

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