

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<sup>1</sup>

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

<sup>1</sup> 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](mailto: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.