

§ 514.10 Confidentiality of data and information in an investigational new animal drug notice and a new animal drug application file for an antibiotic drug.

(a) The rules established in §§ 514.11 and 514.12 of this chapter with regard to the confidentiality of an investigational new animal drug notice and a new animal drug application file shall apply to such notices and files for antibiotic drugs for new animal drug use.

(b) All records showing the Food and Drug Administration's testing of and action on a particular lot of a certifiable antibiotic drug for veterinary use are immediately available for public disclosure.

§ 514.11 Confidentiality of data and information in a new animal drug application file.

(a) For purposes of this section the *NADA file* includes all data and information submitted with or incorporated by reference in the NADA, INAD's incorporated into the NADA, supplemental NADA's, reports under §§ 510.300 and 510.301 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NADA file shall be handled in accordance with the provisions of this section.

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before an approval has been published in the FEDERAL REGISTER, unless it has previously been publicly disclosed or acknowledged.

(c) If the existence of an NADA file has not been publicly disclosed or acknowledged, no data or information in the NADA file is available for public disclosure.

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before an approval has been published in the FEDERAL REGISTER, no data or information contained in the file is available for public disclosure before such approval is published, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a

Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an approval has been published in the FEDERAL REGISTER, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in § 20.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NADA file. Such summaries do not constitute the full reports of investigations under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:

(i) For an NADA approved prior to July 1, 1975, internal agency records that describe such data and information, e.g., a summary of basis for approval or internal reviews of the data and information, after deletion of:

(a) Names and any information that would identify the investigators.

(b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an NADA approved on or after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the approval is published in the FEDERAL REGISTER.

(a) The Center for Veterinary Medicine may at an appropriate time prior to approval of the NADA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, revised by the Center.

(b) The Center for Veterinary Medicine may prepare its own summary of such data and information.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in §20.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in §20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of part 20 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time any one of the following events occurs unless extraordinary circumstances are known:

(1) The NADA has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.

(3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NADA file are not available for public disclosure unless they have been previously disclosed to the public as defined in §20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

[40 FR 13825, Mar. 27, 1975, as amended at 42 FR 3109, Jan. 14, 1977; 42 FR 15675, Mar. 22, 1977; 54 FR 18280, Apr. 28, 1989]

§514.12 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an INAD notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in §514.11.

§514.15 Untrue statements in applications.

Among the reasons why an application for a new animal drug or animal feed bearing or containing a new animal drug may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the product from the conditions of such use stated in the application;

(2) Articles used as components of the product from those listed in the application;

(3) Composition of the product from that stated in the application;

(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product

from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) The unexplained omission in whole or in part from an application or from an amendment or supplement to an application or from any record or report required under the provisions of section 512 of the act and §510.300 or §510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, and the application fails to include a brief statement of the reason for the non-compliance.

[40 FR 13825, Mar. 27, 1975, as amended at 49 FR 7226, Feb. 28, 1984; 50 FR 7517, Feb. 22, 1985]

Subpart B—Administrative Actions on Applications

§514.100 Evaluation and comment on applications.

(a) After the filed application has been evaluated, the applicant will be furnished written comment on any apparent deficiencies in the application.

(b) When the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug appears adequate on its face, but it is not feasible to reach a conclusion as to the safety and effectiveness of the new animal drug solely from consideration of this description, the applicant may be notified that an establishment inspection is required to verify their adequacy.

(c) A request for samples of a new animal drug or any edible tissues and byproducts of animals treated with such a drug, shall specify the quantity deemed adequate to permit tests of analytical methods to determine their adequacy for regulatory purposes. The request should be made as early in the 180-day period as possible to assure timely completion. The date used for computing the 180-day limit for the purposes of section 512(c) of the act shall be moved forward 1 day for each day after the mailing date of the request until all of the requested samples are received. If the samples are not received within 90 days after the request, the application will be considered withdrawn without prejudice.

(d) The information contained in an application may be insufficient to determine whether a new animal drug is safe or effective in use if it fails to include (among other things) a statement showing whether such drug is to be limited to prescription sale and exempt under section 502(f) of the act from the requirement that its labeling bear adequate directions for lay use. If such drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for professional use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer such drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with §201.105 of this chapter, and information concerning hazards, contraindications, side effects, and precautions relevant with respect to any uses for which such drug is to be prescribed.

(2) The application fails to show that the labeling and advertising of such drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for professional use of such drug will contain, in the

same language and emphasis, the information for use including indications, 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 type-written 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) Within 180 days after an application has been filed pursuant to § 514.1, if the Commissioner determines that none of the grounds for denying approval specified in section 512(d) of the act applies:

(1) He 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 Commissioner deems necessary to assure safe and effective use.

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

(b) Within 90 days after an application filed pursuant to § 514.2 if the Commissioner determines that none of the grounds for denying approval specified in section 512(m)(3) of the act applies, he shall notify the applicant that it is approvable by signing and mailing to the sponsor the original copy of the Form FDA 1900.

[40 FR 13825, Mar. 27, 1975, as amended at 51 FR 7392, Mar. 3, 1986]

§ 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.

(xi) Addition of an alternate manufacturer, repackager, or relabeler of the drug product.

(xii) Addition of an alternate supplier of the new drug substance.

(xiii) A change permitted in advance of approval as listed in § 514.8(d).

(xiv) Changes not requiring prior approval which are listed under § 514.8(a)(5) when submitted as supplemental applications.

(2) *Category II.* Supplements that may require a reevaluation of certain safety or effectiveness data in the parent application. Category II supplements include the following:

(i) A change in the active ingredient concentration or composition of the final product.

(ii) A change in quality, purity, strength, and identity specifications of the active or inactive ingredients.

(iii) A change in dose (amount of drug administered per dose).

(iv) A change in the treatment regimen (schedule of dosing).

(v) Addition of a new therapeutic claim to the approved uses of the product.

(vi) Addition of a new or revised animal production claim.

(vii) Addition of a new species.

(viii) A change in the prescription or over-the-counter status of a drug product.

