

(3) Whether the submission is an original or supplemental application.

(4) Identification of the Type A medicated article, as defined in §558.3 of this chapter, used by generic name, potency, and manufacturer.

(5) The species of animal(s) for which the feed is intended.

(6) The form of feed to be produced, i.e., mash, meal crumbles, pellets, liquid, or other specified form.

(7) Whether the feed is a Type B or Type C medicated feed.

(8) Whether the feed is for sale or for own use (not for sale).

(9) Level of the drug(s) in the finished feed, and the amount of Type A medicated article per ton contained therein.

(10) Identification of the regulation(s) in subchapter E of this chapter on which approval relies.

(11) Labeling representative of each intended use as stated in the claim. Each generic label shall include the claim, drug level, mixing directions, feeding directions, caution and/or warning statements, and any other special directions required by the published regulation. This shall consist of bag labels, invoice copy, bulk labels, and placards when applicable.

(12) A commitment to establish and maintain a program of sampling and analysis consisting of an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the date of manufacture of the medicated feed.

(13) A statement of the minimum and maximum assay value permitted from the labeled amount of the drug.

(14) Identification of the agent authorized to act on behalf of the applicant.

(15) The applicant's name, responsible individual's title and original signature, and date.

(c) Upon approval, one copy of the application will be signed by an authorized employee of the Food and Drug Administration designated by the Com-

missioner, and it will be returned to the applicant.

(d) Applications (Form FDA 1900) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

(Approved by the Office of Management and Budget under control number 0910-0011)

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#### **§514.6 Amended applications.**

The applicant may submit an amendment to an application that is pending, including changes that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, and controls to preserve them, in which case the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

#### **§514.7 Withdrawal of applications without prejudice.**

The sponsor may withdraw his pending application from consideration as a new animal drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The original application will be retained by the Food and Drug Administration although it is considered withdrawn. The applicant shall be furnished a copy at cost on request.

#### **§514.8 Supplemental new animal drug applications.**

(a)(1) After a new animal drug application is approved, a supplemental new animal drug application may propose changes. A supplemental application may omit statements made in the approved application concerning which