Food and Drug Administration, HHS

industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term polychlorinated biphenyls (PCB's) is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The 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 Branch, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

510.105 Labeling of drugs for use in milk-producing animals.
510.106 Labeling of antibiotic and anti-biotic-containing drugs intended for use in milk-producing animals.
510.110 Antibiotics used in food-producing animals.
510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

Subpart C—Reserved

Subpart D—Records and Reports

510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.
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.
510.302 Reporting forms.
510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Subpart E—Requirements for Specific New Animal Drugs

510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.
510.440 Injectable iron preparations.
510.455 New animal drug requirements regarding free-choice administration in feeds.

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.
§510.3

Subpart G—Sponsors of Approved Applications

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


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

Subpart A—General Provisions

§510.3 Definitions and interpretations.

As used in this part:


(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) The term sponsor means the person responsible for an investigation of a new animal drug, including responsibility for compliance with applicable provisions of the act and regulations. 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.

(l) Designated journal(s) means journals listed in §510.95.

§ 510.95 Designated journals.

The following journals are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

- All Pet's Magazine (Jersey City).
- American Journal of Veterinary Research (Chicago).
- Animal Nutrition & Health (Sausalito, CA).
- Avian Diseases (Amherst).
- British Poultry Science (Edinburgh).
- Canadian Journal of Comparative Medicine and Veterinary Science (Gardenvale, Quebec).
- Canadian Veterinary Journal (Guelph, Ontario).
- Cornell Veterinarian (Ithaca).
- Experimental Parasitology (New York).
- The Feed Bag (Milwaukee).
- Feedstuffs (Minneapolis).
- Hoard's Dairyman (Fort Atkinson).
- Journal of the American Veterinary Medical Association (Chicago).
- Journal of Dairy Science (Champaign).
- Journal of Economic Entomology (Baltimore).
- Modern Veterinary Practice (formerly North American Veterinarian) (Wheaton, IL).
- National Hog Farmer (Grundy Center, IA).
- New Zealand Veterinary Journal (Wellingt0n).
- Poultry Science (Guelph, Ontario).
- Praktische Tierarzt (Postfach, Germany).
- Research in Veterinary Science (Chicago).
- Small Animal Clinician (Kansas City, MO).
- Veterinaermedizin (Konstanz, Germany).
- Veterinarian (London).
- Veterinarian (International) (New York).
- The Veterinary Bulletin (Farnham Royal, England).
- Veterinary Medicine (Kansas City, MO).
- Veterinary Record (Croydon, England).

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- Canadian Veterinary Journal (Guelph, Ontario).
- Cornell Veterinarian (Ithaca).
- Experimental Parasitology (New York).
- The Feed Bag (Milwaukee).
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- Modern Veterinary Practice (formerly North American Veterinarian) (Wheaton, IL).
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- Praktische Tierarzt (Postfach, Germany).
- Research in Veterinary Science (Chicago).
- Small Animal Clinician (Kansas City, MO).
- Veterinaermedizin (Konstanz, Germany).
- Veterinarian (London).
- Veterinarian (International) (New York).
- The Veterinary Bulletin (Farnham Royal, England).
- Veterinary Medicine (Kansas City, MO).
- Veterinary Record (Croydon, England).
§ 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 Commissioner has determined by appropriate investigation is needed to insure that the milk will not contain violative residues resulting 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...
Food and Drug Administration, HHS

§ 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 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...
§ 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

(a) On receiving notification that an application submitted pursuant to §514.1 of this chapter for a new animal drug is approved, the applicant shall establish and maintain such records and make such reports as are specified in this section to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the application or whether any applicable regulation should be amended or repealed. The applicant shall maintain adequately organized and indexed files containing full reports of information pertinent to the safety or effectiveness of the new animal drug that have not previously been submitted as part of his application for the drug and which are received or otherwise obtained by him from any source, as follows:

(1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the new animal drug that is the subject of the application or any related drugs. An adequate summary and bibliography of reports in the scientific literature would ordinarily suffice. (The application must identify at the time of each report submission, each drug he considers related to the subject drug.)

(2) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the new animal drug, such as its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effect of microorganisms on the drug.

(3) For information required by this section, adequate identification of its source, when known, including the name and post office address of the person who furnishes such information.