(ix) A change in statements regarding side effects, warnings, precautions, and contraindications, except the addition of approved statements to container, package, and promotional labeling, and prescription drug advertising.

(x) A change in the drug withdrawal period prior to slaughter or in the milk discard time.

(xi) A change in the tolerance for drug residues.

(xii) A change in analytical methods for drug residues.

(xiii) A revised method of synthesis or fermentation of the new drug substance.

(xiv) Updating or changes in the manufacturing process of the new drug substance and/or final dosage form (other than a change in equipment that does not alter the method of manufacture of a new animal drug, or a change from one commercial batch size to another without any change in manufacturing procedure), or changes in the methods, facilities, or controls used for the manufacture, processing, packaging, or holding of the new animal drug (other than use of an establishment not covered by the approval that is in effect) that give increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess.

[55 FR 46052, Nov. 1, 1990; 55 FR 49973, Dec. 3, 1990; 56 FR 12422, Mar. 25, 1991]

§ 514.110 Reasons for refusing to file applications.

(a) The date of receipt of an application for a new animal drug shall be the date on which the application shall be deemed to be filed.

(b) An application for a new animal drug shall not be considered acceptable for filing for any of the following reasons:

(1) It does not contain complete and accurate English translations of any pertinent part in a foreign language.

(2) Fewer than three copies are submitted.

(3) It is incomplete on its face in that it is not properly organized and indexed.

(4) On its face the information concerning required matter is so inadequate that the application is clearly not approvable.

(5) The new animal drug is to be manufactured, prepared, propagated, compounded, or processed in whole or in part in any State in an establishment that has not been registered or exempted from registration under the provisions of section 510 of the act.

(6) The sponsor does not reside or maintain a place of business within the United States and the application has not been countersigned by an attorney, agent, or other representative of the applicant, which representative resides in the United States and has been duly authorized to act on behalf of the applicant and to receive communications on all matters pertaining to the application.

(7) The new animal drug is a drug subject to licensing under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*). Such applications will be referred to the U.S. Department of Agriculture for action.

(8) It fails to include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reasons for the non-compliance.

(9) [Reserved]

(10) The applicant fails to submit a complete environmental assessment which addresses each of the items specified in the applicable format under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter

(c) If an application is determined not to be acceptable for filing, the applicant shall be notified within 30 days of receipt of the application and shall be given the reasons therefore.

(d) If the applicant disputes the findings that his application is not acceptable for filing, he may make written request that the application be filed over protest, in which case it will be filed as of the day originally received.

[40 FR 13825, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985]

§ 514.111 Refusal to approve an application.

(a) The Commissioner shall, within 180 days after the filing of the application, inform the applicant in writing of

his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to a new animal drug, that:

(1) The reports of investigations required to be submitted pursuant to section 512(b) of the act do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or

(2) The results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; or

(3) The methods used in and the facilities and controls used for the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions. In making this determination the Commissioner shall consider, among other relevant factors:

(i) The probable consumption of such drug and of any substance formed in or on food because of the use of such drug;

(ii) The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substances;

(iii) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data; and

(iv) Whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice; or

(5)(i) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of adequate and well-controlled investigations, including clinical (field) investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

(ii) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical (field) investigations. They provide the basis for the determination whether there is *substantial evidence* to support the claims of effectiveness for *new animal drugs*.

(a) The plan or protocol for the study and the report of the results of the effectiveness study must include the following:

(1) A clear statement of the objectives of the study.

(2) A method of selection of the subjects that—

(i) Provides adequate assurance that they are suitable for the purposes of the study, diagnostic criteria of the condition to be treated or diagnosed, confirmatory laboratory tests where appropriate, and, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(ii) Assigns the subjects to test groups in such a way as to minimize bias; and

(iii) Assures comparability in test and control groups of pertinent variables, such as species, age, sex, duration and severity of disease, management practices, and use of drugs other than those being studied. When the effect of such variables is accounted for by an appropriate design, and when, within the same animal, effects due to the test drug can be obtained free of the effects of such variables, the same

animal may be used for both the test drug and the control using the controls set forth in paragraph (a)(5)(ii)(a)(4)(i), (ii), or (iii) of this section.

(3) An explanation of the methods of observation and recording of the animal response variable studied and the means of excluding bias or minimizing bias in the observations.

(4) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. Level and methods of “blinding,” if used, are to be documented. Generally, four types of comparisons are recognized:

(i) No treatment: Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated animals.

(ii) Placebo control: Comparison of the results of use of the new animal drug entity with an inactive preparation designed to resemble the test drug as far as possible.

(iii) Active treatment control: An effective regimen of therapy may be used for comparison, e.g., where the condition treated is such that no treatment or administration of a placebo would be contrary to the well-being of the animals.

(iv) Historical control: In some circumstances involving diseases with high and predictable mortality (leukemia or tetanus) or with signs and symptoms of predictable duration or severity (some forms of parasitism, bovine hypocalcemia, canine eclampsia) or in the case of prophylaxis where morbidity is predictable, the results of use of a new animal drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable animals with no treatments or with a regimen (therapeutic, diagnostic, prophylactic) whose effectiveness is established.

(5) A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

(6) Any of the criteria in this paragraph (a)(5)(ii) may be waived in whole or in part, either before the investigation or in the evaluation of a completed study, by the Director of the Center for Veterinary Medicine with respect to a specific clinical (field) investigation. A petition for such a waiver may be filed by any person who would be adversely affected by application of the criteria to a particular clinical investigation. The petition should show that some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be or have been followed, the results of which will yield or have yielded data that can and should be accepted as substantial evidence of the drug's effectiveness. A petition for a waiver shall set forth clearly and concisely the specific provision or provisions in the criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical (field) investigation, what alternative procedures, if any, are to be or have been employed, what results have been obtained, and the basis on which it can be or has been concluded that the clinical (field) investigation will yield or has yielded substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(b) Standardized test drug: For such an investigation to be considered adequate for consideration for approval of a new animal drug, the test drug must be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(c) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the require-

ment for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

(6) Failure to include an appropriate proposed tolerance for residues in edible products derived from animals or a withdrawal period or other restrictions for use of such drug if any tolerance or withdrawal period or other restrictions for use are required in order to assure that the edible products derived from animals treated with such drug will be safe.

