

temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[42 FR 52821, Sept. 30, 1977, as amended at 46 FR 8460, Jan. 27, 1981; 59 FR 14365, Mar. 28, 1994; 68 FR 24879, May 9, 2003; 88 FR 45066, July 14, 2023]

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PART 510—NEW ANIMAL DRUGS

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AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

SOURCE: 40 FR 13807, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 510.3 Definitions and interpretations.

As used in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 321-392).

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Commissioner* means the Commissioner of Food and Drugs.

(e) *Person* means individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(h) The term *animal feed* means an article which is intended for use for food for animals other than man and which is intended for use as a substantial

source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) *Animals used only for laboratory research* and *laboratory research animals* mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) *Sponsor* means the person requesting designation for a minor-use or minor-species drug as defined in part 516 of this chapter, who must be the real party in interest of the development and the intended or actual production and sales of such drug (in this

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context, the sponsor may be an individual, partnership, organization, or association). Sponsor also means the person responsible for an investigation of a new animal drug. In this context, the sponsor may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs. Sponsor also means the person submitting or receiving approval for a new animal drug application (in this context, the sponsor may be an individual, partnership, organization, or association). In all contexts, the sponsor is responsible for compliance with applicable provisions of the act and regulations.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989; 64 FR 69190, Dec. 10, 1999; 72 FR 41017, July 26, 2007]

§ 510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Holds a license issued under § 515.20 of this chapter; or

(2) Will, if the consignee is not the user of the drug, ship such drug only to a holder of an approved application under § 515.10 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

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(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in part 558 of this chapter.

[40 FR 13807, Mar. 27, 1975, as amended at 64 FR 63203, Nov. 19, 1999]

§ 510.95 [Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 526 of this chapter provides for new animal drugs intended for intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(c)(ii) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the following statement: “Warning: Milk that has been taken from animals during treatment and for __ hours after the latest treatment must not be used for food”, the blank being filled in with the figure that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry violative residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

[40 FR 13807, Mar. 27, 1975, as amended at 63 FR 32980, June 17, 1998; 64 FR 51241, Sept. 22, 1999]

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement "Warning: Not for use in animals producing milk, since this use will result in contamination of the milk" or the statement "Warning: Milk that has been taken from animals during treatment and for _ hours after the latest treatment must not be used for food", the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no violative residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, the Commissioner may exempt the drug from bearing either of the above warning statements.

[63 FR 32980, June 17, 1998]

§ 510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act

with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, § 510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to establish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the date of publication of § 510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to transfer this resistance, and the development of sensitivity to antibiotics in humans, unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.

(d) Based on evaluation of information available, including the conclusions of the aforementioned ad hoc Committee, the Commissioner concludes that antibiotic preparations intended for use in food-producing animals, other than topical and ophthalmic preparations, are not generally recognized among qualified experts as having been shown to be safe for their intended use(s) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

(e) Therefore, all exemptions from the provisions of section 409 of the act for use of antibiotics in food-producing animals based on sanctions or approvals granted prior to enactment of the Food Additives Amendment of 1958 (Pub. L. 85-929; 72 Stat. 1784) will be revoked and the uses which are concluded to be safe will be covered by food additive regulations. On those

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products for which there are inadequate residue data, actions will be initiated to withdraw approval of new-drug applications under the provisions of section 505 of the act. Antibiotic preparations, other than those for topical and ophthalmic application in food-producing animals, which are not covered by food additive regulations will be subject to regulatory action within 180 days after publication of the forthcoming revocation order.

(f) Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations, including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 64 FR 403, Jan. 5, 1999]

§ 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Non-medical Uses of Antibiotics, was formed by the Food and Drug Administration to study, and advise the Commissioner on, the use of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of Public Affairs, Room 15–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(b) On the basis of the report of the Committee and other information, sponsors of drugs containing any antibiotic intended for use in food-producing animals shall submit data for determining whether or not such antibiotics and their metabolites are present as residues in edible tissues, milk, and eggs from treated animals; however, in the case of a drug for which such data have already been submitted and for which a regulation has been promulgated under section 409 of the act, only such data as has been ac-

cumulated since the issuance of the regulation need be submitted.

