4. Only two of the three required assays were performed on medicated feeds containing monensin and melengestrol acetate, as required by 21 CFR 225.58(b)(1).

5. Proper labeling for medicated feed manufactured containing 300 grams per ton chlortetracycline was not available, as required by 21 CFR 225.80.

6. The drug scale, ingredient scale, and the bagger scale had not been tested for accuracy within the last year, as required by 21 CFR 225.30(b)(4).

7. No written procedures for flushing and sequencing were available, as required by 21 CFR 225.65(b).

8. Incoming labels were not proofread, dated, or initialed by a responsible person, as required by 21 CFR 225.80(b)(2).

9. No investigation or corrective action was taken after receipt of failed assay result for medicated feed, as required by 21 CFR 225.58(d) and (e).

10. No drug receipt records or daily drug inventory were maintained for Category I, Type A medicated articles, as required by 21 CFR 225.42(b)(5) and (b)(6).

As a result of the failed CGMP inspection, FDA sent a letter dated March 12, 1993 (Ref. 2), (with a copy of the Form FDA 483 enclosed) to the firm's president. The letter discussed potential regulatory consequences that could result due to facility personnel deviating from CGMP requirements. It urged that the firm's president ''* * * ensure complete and **lasting** [emphasis added] correction of all regulatory deficiencies.'' The letter also informed the firm's president that FDA would not approve additional MFA's until the violations were corrected and verified. Finally, the letter closed by stating that if the violations were not corrected, FDA might issue a notice of opportunity for a hearing on a proposal to withdraw approval of the firm's MFA's.

In response to the FDA letter, the firm's president sent a letter dated April 7, 1993 (Ref. 3), to FDA listing the actions that had been taken to correct all violations listed on the Form FDA 483.

The firm was inspected again on May 3, 4, 10, and 11, 1994. That inspection revealed continued violations of CGMP regulations for the manufacture of medicated animal feeds including the following:

1. Failed assay results had not been investigated, and the required corrective actions had not been instituted, as required by 21 CFR 225.58(d) and (e).

2. The three drug potency assays required per calendar year were not performed on medicated feeds containing Aureo S 700 (chlortetracycline and sulfamethazine), as required by 21 CFR 225.58(b)(1).

3. Master Record Files did not always indicate the amount of drug source material to be used in a batch of medicated feed, as required by 21 CFR 225.102(b)(1).

4. Liquid meters to measure molasses and white grease had not been tested for accuracy within the last year, as required by 21 CFR 225.30(b)(4).

5. A container (bearing expiration date 10/92) with 10 pounds of tiamulin indicated inadequate drug control, as required by 21 CFR 225.42(a).

A Form FDA 483 (Ref. 4) containing the observed violations was presented to and discussed with the firm's president.

Consequently, FDA sent a certified letter dated August 23, 1994 (Ref. 5), to the president of Benton County Ag Center, Inc., notifying him of FDA's intention to withdraw approval of the 11 MFA's currently held by his firm. The firm has not submitted a formal response to the letter.

Accordingly, FDA is now proposing to withdraw approval of the MFA's held by Benton County Ag Center, Inc., as identified above, under section 512(m)(4)(B)(ii) of the act and 21 CFR 514.115(c)(2).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

References

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

1. Form FDA 483, inspection of December 22, 1992.

2. Letter, FDA to Benton County Ag Center, Inc., dated March 12, 1993.

3. Letter, Benton County Ag Center, Inc., to FDA, dated April 7, 1993.

4. Form FDA 483, inspection of May 3, 4, 10, and 11, 1994.

5. Letter, FDA to Benton County Ag Center, Inc., dated August 23, 1994.

Therefore, notice is given to Benton County Ag Center, Inc., and to any other interested persons who may be adversely affected, that CVM proposes to issue an order under section 512(m)(4)(B)(ii) of the act and 21 CFR 514.115(c)(2) withdrawing approval of MFA's F 93–642, F 127–333, F 131–878, F 139–280, F 141–603, F 141–604, F 141–757, F 144–054, F 147–607, F 147–617, F 147–641, and all amendments and supplements thereto, on the grounds that new information, evaluated together with the evidence available when the applications were approved, shows that the methods used in, or the facilities and controls used for, the manufacturing, processing, and packing of such animal feeds are: (1) Inadequate to ensure and preserve the identity, strength, quality, and purity of the NAD's therein, and (2) were not made adequate within a reasonable time after receipt of written notice from FDA specifying the inadequacies.

In accordance with provisions of section 512 of the act and regulations promulgated for the efficient enforcement of it (21 CFR part 514), and under authority delegated to the Director, Center for Veterinary Medicine (21 CFR 5.84), CVM hereby provides an opportunity for a hearing to show why approval of the MFA's identified in this notice, and all amendments and supplements to the applications, should not be withdrawn under section 512(m)(4)(B)(ii) of the act and 21 CFR 514.115(c)(2). Any hearing would be subject to the provisions of 21 CFR part 12.

An applicant who decides to seek a hearing shall file on or before May 26, 1995, a written notice of appearance, request for a hearing, and the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 514.200.

Procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, submission of information and analysis to justify a hearing, other comments, and a grant or denial of a hearing, are contained in 21 CFR 514.200.

The failure of a sponsor to file a timely, written appearance and request for a hearing as required by 21 CFR 514.200 shall be construed as an election not to avail himself of the opportunity for a hearing. In such case, the Director, Center for Veterinary Medicine, under the authority delegated to him in 21 CFR 5.84(a)(2), without further notice will enter a final order withdrawing approval of the applications.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it clearly appears from the face of the documentation and analysis in the request for a hearing that there is no