(7) Based on a fair evaluation of all material facts, the labeling is false or misleading in any particular; or

(8) Such drug induces cancer when ingested by man or animal or, after appropriate tests for evaluation of the safety of such drug, induces cancer in man or animal, except that this subparagraph shall not apply with respect to such drug if the Commissioner finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice:

(i) Such drug will not adversely affect the animal for which it is intended; and

(ii) No residue of such drug will be found (by methods of examination prescribed or approved by the Commissioner by regulations) in any edible portion of such animal after slaughter or in any food yielded by, or derived from the living animals.

(9) The applicant fails to submit an adequate environmental assessment under §25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under §25.24 of this chapter.

(10) The drug fails to satisfy the requirements of subpart E of part 500 of this chapter.

(11) Any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter and no

reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(b) The Commissioner shall within 90 days after the filing of the application inform the applicant in writing of his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to an animal feed bearing or containing a new animal drug that:

(1) There is not in effect a regulation established pursuant to section 512(i) of the act (identified in such application) on the basis of which such application may be approved; or

(2) Such animal feed (including the proposed use of any new animal drug therein or thereon) does not conform to an applicable regulation published pursuant to section 512(i) of the act (identified in such application), or that the purposes or conditions or indications of use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable purposes and conditions or indications for use (including warnings) published pursuant to section 512(i) of the act or such labeling omits or fails to conform to other applicable information published pursuant to such section; or

(3) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(4) Based on a fair evaluation of all the material facts, such labeling is false or misleading in any particular.

(c) The Commissioner, as provided in § 514.200 of this chapter, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

[40 FR 13825, Mar. 27, 1975, as amended at 43 FR 22675, May 26, 1978; 44 FR 16007, Mar. 16, 1979; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 49588, Dec. 31, 1987; 54 FR 18280, Apr. 28, 1989]

§ 514.112 Return of applications for animal feeds bearing or containing new animal drugs.

Applications submitted pursuant to § 514.2 will be returned to the applicant if such applications are incomplete or inaccurate or do not contain an identification of the applicable regulation(s). These regulations include those published pursuant to section 512(i) of the act, and are found in part 558 of this chapter. In addition, § 510.515 of this chapter may also provide a basis on which approval of the application relies, as required by § 514.2(b)(10). All reasons for the return of the application will be made known to the applicant.

[51 FR 7392, Mar. 3, 1986]

§ 514.115 Withdrawal of approval of applications.

(a) The Secretary may suspend approval of an application approved pursuant to section 512(c) or (m)(2) of the act and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such new animal drug or animal feed is intended.

(b) The Commissioner shall notify in writing the person holding an application approved pursuant to section 512(c) or (m)(2) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes

and unless there is in effect an approval of the supplemental application, or such changes are those for which written authorization or approval is not required as provided for in § 514.8. The supplemental application shall be treated in the same manner as the original application.

(3) That in the case of an application for use of a new animal drug approved or deemed approved pursuant to section 512(c) of the act:

(i) Experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(ii) New evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that section 512(d)(1)(H) of the act applies to such drug; or

(iii) On the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

(4) That any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(c) The Commissioner may notify in writing the person holding an application approved pursuant to section

512(c) or (m)(2) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(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 section 512(l)(1) or (m)(5)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by section 512(l)(2) or (m)(5)(B) of the act; or

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

(3) That on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug or animal feed, 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 Secretary specifying the matter complained of.

(d) Approval of an application pursuant to section 512(c) or (m)(2) of the act will be withdrawn on the basis of a request for its withdrawal submitted in writing by a person holding an approved new animal drug application on the grounds that the drug subject to such application is no longer being marketed and information is included in support of this finding, provided none of the conditions cited in paragraphs (a), (b), and (c) of this section pertain to the subject drug. A written request for such withdrawal shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Withdrawal of approval of an application under the

provisions of this paragraph shall be without prejudice.

(e) On the basis of the withdrawal of approval of an application for a new animal drug approved pursuant to section 512(c) of the act, the regulation published pursuant to section 512(i) of the act covering the conditions of use of such drug as provided for in the application shall be revoked. An application providing for the manufacture of animal feeds bearing or containing such drug and approved pursuant to section 512(m)(2) of the act shall be deemed as withdrawn upon publication in the FEDERAL REGISTER of the order revoking the corresponding regulation.

[40 FR 13825, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985]

§ 514.116 Notice of withdrawal of approval of application.

When an approval of an application submitted pursuant to section 512 of the act is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

§ 514.120 Revocation of order refusing to approve an application or suspending or withdrawing approval of an application.

The Commissioner, upon his own initiative or upon request of an applicant stating reasonable grounds therefor and if he finds that the facts so require, may issue an order approving an application that previously has had its approval refused, suspended, or withdrawn.

§ 514.121 Service of notices and orders.

All notices and orders under this subchapter E and section 512 of the act pertaining to new animal drug applications shall be served:

(a) In person by any officer or employee of the Department designated by the Commissioner; or

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

Subpart C—Hearing Procedures

§ 514.200 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 to refuse to approve an application or to withdraw the approval of an application will specify the grounds upon which he proposes to issue his order. On request of the applicant, the Commissioner will explain the reasons for his 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 he 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, his failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, he 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 should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he 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 data in the application and from the reasons and a 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 withdrawal of approval of the application (for example, no adequate and well-controlled clinical investigations to support the

claims of effectiveness have been identified), the Commissioner will enter an order on this data, stating his 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 he 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 his appearance.

[40 FR 13825, Mar. 27, 1975, as amended at 43 FR 1941, Jan. 13, 1978]

§ 514.201 Procedure for hearings.

Hearings relating to new animal drugs under section 512 (d), (e), (m)(3), and (m)(4) of the act shall be governed by part 12 of this chapter.

[42 FR 4717, Jan. 25, 1977, as amended at 42 FR 10980, Feb. 25, 1977; 42 FR 15675, Mar. 22, 1977]

Subparts D-E [Reserved]

Subpart F—Judicial Review

§ 514.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 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.