(c) The required data shall be submitted within 180 days of the date of publication of this section in the FEDERAL REGISTER; except that in the case of data on intramammary infusion preparations the data shall be submitted within 60 days of such publication. Data demonstrating the absence in milk of residues of intramammary infusion preparations when used as directed in their labeling are needed within the 60-day period because of the importance of milk in the human diet.

(d) Regulatory proceedings including revocation of prior sanctions, or actions to suspend or amend new drug or antibiotic approvals granted prior to passage of the Food Additives Amendment of 1958 (72 Stat. 1784), may be initiated with regard to the continued marketing of any antibiotic preparation on which the required information is not submitted within the period of time prescribed by paragraph (c) of this section.

(e) Questions relating to the acceptability of proposed research protocols and assay methods for determining the amount of antibiotic residues in food should be directed to the Director, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 46 FR 8460, Jan. 27, 1981; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

Subpart C—Import Tolerances for Residues of Unapproved New Animal Drugs in Food

SOURCE: 86 FR 52410, Sept. 21, 2021, unless otherwise noted.

§ 510.201 Scope.

This subpart applies to tolerances for residues of new animal drugs not approved or conditionally approved for use in the United States, but lawfully used in another country and present in imported, animal-derived food and food products.

§ 510.202 Definitions.

The following definitions of terms apply when used in this subpart:

CNADA means an application for conditional approval of a new animal drug submitted under section 571 of the Federal Food, Drug, and Cosmetic Act, and includes all amendments and permissible supplements.

Import tolerance means a tolerance for a residue of a new animal drug not approved or conditionally approved for use in the United States, but present in any imported edible portion of any animal.

NADA means a new animal drug application submitted under section 512 of the Federal Food, Drug, and Cosmetic Act, including all amendments and permissible supplements, for approval of a new animal drug.

Request means a request to establish or amend an import tolerance.

§ 510.203 Initiation of a proceeding to establish or amend an import tolerance.

(a) Any interested person may request that the Commissioner establish or amend an import tolerance. Such a request must be in the form specified in § 510.205 of this chapter.

(b) The Commissioner may initiate a proceeding to establish or amend an import tolerance on his or her own initiative pursuant to § 10.25(b) of this chapter.

§ 510.205 Content and administration of a request.

(a) Pertinent information previously submitted to and currently retained in the files of the Food and Drug Administration (FDA) may be incorporated in, and will be considered as part of, a request on the basis of specific reference to such information. If the requester refers to any nonpublic information other than its own, the requester shall obtain a written right of reference to that nonpublic information and submit the right of reference with the request. Any reference to published information offered in support of a request should be accompanied by reprints or copies of such references.

(b) Requests shall be submitted and addressed to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Requests may be submitted in an

electronic format as authorized by FDA. See FDA's Electronic Submissions Gateway website: <https://www.fda.gov/industry/electronic-submissions-gateway>.

(c) Any material submitted in a foreign language shall be accompanied by a complete and accurate English translation. Translations of literature printed in a language other than English shall be accompanied by copies of the original publication.

(d) The request must be dated and must be signed by the requester or by his or her authorized attorney, agent, or official and shall state the requester's correspondence address. If the requester or such authorized representative does not reside or have a place of business within the United States, the requester must also furnish the name and post office address of, and the request must be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States.

(e) The request must include the following information:

(1) The established name and all pertinent information concerning the new animal drug, including chemical identity and composition of the new animal drug, and its physical, chemical, and biological properties;

(2) The conditions of use for the new animal drug, including the route of administration and dosage, together with all labeling, directions, and recommendations regarding the use in countries in which the new animal drug is lawfully used;

(3) The proposed import tolerance(s) for residues of the new animal drug;

(4) Human food safety information to support the proposed import tolerance(s) in either of the following forms:

(i) If a permanent maximum residue limit (MRL) has been established by the Codex Alimentarius Committee (Codex MRL), the requester shall provide the permanent Codex MRL and monographs and reports from the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations and/or monographs and reports from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) that

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support the development of the permanent Codex MRL. FDA may request additional information as needed.

