

Subpart B—Administrative Actions on Licenses

- 515.20 Approval of medicated feed mill license applications.
- 515.21 Refusal to approve a medicated feed mill license application.
- 515.22 Suspension and/or revocation of approval of a medicated feed mill license.
- 515.23 Voluntary revocation of medicated feed mill license.
- 515.24 Notice of revocation of a medicated feed mill license.
- 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.
- 515.26 Services of notices and orders.

Subpart C—Hearing Procedures

- 515.30 Contents of notice of opportunity for a hearing.
- 515.31 Procedures for hearings.

Subpart D—Judicial Review

- 515.40 Judicial review.

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

SOURCE: 64 FR 63204, Nov. 19, 1999 unless otherwise noted.

Subpart A—Applications

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Forms FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine home page at “<http://www.fda.gov/cvm>”.

(b) A completed medicated feed mill license must contain the following information:

- (1) The full business name and address of the facility at which the manufacturing is to take place.
- (2) The facility’s FDA registration number as required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act).
- (3) The name, title, and signature of the responsible individual or individuals for that facility.
- (4) A certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in

accordance with the applicable regulations published under section 512(i) of the act.

(5) A certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds conform to current good manufacturing practice as described in section 501(a)(2)(B) of the act and in part 225 of this chapter.

(6) A certification that the facility will establish and maintain all records required by regulation or order issued under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, and will permit access to, or copying or verification of such records.

(7) A commitment that current approved Type B and/or Type C medicated feed labeling for each Type B and/or Type C medicated feed to be manufactured will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug.

(8) A commitment to renew registration every year with FDA as required in §§ 207.20 and 207.21 of this chapter.

(c) Applications must be completed, signed, and submitted to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(d) Applications that are facially deficient will be returned to the applicant. All reasons for the return of the application will be made known to the applicant.

(e) Upon approval, the original copy of the application will be signed by an authorized employee of FDA designated by the Commissioner of Food and Drugs, and a copy will be returned to the applicant.

§ 515.11 Supplemental medicated feed mill license applications.

(a) After approval of a medicated feed mill license application to manufacture animal feed, a supplemental application shall be submitted for a change in ownership and/or a change in mailing address of the facility site.

(b) Each supplemental application should be accompanied by a fully completed Form FDA 3448 and include an explanation of the change.