(b) Judicial review of an order withdrawing approval of a new drug appli-

cation, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a United States court of appeals pursuant to section 505(h) of the act.

[42 FR 4717, Jan. 25, 1977]

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 caplets.
 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.
 520.462 Clorsulon drench.
 520.530 Cythioate oral liquid.
 520.531 Cythioate tablets.
 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.
 520.600 Dichlorvos.
 520.608 Dicloxacillin sodium monohydrate capsules.
 520.620 Diethylcarbamazine oral dosage forms.
 520.622 Diethylcarbamazine citrate oral dosage forms.
 520.622a Diethylcarbamazine citrate tablets.
 520.622b Diethylcarbamazine citrate syrup.
 520.622c Diethylcarbamazine citrate chewable tablets.
 520.622d Diethylcarbamazine citrate capsules.
 520.623 Diethylcarbamazine citrate, oxibendazole chewable tablets.
 520.763 Dithiazanine iodide oral dosage forms.
 520.763a Dithiazanine iodide tablets.
 520.763b Dithiazanine iodide powder.
 520.763c Dithiazanine iodide and piperazine citrate suspension.
 520.784 Doxylamine succinate tablets.
 520.804 Enalapril tablets.
 520.812 Enrofloxacin tablets.
 520.813 Enrofloxacin oral solution.
 520.816 Epsiprantel tablets.
 520.823 Erythromycin phosphate.
 520.863 Ethylisobutrazine hydrochloride tablets.
 520.903 Febantel oral dosage forms.
 520.903a Febantel paste.
 520.903b Febantel suspension.
 520.903c [Reserved]
 520.903d Febantel-praziquantel paste.
 520.903e Febantel tablets.
 520.905 Fenbendazole oral dosage forms.
 520.905a Fenbendazole suspension.
 520.905b Fenbendazole granules.
 520.905c Fenbendazole paste.
 520.905d Fenbendazole powder.
 520.905e Fenbendazole blocks.
 520.960 Flumethasone tablets.
 520.970 Flunixin oral dosage forms.
 520.970a Flunixin meglumine granules.
 520.970b Flunixin meglumine paste.
 520.1010 Furosemide oral dosage forms.
 520.1010a Furosemide tablets or boluses.
 520.1010b Furosemide powder.
 520.1010c Furosemide syrup.
 520.1044 Gentamicin sulfate oral dosage forms.
 520.1044a Gentamicin sulfate oral solution.
 520.1044b Gentamicin sulfate pig pump oral solution.
 520.1044c Gentamicin sulfate soluble powder.
 520.1100 Griseofulvin.
 520.1120 Haloxon oral dosage forms.
 520.1120a Haloxon drench.
 520.1120b Haloxon boluses.
 520.1130 Hetacillin oral dosage forms.
 520.1130a Hetacillin potassium capsules.
 520.1130b Hetacillin potassium oral suspension.
 520.1130c Hetacillin potassium tablets.
 520.1157 Iodinated casein tablets.
 520.1158 Iodochlorhydroxyquin boluses.
 520.1182 Iron detran oral suspension.
 520.1192 Ivermectin paste.
 520.1193 Ivermectin tablets and chewables.
 520.1194 Ivermectin drench.
 520.1195 Ivermectin liquid.
 520.1196 Ivermectin and pyrantel pamoate chewable tablet.
 520.1197 Ivermectin sustained-release bolus.
 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgitte suspension.
 520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgitte tablets.
 520.1242 Levamisole hydrochloride oral dosage forms.
 520.1242a Levamisole hydrochloride drench and drinking water.
 520.1242b Levamisole hydrochloride tablet or oblet (bolus).