(ii) If no permanent Codex MRL has been established, or upon notification by FDA, the requester must provide full reports of investigations made with respect to the human food safety of the new animal drug. A request may be regarded as incomplete unless it includes full reports of adequate tests by all methods reasonably applicable to show whether or not any imported edible portion of any animal receiving the new animal drug will be safe for human consumption. The reports must include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth, including data submitted to the appropriate regulatory authority in any country where the new animal drug is lawfully used. The request must also include a statement that all such reports have been submitted or contain an explanation of why such reports were not submitted. With respect to each nonclinical laboratory study contained in the request, the requestor must submit 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 reason for the noncompliance, and how this may have impacted the study;

(5) Other human food safety information as deemed necessary by the Commissioner;

(6) A description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use;

(7) An environmental assessment under § 25.40 of this chapter; and

(8) Any information required under §§ 500.80 through 500.92 of this chapter (Subpart E, Regulation of Carcinogenic Compounds Used in Food-Producing Animals), where applicable.

(f) A request to amend an established import tolerance must contain information to support each proposed change. The request may omit state-

ments made in the original request for which no change is proposed.

(g) The requester may withdraw the request at any time before the notification provided for in § 510.207(a) of this chapter has been made publicly available.

§ 510.206 Review of information supporting actions to establish or amend an import tolerance.

In establishing or amending an import tolerance, the Commissioner shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Commissioner to establish tolerances for applications for new animal drugs filed under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act. In establishing or amending an import tolerance, the Commissioner will give appropriate consideration to the anticipated residue concentrations and conditions of use of the new animal drug specified.

§ 510.207 Disclosure of information submitted in a request.

(a) When a request is determined to be complete for FDA's consideration, the Commissioner will provide public notification of the request containing the name of the requester and a brief description of the request in general terms. A copy of the notification will be sent to the requester at the time the information is made available to the public.

(b) Any notification establishing, amending, or revoking an import tolerance will be made publicly available. A summary of the basis for the decision will be publicly released in accordance with the provisions of part 20 of this chapter. If FDA determines that the new animal drug referred to in the request is a new animal drug that induces cancer when ingested by people or animals, and the requester complies with the requirements of §§ 500.80 through 500.92 of this chapter (Subpart E, Regulation of Carcinogenic Compounds Used in Food-Producing Animals), the regulatory method for ascertaining the marker residue in the target tissue will be made publicly available. All information and safety data submitted with the request, or

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previously submitted information incorporated in, and considered as part of, a request on the basis of specific reference to such information, shall be available for public disclosure, also in accordance with the provisions of part 20 of this chapter. Trade secrets and confidential commercial or financial information are exempted from release under § 20.61 of this chapter.

§ 510.209 Establishment, denial, or amendment of an import tolerance.

(a) If an import tolerance is established or amended, the Commissioner will provide public notification of the action, which will be effective from the date of public notification. A copy of the notification will be sent to any requestor at the time the information is made available to the public.

(b) If a request to establish or amend an import tolerance is denied, a notification of the denial will be made publicly available, and a copy of the denial letter, including the reasons for such action, will be sent to the requester.

(c) A tolerance established in an approved NADA or conditionally approved CNADA will supersede an existing import tolerance. In the event the conditionally approved CNADA is not renewed or is withdrawn, or such drug does not achieve approval under section 512 of the Federal Food, Drug, and Cosmetic Act within 5 years following the date of the conditional approval, the Agency will reinstate the import tolerance unless § 510.210(a)(1) or (a)(2) is applicable at that time.

§ 510.210 Revocation of an import tolerance.

(a) The Commissioner, on his or her own initiative or on the petition of an interested person, under § 10.25 of this chapter, may revoke an import tolerance if:

(1) Scientific evidence shows an import tolerance to be unsafe; or

(2) Information demonstrates that the use of a new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the import tolerance.