(4) Copies of all mailing pieces and other labeling, and, if it is a prescription new animal drug, all advertising other than that contained in the application used in promoting the drug, and copies of the currently used package labeling that gives full information for use of the drug whether or not such labeling is contained in the application.

(5) Information concerning the quantity of the new animal drug distributed in a manner and form that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial, pricing, or sales data.

(6) Information concerning any previously unreported changes from the conditions described in an application conforming to the conditions of §514.8(a)(5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section, except routine assay and control records, appropriately identified with the new animal drug application(s) to which they relate, as follows:

Subpart C [Reserved]

Subpart D—Records and Reports

§ 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.
(1) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:
   (i) Information concerning a mixup in the new animal drug or its labeling with another article.
   (ii) Information concerning any bacteriological or significant physical or other change or deterioration in the new animal 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.
(2) 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:
   (i) Information concerning any unexpected side effects, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical use, 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.
   (ii) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activities.
(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the new animal drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling designed to contain samples of a drug shall be complete except for the omission of the drug.
(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraphs (b) (1), (2), and (3) of this section, shall be submitted as follows unless otherwise ordered in a written communication from the Commissioner:
   (i) At intervals within 6 months beginning with the date of approval of the new animal drug application during the first year following such date, and at yearly intervals thereafter.
   (ii) Whenever an applicant is required to submit reports under the provisions of paragraph (b)(4)(i) of this section with respect to more than one application, he may elect to submit as a part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the new animal drug applications for which the reports are submitted.
   (iii) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.
(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section shall be submitted.
(c) The applicant shall, upon request of any properly authorized officer or employee of the Department at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.
(d) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of this section, or that the applicant has refused to permit access to or copying of, or verification of such records or reports, the Commissioner shall give the
applicant notice and opportunity for a hearing on the question of whether to withdraw the approval of the application, as provided in §514.200 of this chapter.

(e) Upon written request of the applicant stating reasonable grounds therefore, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes is confidential.

(f) The applicant required to establish and maintain records and make reports required by this section includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the new animal drug application or any supplement to it; however, to avoid unnecessary duplication in the submission of reports, any such applicant's obligation to submit a report may be met by its submission on his behalf, designated as such, by another person responsible for reporting.

§ 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) 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.

(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 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 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.

§ 510.302 Reporting forms.

(a) The information described in §510.300, except that described in paragraphs (b) (1) and (2) of that section, shall be submitted appropriately identified with the new animal drug application(s) to which they relate, on Form FD-2301 "Transmittal of Periodic Reports and Promotional Material for New Animal Drugs."

(b) All adverse experiences with new animal drugs as described in §510.300(b)(2) or §510.301(b) whether or not related to a required periodic report submitted on a Form FD-2301, shall be reported on Form FD-1932 "Adverse Drug Reaction" (except as
Food and Drug Administration, HHS

§ 510.410

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 New animal drug requirements regarding free-choice administration in feeds.

(a) For the purpose of this section, free-choice administration of animal drugs in feeds involves feeds that are placed in feeding or grazing areas and are not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Such methods of administering drugs 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 animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations for medicated feeds.

(b) The Food and Drug Administration has concluded that there are questions about the safety and effectiveness of drugs when administered in free-choice feeds. Therefore, such methods of administration cause the drugs so administered to be new animal drugs, for which approved new animal drug applications (NADA’s) are required. (See §510.3(i)). In addition, the exemption from the requirement of an approved medicated feed application provided in §558.4 of this chapter does not apply to any free-choice medicated feed.

(c) An NADA or supplemental NADA for products for free-choice feeding submitted for approval under section 512(b) of the act shall provide for:

(1) The manufacture of a finished product for the free-choice administration of a new animal drug. Such an approval will not provide a basis upon which an application can be approved under section 512(m) of the act; or

(2) The manufacture of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. The approved NADA will provide a basis upon which an application can be approved under section 512(m) of the act. Data for a specific free-choice product may, if desired, be generated and submitted to the Food and Drug Administration by the manufacturer of the free-choice feed in the form of a master file which can be referenced in the NADA or supplemental NADA submitted by the new animal drug sponsor.

