

§ 514.105

effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application in accordance with § 201.105 of this chapter.

(e) The information contained in an application will be considered insufficient to determine whether a new animal drug is safe and effective for use when there is a refusal or failure upon written notice to furnish inspectors authorized by the Food and Drug Administration an adequate opportunity to inspect the facilities, controls, and records pertinent to the application.

(f) On the basis of preliminary consideration of an application or supplemental application containing typewritten or other draft labeling in lieu of final printed labeling, an applicant may be informed that such application is approvable when satisfactory final printed labeling identical in content to such draft copy is submitted.

(g) When an application has been found incomplete on the basis of a need for the kind of information described in § 514.6, such application shall be considered withdrawn without prejudice to future filing on the date of issuance of the letter citing the inadequacies contained in the application, unless within 30 days the sponsor chooses to avail himself of the opportunity for hearing as prescribed by § 514.111.

§ 514.105 Approval of applications.

(a) The Commissioner shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which the new animal drug may be used, including the name and address of the applicant; the conditions and indications for use covered by the application; any tolerance, withdrawal period, or other use restrictions; any tolerance required for the new animal drug substance or its metabolites in edible products of food-producing animals; and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed; and such other information the

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Commissioner deems necessary to assure safe and effective use.

(b) He shall notify the applicant by sending him a copy of the proposed publication as described in paragraph (a)(1) of this section.

[40 FR 13825, Mar. 27, 1975, as amended at 51 FR 7392, Mar. 3, 1986; 64 FR 63203, Nov. 19, 1999]

§ 514.106 Approval of supplemental applications.

(a) Within 180 days after a supplement to an approved application is filed pursuant to § 514.8, the Commissioner shall approve the supplemental application in accordance with procedures set forth in § 514.105(a)(1) and (2) if he/she determines that the application satisfies the requirements of applicable statutory provisions and regulations.

(b) The Commissioner will assign a supplemental application to its proper category to ensure processing of the application.

(1) *Category I.* Supplements that ordinarily do not require a reevaluation of any of the safety or effectiveness data in the parent application. Category I supplements include the following:

(i) A corporate change that alters the identity or address of the sponsor of the new animal drug application (NADA).

(ii) The sale, purchase, or construction of manufacturing facilities.

(iii) The sale or purchase of an NADA.

(iv) A change in container, container style, shape, size, or components.

(v) A change in approved labeling (color, style, format, addition, deletion, or revision of certain statements, e.g., trade name, storage, expiration dates, etc).

(vi) A change in promotional material for a prescription drug not exempted by § 514.8(a)(3)(i) and (a)(3)(ii).

(vii) Changes in manufacturing processes that do not alter the method of manufacture or change the final dosage form.

(viii) A change in bulk drug shipments.

(ix) A change in an analytical method or control procedures that do not alter the approved standards.

(x) A change in an expiration date.