(b) The Commissioner will provide public notification under § 510.207(b) that will specify the basis for the deci-

sion and will be effective at the time the information is made available to the public.

(c) A petition for revocation must be submitted in the form specified in § 10.30 of this chapter.

§ 510.212 Administrative reconsideration of action.

(a) The Commissioner may at any time, on his or her own initiative or on the petition of an interested person under part 10 of this chapter, reconsider part or all of a decision to establish, not establish, amend, or revoke an import tolerance.

(b) A petition for reconsideration must be submitted in accordance with § 10.20 of this chapter and in the form specified in § 10.33 of this chapter no later than 30 days after the date of public notification of the decision involved. The Commissioner may, for good cause, permit a petition to be filed more than 30 days after public notification of the decision. The petition for reconsideration must demonstrate that relevant information contained in the administrative record was not previously or not adequately considered by the Commissioner. No new information may be included in a petition for reconsideration.

(c) An interested person who wishes to rely on information not included in the administrative record shall submit either a petition to amend an import tolerance under § 510.205 or to revoke an import tolerance under § 510.210 and § 10.25 of this chapter.

§ 510.213 Administrative stay of action.

(a) The Commissioner may at any time, on his or her own initiative or on the request of an interested person under part 10 of this chapter, stay or extend the effective date of a decision to establish, not establish, amend, or revoke an import tolerance.

(b) A request for stay must be submitted in accordance with § 10.20 of this chapter and in the form specified in § 10.35 of this chapter no later than 30 days after public notification of the decision involved. The Commissioner may, for good cause, permit a petition to be filed more than 30 days after public notification of the decision.

Subpart D—Records and Reports**§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.**

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) or index listing(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application or request for determination of eligibility for indexing.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the new animal drug application or in support of the index listing or not encountered during clinical trials of the drug, or conditions or developments occur-

ring at a rate higher than shown by information previously submitted as part of the new animal drug application or in support of the index listing or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 72 FR 69121, Dec. 6, 2007]

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location:

(a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and

(b) Approved or index listed labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

[64 FR 63203, Nov. 19, 1999, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart E—Requirements for Specific New Animal Drugs**§ 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.**

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary

prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]

§ 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

§ 510.455 Requirements for free-choice medicated feeds.

(a) *What is free-choice medicated feed?* For the purpose of this part, free-choice medicated feed is medicated feed that is placed in feeding or grazing areas and is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Free-choice feeds include, but are

not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements ("lick tank" supplements) containing one or more new animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations in part 225 of this chapter for medicated feeds.

(b) *What is required for new animal drugs intended for use in free-choice feed?* Any new animal drug intended for use in free-choice feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)) or listed in the index under section 572 of the act (21 U.S.C. 360ccc-1). Such approvals under section 512 of the act must be:

- (1) An original new animal drug application (NADA),
- (2) A supplemental NADA, or
- (3) An abbreviated NADA.

(c) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in free-choice feed?* An approval under section 512 of the act for a Type A medicated article intended for use in free-choice feed must contain the following information:

(1) Data, or reference to data in a master file (MF), showing that the target animal consumes the new animal drug in the Type C free-choice feed in an amount that is safe and effective (consumption/effectiveness data); and

(2) Data, or reference to data in an MF, showing the relevant ranges of conditions under which the drug will be chemically and physically stable in the Type C free-choice feed under field conditions.