- 520.1242c Levamisole hydrochloride and piperazine dihydrochloride.
- 520.1242d Levamisole resinate.
- 520.1242e Levamisole hydrochloride effervescent tablets.
- 520.1242f Levamisole hydrochloride gel.
- 520.1242g Levamisole resinate and famphur paste.
- 520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.
- 520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.
- 520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.
- 520.1263c Lincomycin hydrochloride soluble powder.
- 520.1284 Sodium liothyronine tablets.
- 520.1288 Lufenuron tablets.
- 520.1289 Lufenuron suspension.
- 520.1320 Mebendazole oral.
- 520.1326 Mebendazole and trichlorfon oral dosage forms.
- 520.1326a Mebendazole and trichlorfon powder.
- 520.1326b Mebendazole and trichlorfon paste.
- 520.1330 Meclofenamic acid granules.
- 520.1331 Meclofenamic acid tablets.
- 520.1341 Megestrol acetate tablets.
- 520.1380 Methocarbamol tablets.
- 520.1408 Methylprednisolone tablets.
- 520.1409 Methylprednisolone, aspirin tablets.
- 520.1422 Metoserpate hydrochloride.
- 520.1430 Mibolerone.
- 520.1445 Milbemycin oxime tablets.
- 520.1448 Monensin oral dosage forms.
- 520.1448a Monensin blocks.
- 520.1448b Monensin-mineral granules.
- 520.1450 Morantel tartrate oral dosage forms.
- 520.1450a Morantel tartrate bolus.
- 520.1450b Morantel tartrate cartridge.
- 520.1450c Morantel tartrate sustained-release trilaminar cylinder/sheet.
- 520.1468 Naproxen granules.
- 520.1484 Neomycin sulfate soluble powder.
- 520.1485 Neomycin sulfate oral solution.
- 520.1628 Oxfendazole powder and pellets.
- 520.1629 Oxfendazole paste.
- 520.1630 Oxfendazole suspension.
- 520.1631 Oxfendazole and trichlorfon paste.
- 520.1638 Oxibendazole paste.
- 520.1640 Oxibendazole suspension.
- 520.1660 Oxytetracycline.
- 520.1660a Oxytetracycline and carbomycin in combination.
- 520.1660b Oxytetracycline hydrochloride capsules.
- 520.1660c Oxytetracycline hydrochloride tablets.
- 520.1660d Oxytetracycline hydrochloride soluble powder.
- 520.1696 Penicillin oral dosage forms.
- 520.1696a Buffered penicillin powder, penicillin powder with buffered aqueous diluent.
- 520.1696b Penicillin G potassium in drinking water.
- 520.1696c Penicillin V potassium for oral solution.
- 520.1696d Penicillin V potassium tablets.
- 520.1720 Phenylbutazone oral dosage forms.
- 520.1720a Phenylbutazone tablets and boluses.
- 520.1720b Phenylbutazone granules.
- 520.1720c Phenylbutazone paste.
- 520.1720d Phenylbutazone gel.
- 520.1802 Piperazine-carbon disulfide complex oral dosage forms.
- 520.1802a Piperazine-carbon disulfide complex suspension.
- 520.1802b Piperazine-carbon disulfide complex boluses.
- 520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.
- 520.1803 Piperazine citrate capsules.
- 520.1804 Piperazine phosphate capsules.
- 520.1805 Piperazine phosphate with thenium cloylate tablets.
- 520.1806 Piperazine monohydrochloride liquid.
- 520.1840 Poloxalene.
- 520.1846 Polyoxyethylene (23) lauryl ether blocks.
- 520.1870 Praziquantel tablets.
- 520.1871 Praziquantel/pyrantel pamoate tablets.
- 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.
- 520.1880 Prednisolone tablets.
- 520.1900 Primidone tablets.
- 520.1920 Prochlorperazine, isopropamide sustained release capsules.
- 520.1921 Prochlorperazine, isopropamide, with neomycin sustained-release capsules.
- 520.1962 Promazine hydrochloride.
- 520.2002 Propiopromazine hydrochloride.
- 520.2041 Pyrantel pamoate chewable tablets.
- 520.2042 Pyrantel pamoate tablets.
- 520.2043 Pyrantel pamoate suspension.
- 520.2044 Pyrantel pamoate paste.
- 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.
- 520.2087 Roxarsone soluble powder.
- 520.2088 Roxarsone tablets.
- 520.2089 Roxarsone liquid.
- 520.2095 Sarafloxacin soluble powder.
- 520.2100 Selenium, vitamin E capsules.
- 520.2122 Spectinomycin dihydrochloride oral solution.
- 520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.
- 520.2123a Spectinomycin dihydrochloride pentahydrate tablets.
- 520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.
- 520.2150 Stanozolol oral dosage forms.
- 520.2150a Stanozolol tablets.
- 520.2150b Stanozolol chewable tablets.
- 520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.

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- 520.2158a Streptomycin sulfate oral solution.
 - 520.2158b Dihydrostreptomycin tablets.
 - 520.2158c Dihydrostreptomycin oral suspension.
 - 520.2160 Styrylpyridinium, diethylcarbamide oral dosage forms.
 - 520.2170 Sulfabromomethazine sodium boluses.
 - 520.2184 Sodium sulfachloropyrazine monohydrate.
 - 520.2200 Sulfachlorpyridazine oral dosage forms.
 - 520.2200a Sulfachlorpyridazine bolus.
 - 520.2200b Sulfachlorpyridazine medicated milk and drinking water.
 - 520.2200c Sulfachlorpyridazine tablets.
 - 520.2220 Sulfadimethoxine oral dosage forms.
 - 520.2220a Sulfadimethoxine oral solution and soluble powder.
 - 520.2220b Sulfadimethoxine tablets and boluses.
 - 520.2220c Sulfadimethoxine oral suspension.
 - 520.2220d Sulfadimethoxine-ormetoprim tablets.
 - 520.2240 Sulfaethoxypyridazine.
 - 520.2240a Sulfaethoxypyridazine drinking water.
 - 520.2240b Sulfaethoxypyridazine tablets.
 - 520.2260 Sulfamethazine oral dosage forms.
 - 520.2260a Sulfamethazine oblets and boluses.
 - 520.2260b Sulfamethazine sustained-release boluses.
 - 520.2260c Sulfamethazine sustained-release tablets.
 - 520.2261 Sulfamethazine sodium oral dosage forms.
 - 520.2261a Sulfamethazine sodium drinking water solution.
 - 520.2261b Sulfamethazine sodium soluble powder.
 - 520.2280 Sulfamethizole and methenamine mandelate tablets.
 - 520.2320 Sulfantran and aklomide in combination.
 - 520.2325 Sulfaquinoxaline oral dosage forms.
 - 520.2325a Sulfaquinoxaline drinking water.
 - 520.2325b Sulfaquinoxaline drench.
 - 520.2330 Sulfisoxazole tablets.
 - 520.2345 Tetracycline oral dosage forms.
 - 520.2345a Tetracycline hydrochloride capsules.
 - 520.2345b Tetracycline tablets.
 - 520.2345c Tetracycline boluses.
 - 520.2345d Tetracycline hydrochloride soluble powder.
 - 520.2345e Tetracycline oral liquid.
 - 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.
 - 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.
 - 520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.
 - 520.2362 Thienem cloylate tablets.
 - 520.2380 Thiabendazole oral dosage forms.
 - 520.2380a Thiabendazole top dressing and mineral protein feed block.
 - 520.2380b Thiabendazole drench or oral paste.
 - 520.2380c Thiabendazole bolus.
 - 520.2380d Thiabendazole, piperazine citrate suspension.
 - 520.2380e Thiabendazole with trichlorfon.
 - 520.2380f Thiabendazole, piperazine phosphate powder.
 - 520.2455 Tiamulin soluble powder.
 - 520.2456 Tiamulin liquid concentrate.
 - 520.2460 Ticarbodine oral dosage forms.
 - 520.2460a Ticarbodine tablets.
 - 520.2460b Ticarbodine capsules.
 - 520.2473 Tioxidazole oral dosage forms.
 - 520.2473a Tioxidazole granules.
 - 520.2473b Tioxidazole paste.
 - 520.2481 Triamcinolone acetonide tablets.
 - 520.2482 Triamcinolone acetonide oral powder.
 - 520.2520 Trichlorfon oral dosage forms.
 - 520.2520a Trichlorfon oral.
 - 520.2520b Trichlorfon and atropine.
 - 520.2520e Trichlorofon boluses.
 - 520.2520f Trichlorofon granules.
 - 520.2520g Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.
 - 520.2582 Triflupromazine hydrochloride tablets.
 - 520.2604 Trimeprazine tartrate and prednisolone tablets.
 - 520.2605 Trimeprazine tartrate and prednisolone capsules.
 - 520.2610 Trimethoprim and sulfadiazine tablets.
 - 520.2611 Trimethoprim and sulfadiazine oral paste.
 - 520.2612 Trimethoprim and sulfadiazine oral suspension.
 - 520.2613 Trimethoprim and sulfadiazine powder.
 - 520.2640 Tylosin.
- AUTHORITY: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).
- SOURCE: 40 FR 13838, Mar. 27, 1975, unless otherwise noted.

