)(2), (d)(3), (d)(3)(iii), and (d)(4) by removing ''Type B'' wherever it appears;

b. In paragraph (d)(2) by removing the last sentence;

c. In paragraphs (d)(2), (d)(3), and (d)(3)(iii) by removing ''positionally'' and by adding in its place ''physically'';

d. In paragraph (d)(3)(ii) by removing ''positional'' and by adding in its place ''physical'';

e. In paragraph (d)(3)(iii) by removing the second complete sentence ''Approval of the supplement will not be published in the **Federal Register** because such approval will not affect or alter conditions or use of the product in the new animal drug application or the regulation.''; and in the third complete sentence by removing ''will, however, provide'' and by adding in its place ''will provide'';

f. In paragraph (d)(3)(iii) by removing the phrase ''submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for liquid Type B feed'' and by adding in its place the phrase ''manufacture under a medicated feed mill license the liquid medicated feed described in the master file'';

g. In paragraph (e)(2)(iv) by removing the phrase ''; each use of this Type C free-choice feed must be the subject of an approved FD–1900 as provided in § 510.455 of this chapter.''; and

h. In paragraph (e)(3)(iv) by removing the last sentence.

§ 558.342 [Amended]

8. Section 558.342 *Melengestrol* is amended in paragraphs (d)(1)(i) and (d)(1)(ii) by removing the phrase ''Type B or C''; and in paragraph (d)(2) by removing ''positionally'' and by adding in its place ''physically''.

9. Section 558.355 is amended:

a. In paragraph (f)(3)(i)(*b*)(*1*) by adding the phrase ''as defined in paragraph (d)(12) of this section'' at the end of the fourth sentence; and by removing the rest of the paragraph after the fourth sentence;

b. In paragraph (f)(6)(i)(*b*)(*1*) by adding the phrase ''as defined in paragraph (d)(12) of this section'' at the end of the fifth sentence; and by removing the rest of the paragraph after the fifth sentence;

c. In paragraphs (f)(3)(i)(*b*)(*2*), (f)(3)(i)(*b*)(*2*)(*iii*), (f)(6)(i)(*b*)(*2*), and (f)(6)(i)(*b*)(*2*)(*iii*) by removing ''Type B'' wherever it appears;

d. In paragraphs (f)(3)(i)(*b*)(*2*), (f)(3)(i)(*b*)(*2*)(*ii*), (f)(6)(i)(*b*)(*2*), and (f)(6)(i)(*b*)(*2*)(*ii*) by removing ''positionally'' and ''positional'' wherever they appear and by adding in their respective places ''physically'' and ''physical'';

e. In paragraphs (f)(3)(i)(*b*)(*2*) and (f)(6)(i)(*b*)(*2*) in the first sentence after the word ''directions'' by adding the phrase ''defined in paragraph (d)(12) of this section'';

f. In paragraphs (f)(3)(i)(*b*)(*2*)(*iii*) and (f)(6)(i)(*b*)(*2*)(*iii*) by removing the second complete sentence ''Approval of the supplement will not be published in the **Federal Register** because such approval will not affect or alter conditions or use of the product in the new animal drug application or the regulation.''; and in the third complete sentence by removing the phrase ''will, however, provide'' and by adding in its place ''will provide'';

g. In paragraphs (f)(3)(i)(*b*)(*2*)(*iii*) and (f)(6)(i)(*b*)(*2*)(*iii*) by removing the phrase ''submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed'' and by adding in its place the phrase ''manufacture the liquid medicated feed under a medicated feed mill license described in the master file'';

h. In paragraph (f)(3)(i)(*b*)(*2*)(*iii*) in the last sentence by removing ''(f)(3)(i)(*b*)(*1*)'' and by adding in its place ''(d)(12)'';

i. In paragraph (f)(3)(ix)(*b*) in the seventh sentence by removing the phrase '': Recirculate or agitate immediately prior to use for not less than 10 minutes, moving at least 1 percent of the tanks contents per minute from the bottom of the tank to the top'' and by adding in its place ''as defined in paragraph (d)(12) of this section''; and by removing the eighth and tenth sentences;

j. In paragraph (f)(6)(i)(*b*)(*2*) and in (f)(6)(i)(*b*)(*2*)(*iii*) in the last sentence by removing ''(f)(6)(i)(*b*)(*1*)'' and by adding in its place ''(d)(12)''; and

k. By adding paragraph (d)(12) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(12) Mixing directions for liquid feeds requiring recirculation or agitation:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

* * * * *

§ 558.625 [Amended]

10. Section 558.625 *Tylosin* is amended in paragraphs (c)(1)(i) and (c)(1)(ii) by removing ''Type B'' and by removing the phrase ''no fewer than 10 minutes'' and adding in its place the phrase ''not less than 10 minutes''.

Dated: May 12, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12974 Filed 5–27–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[OAR–2002–0053, FRL–7504–8]

Standards of Performance for Stationary Gas Turbines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: On April 14, 2003, the EPA published a direct final rule to amend the standards of performance for stationary gas turbines, along with a parallel proposal to be used as a basis for final action in the event that we received any adverse comments on the direct final rule amendments. Since a public hearing was requested and held on May 14, 2003, we are announcing a 30-day extension of the public comment period.

DATES: Submit comments on or before June 13, 2003.

ADDRESSES: *Comments.* By U.S. Postal Service, send comments (in duplicate, if possible) to: EPA Docket Center (6102T), Attention Docket Number OAR–2002–0053, U.S. EPA, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. In person or by courier, deliver comments (in duplicate, if possible) to: Air and Radiation Docket, Attention Docket Number OAR–2002–0053, U.S. EPA, 1301 Constitution Avenue, NW., Room B–108, Washington, DC 20460. We request that a separate copy also be sent to the contact person listed below (*see* **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Mr. Jaime Pagán, Combustion Group, Emission Standards Division (C439–01), U.S. EPA, Research Triangle Park, North Carolina 27711; telephone number (919) 541–5340; facsimile number (919) 541–5450; electronic mail address *pagan.jaime@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** issued on April 14, 2003, when EPA published a direct final rule (68 FR 17990) and a parallel proposal (68 FR 18003) amending the standards of performance for stationary gas turbines (40 CFR part 60, subpart GG). The amendments codified several alternative testing and monitoring procedures that have routinely been approved by EPA. The amendments also reflected changes in emission control technologies and turbine design since the original promulgation of the rule on September 10, 1979. b

We stated in the preamble to the direct final rule and parallel proposal that if we received significant material adverse comment on one or more distinct provisions of the direct final rule, we would publish a timely withdrawal of those distinct provisions in the **Federal Register**. The direct final rule stated that the deadline for submitting public comments was May 14, 2003, and that the effective date of the provisions would be May 29, 2003. The proposal also stated that if a public hearing was requested by April 24, 2003, the hearing would be held on May 14, 2003, at the New EPA Facility Complex in Research Triangle Park, North Carolina, at 10 a.m., and that the comment period would be extended until 30 days after the date of the public hearing. The EPA is hereby extending the comment period, which was set to end on May 14, 2003, to June 13, 2003.

To submit comments, or access the official public docket, please follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section of the April 14, 2003 (68 FR 17990)