

§ 515.26

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.

Subpart C—Hearing Procedures

§ 515.30 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs (the Commissioner) to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license will specify the grounds upon which the Commissioner proposes to issue this order. On request of the applicant, the Commissioner will explain the reasons for the action. The notice of opportunity for a hearing will be published in the FEDERAL REGISTER and will specify that the applicant has 30 days after issuance of the notice within which the Commissioner is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, this failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner

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without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, the applicant is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis of the information the applicant is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his/her findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and the Judge shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the appearance.

§ 515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 512(m)(3) and (m)(4)

of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

520.23 Acepromazine maleate tablets.
520.44 Acetazolamide sodium soluble powder.
520.45 Albendazole oral dosage forms.
520.45a Albendazole suspension.
520.45b Albendazole paste.
520.48 Altrenogest solution.
520.62 Aminopentamide hydrogen sulphate tablets.
520.82 Aminopropazine fumarate oral dosage forms.
520.82a Aminopropazine fumarate tablets.
520.82b Aminopropazine fumarate, neomycin sulfate tablets.
520.88 Amoxicillin oral dosage forms.
520.88a Amoxicillin trihydrate film-coated tablets.
520.88b Amoxicillin trihydrate for oral suspension.
520.88c Amoxicillin trihydrate oral suspension.
520.88d Amoxicillin trihydrate soluble powder.
520.88e Amoxicillin trihydrate boluses.
520.88f Amoxicillin trihydrate tablets.
520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.
520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.
520.90 Ampicillin oral dosage forms.
520.90a Ampicillin capsules.
520.90b Ampicillin trihydrate tablets.
520.90c Ampicillin trihydrate capsules.
520.90d Ampicillin trihydrate for oral suspension.
520.90e Ampicillin trihydrate soluble powder.
520.90f Ampicillin trihydrate boluses.

520.100 Amprolium oral dosage forms.
520.100a Amprolium drinking water.
520.100b Amprolium drench.
520.100c Amprolium crumbles.
520.110 Apramycin sulfate soluble powder.
520.154 Bacitracin oral dosage forms.
520.154a Soluble bacitracin methylene disalicylate.
520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.
520.154c Bacitracin zinc soluble powder.
520.182 Bicyclohexylammonium fumagillin.
520.222 Bunamidine hydrochloride.
520.246 Butorphanol tartrate tablets.
520.260 *n*-Butyl chloride capsules.
520.300 Cambendazole oral dosage forms.
520.300a Cambendazole suspension.
520.300b Cambendazole pellets.
520.300c Cambendazole paste.
520.309 Carprofen.
520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.
520.312 Carnidazole tablets.
520.314 Cefadroxil tablets.
520.315 Cefadroxil powder for oral suspension.
520.390 Chloramphenicol oral dosage forms.
520.390a Chloramphenicol tablets.
520.390b Chloramphenicol capsules.
520.390c Chloramphenicol palmitate oral suspension.
520.420 Chlorothiazide tablets and boluses.
520.434 Chlorphenesin carbamate tablets.
520.445 Chlortetracycline oral dosage forms.
520.445a Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.
520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).
520.445c Chlortetracycline tablets and boluses.
520.446 Clindamycin hydrochloride capsules.
520.447 Clindamycin hydrochloride liquid.
520.452 Clenbuterol syrup.
520.455 Clomipramine hydrochloride tablets.
520.462 Clorsulon drench.
520.530 Cythioate oral liquid.
520.531 Cythioate tablets.
520.534 Decoquinat.
520.540 Dexamethasone oral dosage forms.
520.540a Dexamethasone powder.
520.540b Dexamethasone tablets and boluses.
520.540c Dexamethasone chewable tablets.
520.550 Dextrose/glycine/electrolyte.
520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.
520.580 Dichlorophene and toluene capsules.
520.581 Dichlorophene tablets.
520.600 Dichlorvos.
520.608 Dicloxacinil sodium monohydrate capsules.
520.620 Diethylcarbamazine oral dosage forms.