(d) *How are consumption/effectiveness and/or stability data to be submitted?* The data must be submitted as follows:

- (1) Directly in the NADA, by a sponsor; and/or
- (2) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(e) *What will be stated in the published approval for a new animal drug intended for use in free-choice feed?* The approval of a new animal drug intended for use

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in free-choice feed, as published in this subchapter, will include:

(1) The formula and/or specifications of the free-choice medicated feed, where the owner of this information requests such publication, or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-choice medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All free-choice medicated feeds that contain a Category II drug, and

(2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

[69 FR 30197, May 27, 2004, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart G—Sponsors of Approved Applications

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

Subpart F [Reserved]

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527	057699
Accord Healthcare, Inc., 126 E Lincoln Ave., Rahway, NJ 07065	016729
ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305–3115	012286
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788	011788
Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031	059399
Alexion Pharmaceuticals, Inc., 121 Seaport Blvd., Boston, MA 02210	069334
American Regent, Inc., Animal Health Division, Shirley, NY 11967	010797
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
Anivive Lifesciences, Inc., 3777 Worsham Ave., Long Beach, CA 90808	086121
Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043	086073
AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754	086053
Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009	051072
Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France	086009
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756	067188
Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807	099207
Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777	062250
Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland	061133
Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096	000010
Ceva Sante Animale, 10 Avenue de la Ballastiere, 33500 Libourne, France	013744
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
Cronus Pharma Specialities India Private Ltd., Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India	069043
Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	043264
Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211	017033
Diamond Animal Health, Inc., 2538 SE 43rd St., Des Moines, IA 50327	053701
Domes Pharma S.A., ZAC de Champ Lamet, 3 rue Andre Citroen, Pont-du-Chateau, Auvergne-Rhône-Alpes, 63430, FRANCE	086189
ECO LLC, 11224 Aurora Ave., Urbandale, IA 50322	066916
Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	058198
Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928	017135
Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland	086101
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	058829
Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747	025463
Genus Lifesciences Inc., 700 N Fenwick St., Allentown, PA 18109	064950
GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702	042976

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(1) ALPHABETICAL LISTING OF SPONSORS—Continued

Firm name and address	Drug labeler code
Happy Jack, Inc., Snow Hill, NC 28580	023851
Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964	063075
HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652	042791
Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	016592
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	000115
Intervet, Inc., 126 E Lincoln Ave., Rahway, NJ 07065	000061
Ishihara Sangyo Kaisha, Ltd., 3-15, Edobori 1-chome, Nishi-ku, Osaka 550-0002, Japan	064642
Ivaos Animal Health, 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069	086064
Jaguar Animal Health, 200 Pine St., Suite 600, San Francisco, CA 94104	086149
Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509	051031
Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601	061690
Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861	054925
Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432	086039
Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186	015914
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	051079
Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505	063286
Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120	049968
Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511	059051
Noble Pharma, LLC, 4602 Domain Dr., Menomonie, WI 54751	086119
Norbrook Laboratories Ltd., Cambane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom	055529
Orion Corp., Orionintie 1, 02200 Espoo, Finland	052483
Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia	068504
Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	055246
Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970	050057
Pharmacosmos, Inc., 120 Headquarters Plz., Morristown, NJ 07960	042552
Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway	015331
Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	069254
Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	066104
Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India	065085
Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053-120, Campinas, Sao Paulo, Brazil	060728
Purina Animal Nutrition LLC, 4001 Lexington Ave., North Arden Hills, MN 55126-2910	017800
QBiotics Group Ltd., Suite 3A, Level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia	086132
Quo Vadamus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349	076475
Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., Suite 2400, Blacksburg, VA 24060	086134
Ridley USA, Inc., 111 W Cherry St., Suite 500, Mankato, MN 56001	067949
Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138	021091
Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215	058005
Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151	017153
Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752	037990
Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248	050378
Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532	051672
Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503	052923
Union Agener, Inc., 1788 Lovers Ln., Augusta, GA 30901	086106
VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524	086072
Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5	059320
Vetoquinol USA, Inc., 4250 N Sylvania Ave., Fort Worth, TX 76137	017030
Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161	051311
Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin 2, Dublin, D02HX82, Ireland	066679
Wildcat Feeds, 215 NE Strait Ave., Topeka, KS 66616	086113
Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550	053923
Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	054771
ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534	086117

(2) NUMERICAL LISTING OF SPONSORS

Drug labeler code	Firm name and address
000010	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.
000061	Intervet, Inc., 126 E Lincoln Ave., Rahway, NJ 07065
000115	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
010797	American Regent, Inc., Animal Health Division, Shirley, NY 11967.
011788	Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788.
012286	ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
012578	Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.
013744	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.
015331	Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway.