§ 520.23 Acepromazine maleate tablets.

- (a) *Sponsors.* See drug labeler codes in § 510.600(c) of this chapter for identification of sponsors as follows:
 - (1) For No. 000856, use of 5-, 10-, or 25-milligram tablets as in paragraph (b) of this section.
 - (2) For No. 054273, use of 10- or 25-milligram tablets as in paragraph (c) of this section.
- (b) *Conditions of use.* It is used in dogs and cats as follows:
 - (1) *Indications for use.* It is used in dogs and cats as a tranquilizer.
 - (2) *Amount.* Dogs: 0.25 to 1.0 milligram per pound of body weight; Cats:

0.5 to 1.0 milligram per pound of body weight.

(3) *Limitations.* The drug is administered orally. Dosage may be repeated as required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Conditions of use.* It is used in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 1.0 milligram per pound of body weight.

(3) *Limitations.* The drug is administered orally. Dosage may be repeated as required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 44443, Sept. 4, 1981, as amended at 49 FR 49091, Dec. 18, 1984; 52 FR 666, Jan. 8, 1987; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991]

§ 520.44 Acetazolamide sodium soluble powder.

(a) *Specifications.* The drug is in a powder form containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an aid in the treatment of mild congestive heart failure and for rapid reduction of intraocular pressure.¹

(2) It is administered orally at a dosage level of 5 to 15 milligrams per pound of body weight daily.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 520.45 Albendazole oral dosage forms.

§ 520.45a Albendazole suspension.

(a)(1) *Specifications.* The product contains 11.36 percent albendazole.

(2) *Sponsor.* See No. 000069 in § 510.600 of this chapter.

(3) *Related tolerances.* See § 556.34 of this chapter.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(4)(i) *Conditions of use in cattle—(I) Amount.* 4.54 milligrams per pound of body weight (10 milligrams per kilogram).

(ii) *Indications for use.* For removal and control of the following internal parasites of cattle: Adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus*, *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) [Reserved]

(b)(1) *Specifications.* The product contains 4.55 percent albendazole.

(2) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in sheep—(i) Amount.* 7.5 milligrams per kilogram of body weight (3.4 milligrams per pound).

(ii) *Indications for use.* For removal and control of the following internal parasites of sheep: Adult liver flukes (*Fasciola hepatica*, *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcincta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach

worm (*Trichostrongylus axei*); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 25115, June 13, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 65711, Dec. 21, 1994; 60 FR 55658, Nov. 2, 1995; 61 FR 4875, Feb. 9, 1996]

§ 520.45b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle—(1) Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*)); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations.* Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995]

§ 520.48 Altrenogest solution.

(a) *Specifications.* Each milliliter of altrenogest solution contains 2.2 milligrams of altrenogest.

(b) *Sponsor.* See No. 012579 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer orally at the rate of 1 milliliter per 110 pounds body weight (0.044 milligram per kilogram body weight). Give one dose daily for 15 consecutive days.

(2) *Indications for use.* For suppression of estrus in mares.

(3) *Limitations.* For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food. The drug is contraindicated for use in mares having a previous or current history of uterine inflammation (i.e., acute, subacute, or chronic endometritis). Natural or synthetic gestagen therapy may exacerbate existing low-grade or smoldering uterine inflammation into a fulminating uterine infection in some instances. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 40887, Sept. 12, 1983, as amended at 55 FR 26431, June 28, 1990]

§ 520.62 Aminopentamide hydrogen sulphate tablets.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* Each tablet contains 0.2 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral

spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by oral tablet every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 520.82 Aminopropazine fumarate oral dosage forms.

§ 520.82a Aminopropazine fumarate tablets.

(a) *Specifications.* The drug is in tablet form. Each tablet contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.¹

(2) It is administered at a dosage level of 1 to 2 milligrams per pound of body weight. The dosage can be repeated every 12 hours, as indicated.¹

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996]

§ 520.82b Aminopropazine fumarate, neomycin sulfate tablets.

(a) *Specifications.* The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base

and neomycin sulfate equivalent to 50 milligrams of neomycin base.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.¹

(2) It is administered at a dosage level of one to two tablets per 10 pounds of body weight twice daily for 3 days.¹

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996]

§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams of amoxicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* 5 milligrams per pound of body weight, twice a day.

(ii) *Indications for use.* Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

(iii) *Limitations.* Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Cats*—(i) *Amount*. 50 milligrams (5 to 10 milligrams per pound of body weight) once a day.

(ii) *Indications for use*. Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to *S. aureus*, *Streptococcus* spp., and *E. coli*; genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract due to *E. coli*; and skin and soft tissue (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(1) *Conditions of use*—(i) *Dogs*—(A) *Amount*. 5 milligrams per pound of body weight twice daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Cats*—(A) *Amount*. 50 milligrams (5 to 10 milligrams per pound) once daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal tract due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(c) *Sponsor*. See Nos. 000031 and 000093 in § 510.600(c) of this chapter.

(1) *Conditions of use*. *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis* and *Staphylococcus* spp.

(iii) *Limitations*. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997]

§ 520.88c Amoxicillin trihydrate oral suspension.

(a) *Specifications*. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use. Swine*—(1) *Amount.* 40 milligrams orally, twice a day using a dosing pump.

