(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by sections 512(m)(5)(B) or 504(a)(3)(B) of the act; or

(2) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(4) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) of the act, and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of.

§ 515.23 Voluntary revocation of medicated feed mill license.

A license issued under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) will be revoked on the basis of a request for its revocation submitted in writing by a responsible individual holding such license on the grounds that the facility no longer manufactures any animal feed covered under §558.4(b) of this chapter. A written request for such revocation shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Revocation of approval of a medicated feed mill license under the provisions of this paragraph shall be without prejudice.

§ 515.24 Notice of revocation of a medicated feed mill license.

When a license approved under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) is revoked by the Commissioner of Food and Drugs (the Commissioner), the Commissioner will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

§ 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.

The Commissioner of Food and Drugs (the Commissioner), upon his/her own initiative or upon request of an applicant stating reasonable grounds therefor and if the Commissioner finds that the facts so require, may issue an order approving a medicated feed mill license application that previously has had its approval refused, suspended, or revoked.

§ 515.26 Services of notices and orders.

All notices and orders under this part 515 and section 512 of the Federal Food, Drug, and Cosmetic Act (the act) pertaining to medicated feed mill licenses shall be served:

(a) In person by any officer or employee of the Department of Health and Human Services designated by the Commissioner of Food and Drugs; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at the applicant or respondent's last known address in the records of the Food and Drug Administration.