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
015914	Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186.
016592	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.
016729	Accord Healthcare, Inc., 126 E Lincoln Ave., Rahway, NJ 07065.
017030	Vetoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137.
017033	Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211.
017135	Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928.
017153	Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151.
017762	Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112.
017800	Purina Animal Nutrition LLC, 4001 Lexington Ave., North Arden Hills, MN 55126–2910.
021091	Sergeant’s Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138.
023851	Happy Jack, Inc., Snow Hill, NC 28580.
025463	Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747.
037990	Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752.
042552	Pharmacosmos, Inc., 120 Headquarters Plz., Morristown, NJ 07960.
042791	HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652.
042976	GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702.
043264	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.
049968	Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120.
050057	Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970.
050378	Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248.
051031	Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509.
051072	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478.
051311	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161.
051672	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
052483	Orion Corp., Orionintie 1, 02200 Espoo, Finland.
052923	Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503.
053701	Diamond Animal Health, Inc., 2538 SE 43rd St., Des Moines, IA 50327.
053923	Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550.
054771	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.
054925	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861.
055246	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.
055529	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.
057561	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503.
057699	A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527.
058005	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.
058198	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.
058829	First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123.
059051	Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511.
059320	Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5.
059399	Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031.
060728	Planalquímica Industrial Ltda., Rua das Magnolias nr. Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Alto, Brazil.
060865	Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801.
061133	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.
061651	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.
061690	Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601.
062250	Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777.
062794	Mylan Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478.
063075	Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964.
063286	Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505.
064642	Ishihara Sangyo Kaisha, Ltd., 3–15, Edobori 1-chome, Nishi-ku, Osaka 550–0002, Japan.
064950	Genus Lifesciences Inc., 700 N Fenwick St., Allentown, PA 18109.
065085	Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India.
066104	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666.
066679	Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin 2, Dublin, D02HX82, Ireland.
066916	ECO LLC, 11224 Aurora Ave., Urbandale, IA 50322.
067188	B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.
067949	Ridley USA, Inc., 111 W Cherry St., Suite 500, Mankato, MN 56001.
068504	Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.
069043	Cronus Pharma Specialities India Private Ltd., Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India.
069254	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.
069334	Alexion Pharmaceuticals, Inc., 121 Seaport Blvd., Boston, MA 02210.
076475	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349.
086009	Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France.
086039	Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432.
086053	AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754.
086064	Ivaocs Animal Health, 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069.

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
086072	VetDC, Inc., 320 E Vine Dr., suite 218, Fort Collins, CO 80524.
086073	Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043.
086101	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland.
086106	Union Agener, Inc., 1788 Lovers Ln., Augusta, GA 30901.
086113	Wildcat Feeds, 215 NE Strait Ave., Topeka, KS 66616.
086117	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.
086119	Noble Pharma, LLC, 4602 Domain Dr., Menomonee, WI 54751.
086121	Anivive Lifesciences, Inc., 3777 Worsham Ave., Long Beach, CA 90808.
086132	QBiotics Group Ltd., Suite 3A, Level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia.
086134	Revivacor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., Suite 2400, Blacksburg, VA 24060.
086149	Jaguar Animal Health, 200 Pine St., Suite 600, San Francisco, CA 94104.
086189	Domes Pharma S.A., ZAC de Champ Lamet, 3 rue Andre Citroen, Pont-du-Chateau, Auvergne-Rhône-Alpes, 63430, FRANCE.
099207	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §510.600, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

Sec.

511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.

511.3 Definitions.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

§511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.

(a) *New animal drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the act if it is labeled as follows:

Caution. Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(2) The person distributing or causing the distribution of new animal drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such

tests and that the shipment of the new animal drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new animal drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new animal drug or drugs, which discs are intended for use in determining susceptibility of microorganisms to the new animal drug or drugs.

(b) *New animal drugs for clinical investigation in animals.* A shipment or other delivery of a new animal drug or an animal feed containing a new animal drug intended for clinical investigational use in animals shall be exempt