(2) *Indications for use.* Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) *Limitations.* Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days. Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88d Amoxicillin trihydrate soluble powder.

(a) *Specifications.* Each gram contains amoxicillin trihydrate equivalent to 115.4 milligrams of amoxicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use. Preruminating calves including veal calves*—(1) *Amount.* 400 milligrams per 100 pounds of body weight twice daily.

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* Administer by drench or by mixing in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. For use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993; as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 5525, Feb. 6, 1997]

§ 520.88e Amoxicillin trihydrate boluses.

(a) *Specifications.* Each bolus contains the equivalent of 400 milligrams of amoxicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use. Preruminating calves including veal calves*—(1) *Amount.* 400 milligrams per 100 pounds of body weight twice daily.

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* For oral use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 62 FR 5526, Feb. 6, 1997]

§ 520.88f Amoxicillin trihydrate tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 200, or 400 milligrams of amoxicillin.

(b) *Sponsor.* See Nos. 000031 or 000093 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 milligrams per pound of body weight twice a day.

(ii) *Indications for use.* Treatment of bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *Escherichia coli*; and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *Proteus mirabilis*, and *Staphylococcus* spp.

(iii) *Limitations.* Use for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37320, Aug. 18, 1992, as amended at 62 FR 13302, Mar. 20, 1997]

§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate and clavulanate potassium, equivalent to either 50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid, or 100 milligrams of amoxicillin and 25 milligrams clavulanic acid, or 200 milligrams amoxicillin and 50 milligrams clavulanic acid or 300 milligrams amoxicillin and 75 milligrams clavulanic acid.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) *Staphylococcus aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*.

(iii) *Limitations.* Wounds, abscesses, cellulitis, and superficial/juvenile pyoderma: Treat for 5 to 7 days or for 48 hours after all signs have subsided. If no improvement is seen after 5 days of treatment, discontinue therapy and reevaluate diagnosis. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount.* 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, nonbeta-lactamase producing *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Also, treatment of urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

(iii) *Limitations.* Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and diagnosis reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus*, nonbeta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*.

(iii) *Limitations.* Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount.* 62.5 milligrams (1 milliliter) (50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use.* Treatment of feline skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida*, and *Pasteurella* spp.

(iii) *Limitations.* Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and re-evaluate diagnosis. Maximum duration of treatment should not exceed 30 days. Not for use in cats maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 520.90 Ampicillin oral dosage forms.

§ 520.90a Ampicillin capsules.

(a) *Specifications.* Each capsule contains 125 milligrams or 250 milligrams of ampicillin.

(b) *Sponsor.* See No. 000008 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* 5 to 10 milligrams per pound of body weight, e.g., one 125 mg capsule per 14 to 25 pounds, given 2 to 4 times daily; for animals weighing 6 to 14 pounds, one capsule twice daily.

(ii) *Indications for use.* Treatment of urinary tract infections (cystitis) due to *Proteus* spp., hemolytic and non-hemolytic streptococci, beta hemolytic streptococci, and *Escherichia coli*. In upper respiratory tract infections tracheobronchitis (kennel cough), tonsillitis due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. Not for

use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount.* 125 milligrams twice daily; in more acute conditions three times daily.

(ii) *Indications for use.* Treatment of respiratory tract infections (bacterial pneumonia) due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992]

§ 520.90b Ampicillin trihydrate tablets.

(a) *Specifications.* Each tablet contains ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Amount.* 5 milligrams per pound of body weight, at 8-hour intervals, 1 to 2 hours prior to feeding, to be continued 36 to 48 hours after all symptoms have subsided. If no improvement is seen within 5 days, stop treatment, reevaluate diagnosis, and change therapy.

(2) *Indications for use.* Oral treatment of infections caused by susceptible organisms as follows: Upper respiratory infections, tonsillitis, and bronchitis due to *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and *Pasteurella* spp., urinary tract infections (cystitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli*, *P. mirabilis*, and *Enterococcus* spp.; gastrointestinal infections due to *Staphylococcus* spp., *Streptococcus* spp.,

Enterococcus spp., and *E. coli*.; infections associated with abscesses, lacerations, and wounds caused by *Staphylococcus* spp., and *Streptococcus* spp.

(3) *Limitations*. Not for use in animals which have shown hypersensitivity to penicillin or for infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 520.90c Ampicillin trihydrate capsules.

(a) *Specifications*. Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 milligrams per pound of body weight two or three times daily. In severe or acute conditions, 10 milligrams per pound of body weight, three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (tracheobronchitis and tonsillitis); urinary tract infections (cystitis); bacterial gastroenteritis; generalized infections (septicemia) associated with abscesses, lacerations, and wounds; and bacterial dermatitis.

(iii) *Limitations*. The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 10 to 30 milligrams per pound of body weight or three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (bacterial pneumonia); urinary tract infections (cystitis); and generalized infections (septicemia) associated with abscesses, lacerations, and wounds.

(iii) *Limitations*. The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90d Ampicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted as directed, each milliliter contains ampicillin trihydrate equivalent to 25 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding. In severe or acute conditions, 10 milligrams per pound of body weight 3 times daily.

(ii) *Indications for use*. Treatment of respiratory tract infections (tracheobronchitis and tonsillitis) due to *Escherichia coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., and *Proteus* spp.; bacterial gastroenteritis due to *E. coli*; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus* spp. and *Streptococcus* spp.; bacterial dermatitis due to *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Pseudomonas* spp.

(iii) *Limitations*. Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal

and all other signs of infection have subsided. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 10 to 30 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment of respiratory tract infections (bacterial pneumonia) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Proteus* spp.; urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Corynebacterium* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus* spp., *Streptococcus* spp., *Bacillus* spp., and *Pasteurella* spp.

(iii) *Limitations*. Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90e Ampicillin trihydrate soluble powder.

(a) *Specifications*. Each gram contains ampicillin trihydrate equivalent to 88.2 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*. *Swine*—(1) *Amount*. 5 milligrams of ampicillin per pound of body weight twice daily, orally by gavage or in drinking water for up to 5 days.