(d) Approval of the NADA or supplemental NADA submitted under paragraph (c) of this section will be reflected in a regulation in part 558 of this chapter published under section 512(i) of the act. The regulation will either state the formulation of the approved free-choice product or specify the specific free-choice administration products in which the drug is approved for use. If the approval is for a Type A medicated article, the regulation in part 558 of this chapter will indicate that each use of the Type A medicated article in a free-choice product must be the subject of an approved supplemental NADA.

(e) An application submitted under section 512(m) of the act to provide for manufacture of a specific free-choice feed from an approved Type A medicated article will be approved if, in addition to the information required by the medicated feed application, it includes a reference to the exact formula of the product to be manufactured as follows:

(1) The formula is the same as the one published in the new animal drug regulations; or

(2) The data in a master file have been referenced in an NADA or supplemental NADA; and
(3) Use of the Type A medicated article in the specific formulation has been approved on the basis that:
   (i) The formula is the same as the one for which acceptable data have been submitted in a master file by the medicated feed applicant; or
   (ii) The medicated feed applicant has written authority to reference a master file that has acceptable data for the formula in question.

(Approved by the Office of Management and Budget under control number 0910–0205)
[51 FR 19827, June 3, 1986]

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

§ 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in this subchapter E, part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:
   (1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.
   (2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.
   (3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:
   (1) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of 100 grams of penicillin. When intended for uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.
   (2) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(c) It is intended for use as follows:

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Use levels</th>
<th>Indications for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>For use in the prevention of outbreaks of coccidiosis in poultry flocks; growth promotion and feed efficiency.</td>
</tr>
<tr>
<td>2. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>Do.</td>
</tr>
<tr>
<td>Bacitracin methylene disalicylate.</td>
<td>do</td>
<td>4 to 50 g/ton.</td>
<td>For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.</td>
</tr>
<tr>
<td>3. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>Do.</td>
</tr>
<tr>
<td>Bacitracin methylene disalicylate.</td>
<td>do</td>
<td>4 to 50 g/ton.</td>
<td></td>
</tr>
<tr>
<td>3-Nitro-4-hydroxyphenylarsenic acid.</td>
<td>do</td>
<td>0.0025 to 0.005 percent.</td>
<td></td>
</tr>
<tr>
<td>4. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>Do.</td>
</tr>
<tr>
<td>Procaine penicillin</td>
<td>do</td>
<td>2.4 to 50 g/ton.</td>
<td></td>
</tr>
<tr>
<td>3-Nitro-4-hydroxyphenylarsenic acid.</td>
<td>do</td>
<td>0.0025 to 0.005 percent.</td>
<td></td>
</tr>
</tbody>
</table>
§ 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:

(1) Alphabetical Listing of Sponsors—Continued

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcsa Inc., 60 Baylis Rd., Melville, NY 11747</td>
<td>025463</td>
</tr>
<tr>
<td>American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501</td>
<td>010042</td>
</tr>
<tr>
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<td>Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006</td>
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<td>Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604</td>
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<td>ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105</td>
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<td>Contemorary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067</td>
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<td>Cooperative Research Farms, Box 69, Charlottesville, VA 22908</td>
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<td>Cross Vetpharm Group Ltd., Brookmills Rd., Tallaght, Dublin 4, Ireland</td>
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<td>Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701</td>
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<td>Cyanamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701</td>
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<td>Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Milford, DE 19963</td>
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<td>Diamond Shamrock Corp., Nutrition &amp; Animal Health Div., 1100 Superior Ave., Cleveland, OH 44114</td>
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§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(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:

(1) Alphabetical Listing of Sponsors—Continued

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<td>Carl S. Akey, Inc., P.O. Box 607, Lewisburg, OH 43338</td>
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<td>Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024</td>
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<td>Evivo Pharmaceuticals, An Affiliate of IGI, Inc. Box 209, Harding Hwy., Buena, NJ 08310</td>
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<td>Farmers Feed &amp; Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772</td>
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<td>Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001</td>
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<td>John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611</td>
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<td>Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234</td>
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<td>Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334</td>
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<td>Hubbard Milling Co., 424 North Front St., Man- kato, MN 56001</td>
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<td>Med-Pharmes, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861</td>
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<td>PeptideTech Animal Health Pty., 35-41 Waterloo Rd., North Ryde, New South Wales 2113, Australia</td>
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<td>Peter Sandt Foundation, 2 East Madison St., Waukegan, IL 60085</td>
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<td>Pharmacia &amp; Upjohn Co., 700 Portage Rd., Kalamazoo, MI 49001-0199</td>
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<td>Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812</td>
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<td>R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33758</td>
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<td>South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075</td>
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§510.600
### Food and Drug Administration, HHS

