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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 Division of Dockets Management, 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]

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PART 510—NEW ANIMAL DRUGS

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Subpart G—Sponsors of Approved Applications

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

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 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.

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§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:

(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

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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

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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 devel-

opment 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 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 Nonmedical Uses of Antibiotics, was

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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 accumulated 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

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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 [Reserved]

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 occurring 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 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 F [Reserved]

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.

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

(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., 1009 Slater Rd., suite 210-B, Durham, NC 27703	016729
ADM Alliance 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
Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045	059399
Alaco, Inc., 1500 North Wilmot Rd., suite 290-C, Tucson, AZ 85712	064146
American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140	065531
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754	086053
Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218	076175
Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057-3009	051072
Axcentive SARL, Chemin de Champouse, Quartier Violeti, 13320 Bouc Bel Air, France	086009
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756	067188
Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015	010019
Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	000859
Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777	062250
Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002	000010
Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767	068330
Ceva Sante Animale, 10 Avenue de la Ballastiere, 33500 Libourne, France	013744
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105	021091
Cooperative Research Farms, Box 69, Charlotteville, NY 12036	051267
Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816	069043
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	061623
Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	043264
ECO LLC, 344 Nassau St., Princeton, NJ 08540	066916
Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	000986
Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140	058198
Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013-3928	017135
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	058829
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565
Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747	025463
G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201	010515
GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702	042976
Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661	012164
Happy Jack, Inc., Snow Hill, NC 28580	023851
Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964	063075
Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525	063604
Hikma International Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118	059115
Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045	000409
HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652	042791
Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	016592
IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409	065274
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	000115
Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	000061
JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069	051233
Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia	049480
LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702	086047
Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601	061690
Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967	010797
Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861	054925
Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258	099207
Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640	050604
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	051079
Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103	063286
Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120	049968
Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511	059051
Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53719	050929
Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland	055529
Oasmia Pharmaceutical AB, Vallongatan 1, 75228 Uppsala, Sweden	052818
Orion Corp., Orionintie 1, 02200 Espoo, Finland	052483
OXIS International, Inc., 6040 N. Cutter Circle, Suite 317, Portland, OR 97217-3935	024991
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., 776 Mountain Blvd., Watchung, NJ 07069	042552
Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway	015331

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

Firm name and address	Drug labeler code
Pharmgate LLC, 1015 Ashes Dr., Suite 102, 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 Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017	066794
Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013, 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, 1080 County Road F West, Shoreview, MN 55126–2910	017800
Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101	026637
Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349	076475
Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500	068287
Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500	067949
RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620	058670
Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250	063112
SmartVet USA, Inc., 22201 West Innovation Dr., Suite 170A, Olathe, KS 66061–1304	086001
Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France	059120
Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215	058005
Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151	017153
Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503	054628
Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752	037990
Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062	027053
Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532	051672
Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503	052923
Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204	051330
Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5	059320
Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137	017030
Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	051311
Walco International, Inc., 15 West Putnam, Porterville, CA 93257	049185
Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880	000402
Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248	050378
Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524	053923
Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	054771

(2) NUMERICAL LISTING OF SPONSORS

Drug labeler code	Firm name and address
000010	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.
000061	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.
000115	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
000402	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.
000409	Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045.
000859	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.
000986	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.
010019	Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015.
010515	G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201.
010797	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.
012164	Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661.
012286	ADM Alliance 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 Industriområde, N–7863 Overhalla, Norway.
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
016592	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.
016729	Accord Healthcare, Inc., 1009 Slater Rd., suite 210–B, Durham, NC 27703.
017030	Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137.
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, 1080 County Road F West, Shoreview, MN 55126–2910.
021091	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.
023851	Happy Jack, Inc., Snow Hill, NC 28580.
024991	OXIS International, Inc., 6040 N. Cutter Circle, Suite 317 Portland, OR 97217–3935.
025463	Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747.
026637	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.
027053	Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062.
037990	Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752.
042552	Pharmacosmos, Inc., 776 Mountain Blvd., Watchung, NJ 07069.
042791	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.
042976	GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702.

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(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
043264	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.
049185	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.
049480	Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia.
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	Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248.
050604	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640.
050929	Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53719.
051072	Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057-3009.
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478.
051233	JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069.
051267	Cooperative Research Farms, Box 69, Charlottesville, NY 12036.
051311	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137.
051330	Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204.
051672	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
052483	Orion Corp., Orionintie 1, 02200 Espoo, Finland.
052818	Oasmia Pharmaceutical AB, Vallongatan 1, 75228 Uppsala, Sweden.
052923	Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503.
053923	Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524.
054628	Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503.
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., Station Works, Newry BT35 6JP, Northern Ireland.
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.
058670	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.
058829	First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123.
059051	Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511.
059115	Hikma International Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118.
059120	Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France.
059320	Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5.
059399	Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045
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.
061623	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, 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.
063112	Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.
063286	Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
063604	Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525.
064146	Alaco, Inc., 1500 North Wilmot Rd., suite 290-C, Tucson, AZ 85712.
065085	Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013, India.
065274	IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409.
065531	American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140.
066104	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666.
066794	Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017.
066916	ECO LLC, 344 Nassau St., Princeton, NJ 08540.
067188	B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.
067949	Ridley U.S. Holdings, Inc., 424 N. Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500.
068287	Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500.
068330	Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767.
068504	Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.
069043	Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816.
069254	Pharmgate LLC, 1015 Ashes Dr., Suite 102, Wilmington, NC 28405.
076175	Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218.
076475	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349.
086001	SmartVet USA, Inc., 22201 West Innovation Dr., Suite 170A, Olathe, KS 66061-1304.
086009	Axcentive SARL, Chemin de Champouse, Quartier Violsi, 13320 Bouc Bel Air, France.
086047	LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702.
086053	AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754.
099207	Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258.

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTES: 1. 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.fdsys.gov.

2. At 72 FR 36595, July 5, 2007, §510.600, in the table in paragraph (c)(2), was amended by removing the entry for “062749”; however, the amendment could not be incorporated because the entry did not exist.

3. At 77 FR 46613, Aug. 6, 2012, §510.600 was amended by removing the entry for “012758” in the table in paragraph (c)(2); however, the amendment could not be incorporated because “012758” didn’t exist.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

Sec.

511.1 New animal drugs for investigational use exempt from section 512(a) of the 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 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 from section 512(a) and (m) of the act if all the following conditions are met:

(1) The label shall bear the statements:

Caution. Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear the caution statements required by paragraph (a) or (b) of this section, the statements may be included on the carton label and other labeling on or within the package from which the new animal drug is to be dispensed.

(2) The person or firm distributing or causing the distribution of the new animal drug or animal feed containing a new animal drug shall use due diligence to assure that the new animal drug or animal feed containing a new