(2) *Indications for use*. Oral treatment of porcine colibacillosis (*Escherichia*

coli) and salmonellosis (*Salmonella* spp.) infections in swine up to 75 pounds of body weight, and bacterial pneumonia caused by *Pasteurella multocida*, *Staphylococcus* spp., *Streptococcus* spp., and *Salmonella* spp.

(3) *Limitations*. For use in swine only. Not for use in other animals which are raised for food production. Treated swine must not be slaughtered for food during treatment and for 24 hours following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90f Ampicillin trihydrate boluses.

(a) *Specifications*. Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter for use as in paragraph (d)(1), 000069 for use as in paragraph (d)(2).

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*. *Nonruminating calves*—(1) *Amount*. 5 milligrams per pound of body weight twice daily for up to 5 days.

(i) *Indications for use*. Oral treatment of colibacillosis caused by *Escherichia coli*, bacterial enteritis caused by *Salmonella* spp., and bacterial pneumonia caused by *Pasteurella* spp.

(ii) *Limitations*. Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Amount*. 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(i) *Indications for use*. Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli*.

(ii) *Limitations*. Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995]

§ 520.100 Amprolium oral dosage forms.

§ 520.100a Amprolium drinking water.

(a) *Chemical name.* 1-(4-Amino-2-*n*-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 000006 in § 510.600 (c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens and turkeys—(i) Amount.* 20 percent soluble powder.

(ii) *Indications for use.* Treatment of coccidiosis.

(iii) *Limitations.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) *Calves—(i) Amount.* 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Add 16 fluid ounces of the 9.6 percent solution to each 100 gallons of drinking water; or 4 ounces of the soluble powder to each 50 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each

100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

§ 520.100b Amprolium drench.

(a) *Chemical name.* 1-(4-Amino-2-*n*-propyl - 5 - pyrimidinylmethyl) - 2 - picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is used for calves as follows:

(1) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Add 1½ fluid ounces of the 9.6 percent solution to 1 pint of water or 1½ ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 21

days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

§ 520.100c Amprolium crumbles.

(a) *Specifications.* Amprolium crumbles contain 1.25 percent amprolium.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is top-dressed on or thoroughly mixed in the daily feed ration of calves as follows:

(1) *Amount.* 1.6 ounces of crumbles per 250 pounds of body weight per day (5 milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Administer for 21 consecutive days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

(2) *Amount.* 3.2 ounces of crumbles per 250 pounds of body weight per day (10 milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Administer for 5 consecutive days. For satisfactory diagnosis, a microscopic fecal examination should be done by a veterinarian or diagnostic laboratory before treatment. When treating outbreaks, the drug should be administered promptly after diagnosis is determined. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

[42 FR 41855, Aug. 19, 1977]

§ 520.110 Apramycin sulfate soluble powder.

(a) *Specifications.* A water soluble powder used to make a medicated drinking water containing apramycin sulfate equivalent to 0.375 gram of apramycin activity per gallon of drinking water.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use.* (1) In swine for control of porcine colibacillosis (weanling pig scours) caused by strains of *E. coli* sensitive to apramycin.

(2) It is administered for 7 days in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day. Swine will normally consume 1 gallon per day of medicated water containing 375 milligrams of apramycin for each 66 pounds of body weight. Water consumption should be monitored to determine that the required amount of apramycin is being consumed. The drug concentration should be adjusted according to water consumption which varies depending on ambient temperature, humidity, and other factors.

(3) Prepare fresh medicated water daily.

(4) Do not slaughter treated swine for 28 days following treatment

[47 FR 15771, Apr. 13, 1982, as amended at 49 FR 19642, May 9, 1984; 53 FR 37753, Sept. 28, 1988]

§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Soluble bacitracin methylene disalicylate.

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d)(3) of this section.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use—(1) Growing turkeys—(i) Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare a fresh solution daily.

(2) *Broiler chickens—(i) Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations*. Prepare a fresh solution daily.

(ii) *Amount*. 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use*. Aid in the control of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations*. Prepare a fresh solution daily.

(3) *Swine*—(i) *Amount*. 1 gram per gallon in drinking water.

(ii) *Indications for use*. Treatment of swine dysentery associated with *Treponema hyodysenteriae*. Administer continuously for 7 days or until signs of dysentery disappear.

(iii) *Limitations*. Prepare a fresh solution daily. Treatment not to exceed 14 days. If symptoms persist after 4 to 5 days consult a veterinarian. Not to be given to swine that weigh more than 250 pounds.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.

(a) *Specifications*. Each gram contains 200 units of soluble bacitracin methylene disalicylate, streptomycin sulfate equivalent to 20 milligrams of streptomycin, and 850 milligrams of carob flour.

(b) *Sponsor*. See No. 062925 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use*. Treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., and for the symptomatic treatment of associated diarrhea.

(3) *Limitations*. If no improvement is noted in 2 to 3 days, diagnosis should be reevaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 61 FR 66581, Dec. 18, 1996]

§ 520.154c Bacitracin zinc soluble powder.

(a) *Specifications*. Each pound contains the equivalent of not less than 5 grams of bacitracin.

(b) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.70 of this chapter.

(d) *Conditions of use*. (1) *Broiler chickens*—(i) *Amount*. 100 milligrams per gallon in drinking water.

(A) *Indications for use*. Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations*. Prepare a fresh solution daily.

(ii) *Amount*. 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use*. Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations*. Prepare a fresh solution daily.

(2) *Growing quail*—(i) *Amount*. 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) *Indications for use*. Control of ulcerative enteritis caused by *Clostridium* spp. susceptible to bacitracin zinc.

(iii) *Limitations*. Prepare a fresh solution daily.

[57 FR 37322, Aug. 18, 1992]

§ 520.182 Bicyclohexylammonium fumagillin.

(a) *Specifications*. The drug is a soluble powder containing bicyclohexylammonium fumagillin and appropriate phosphate buffers.

(b) *Sponsor*. See No. 059620 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used for the prevention of nosema in honey bees.¹

(2) It is administered usually in a 2:1 sugar sirup containing a concentration of from 75 to 100 milligrams of

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.