#### § 510.600

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<td>Syntex Animal Health Division of Syntex Agribusines, Inc., 3401 Hively Ave., Palo Alto, CA 94304.</td>
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<td>000693 ............</td>
<td>Pfizer, Inc., 235 East 42nd St., New York, NY 10017.</td>
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<td>Abbott Laboratories, North Chicago, IL 60064.</td>
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<td>000859 ............</td>
<td>Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201.</td>
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<td>000864 ............</td>
<td>Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006.</td>
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<td>000934 ............</td>
<td>Sterling Winthrop, Inc., 9 Great Valley Parkway, Malvern, PA 19355.</td>
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<td>000986 ............</td>
<td>Elanco Animal Health, A Division of Eli Lilly &amp; Co., Lilly Corporate Center, Indianapolis, IN 46285.</td>
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<td>001000 ............</td>
<td>South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075.</td>
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<td>010042 ............</td>
<td>American Cyanamid, Division of American Home Products, P.O. Box 1399, Fort Dodge, IA 50501.</td>
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<td>010090 ............</td>
<td>Franklin Laboratories, Inc., P.O. Box 717, Fort Dodge, IA 50501.</td>
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<td>010200 ............</td>
<td>Franklin Laboratories, P.O. Box 669, Ama- nillo, TX 79110.</td>
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<td>010439 ............</td>
<td>Furst-McNess Co., Freeport, IL 61032.</td>
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<td>010515 ............</td>
<td>G. C. Hardman Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201.</td>
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<td>010797 ............</td>
<td>Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.</td>
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<td>011014 ............</td>
<td>R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33758.</td>
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<td>011461 ............</td>
<td>Shell Chemical Co., Division of Shell Oil Co., Animal Health, One Shell Plaza, Houston, TX 77001.</td>
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<td>011485 ............</td>
<td>Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015.</td>
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<td>011509 ............</td>
<td>Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604.</td>
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<td>011526 ............</td>
<td>Rhone-Poulenc, Inc., P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08852.</td>
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<td>011655 ............</td>
<td>Lambert-Kay, A Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512-0181.</td>
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<td>011722 ............</td>
<td>Pika d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia</td>
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<td>011749 ............</td>
<td>Seeco Inc., Box 1014, North Highway 71, Willmar, MN 56201.</td>
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<td>011789 ............</td>
<td>Vet-A-Mix, Inc., P.O. Box A, Shenzhen, IA 51601.</td>
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<td>012164 ............</td>
<td>Halocon Laboratories, Division of Halocon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661.</td>
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<td>012190 ............</td>
<td>Hubbard Milling Co., 424 North Front St., Hammond, IN 46323.</td>
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<td>012487 ............</td>
<td>Osborn Laboratories, Inc., 2d and Oak Sts., Le Sueur, MN 56058.</td>
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<td>012799 ............</td>
<td>Hoechst Roussel Vet, Pymville Corporate Park 111, P.O. Box 4010, Clinton, NJ 08809–4010.</td>
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<td>015565 ............</td>
<td>Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.</td>
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<td>015579 ............</td>
<td>Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.</td>
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<td>016968 ............</td>
<td>Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318.</td>
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<td>017030 ............</td>
<td>Evsco Pharmaceuticals, Inc., 500 South Parkway Drive, P.O. Box 209, Harding Hwy., Buena, NJ 08310.</td>
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<td>017135 ............</td>
<td>Farnam Companies, Inc., 301 West Osborne, Phoenix, AZ 85013–9328.</td>
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<td>017139 ............</td>
<td>Waterfield Mills Co., 2055 Mitchell Ave, Waterloo, IA 50704.</td>
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<td>Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151.</td>
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<td>017287 ............</td>
<td>Chemdex, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215.</td>
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<td>017473 ............</td>
<td>Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701.</td>
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<td>017519 ............</td>
<td>ADM Animal Health &amp; Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508.</td>
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<td>017762 ............</td>
<td>Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112.</td>
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<td>017800 ............</td>
<td>Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812.</td>
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<td>021091 ............</td>
<td>ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.</td>
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<td>021641 ............</td>
<td>Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214.</td>
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<td>021676 ............</td>
<td>Farmland Industries, Inc., Kansas City, MO 64116.</td>
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<td>021980 ............</td>
<td>Golden Sun Feeds, Inc., 111 South Fifth St., Esteville, IA 51534.</td>
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## §510.600 21 CFR Ch. I (4–1–00 Edition)

### (2) NUMERICAL LISTING OF SPONSORS—Continued

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<td>023851</td>
<td>Happy Jack, Inc., Snow Hill, NC 28580.</td>
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<td>024174</td>
<td>Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.</td>
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<td>025463</td>
<td>Altana Inc., 60 Baylis Rd., Melville, NY 11747.</td>
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<td>026186</td>
<td>Henwood Feed Additives, Division of Feed Specialties Co., Inc., 211 Western Rd., Box 577, Lewistown, OH 43538.</td>
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<td>026228</td>
<td>M &amp; M Livestock Products Co., Eagle Grove, IA 50533.</td>
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<td>027190</td>
<td>Norco Mills of Norbik, Inc., P.O. Box 56, Norfolk, NE 68701.</td>
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<td>027454</td>
<td>Nutris Trading Co., Inc., P.O. Box 2, Route 202, Pomona, NY 10970.</td>
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<td>027863</td>
<td>Matox &amp; Moore, Inc., 1503 East Riverside Dr., Indianapolis, IN 46207.</td>
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<td>028260</td>
<td>The Rath Packing Co., P.O. Box 330, Waterloo, IA 50704.</td>
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<td>028459</td>
<td>Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.</td>
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<td>Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536.</td>
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<td>030841</td>
<td>Feed Service Co., Inc., 303 Lundi Blvd, P.O. Box 696, Mankato, MN 56001.</td>
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<td>032707</td>
<td>Premier Malt Products, Inc., Milwaukee, WI 53201.</td>
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<td>032761</td>
<td>BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118.</td>
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<td>033008</td>
<td>Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354.</td>
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<td>033932</td>
<td>Agro Inc., 11100 N. Congress Ave., Kansas City, MO 64153.</td>
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<td>033999</td>
<td>Protein Blenders, Inc., Box 631, Highway 21 South, Iowa City, IA 52240.</td>
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<td>034936</td>
<td>Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048.</td>
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<td>035669</td>
<td>Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247.</td>
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<td>035393</td>
<td>Young’s, Inc., Roaring Spring, PA 16673.</td>
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<td>Square Deal Fortification Co., Kuts, IN 46530.</td>
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<td>036904</td>
<td>PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430.</td>
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<td>037310</td>
<td>Illini Feeds, Box T, Oneida, IL 61467.</td>
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<td>Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752.</td>
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<td>J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.</td>
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<td>043738</td>
<td>Battelle Guthrie &amp; Co., Ltd., 315 North H St., Fresno, CA 93701.</td>
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<td>043729</td>
<td>Nixon and Co., Kiewitt Plaza, Omaha, NE 68102.</td>
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<td>Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601.</td>
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<td>International Nutrition, Inc., 6664 L St., Omaha, NE 68117.</td>
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<td>043735</td>
<td>Glain-D-Lac Co., 1818 Leavenworth St., Omaha, NE 68110.</td>
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<td>043737</td>
<td>Peter Hard Foundation, 2 East Madison St, Waukegan, IL 60085.</td>
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<td>043738</td>
<td>McClennan Laboratories, Inc., 1900 Sixth Ave., Lakeview, CA 92353.</td>
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<td>043743</td>
<td>V.P.O., Inc., 4444 South 76th St., Omaha, NE 68127.</td>
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<td>Farmers Feed &amp; Supply Co., Ninth St. at Northwestern Tract, Tipton, IA 52772.</td>
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<td>Cynamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701.</td>
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<td>Jorgensen Laboratories, Inc., 1450 North Van Buren Ave., Loveland, CO 80538.</td>
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<td>045673</td>
<td>Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024.</td>
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<td>Custom Feed Blenders Corp., 540 Hawk-eye Ave., Fort Dodge, IA 50501.</td>
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<td>Rhone Merieux Canada, Inc., 246 Boul. Labbe Blvd., North Victoriaville, QC, G6P 1B1 Canada.</td>
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<td>047191</td>
<td>Carnation Co., 5045 Wilshire Blvd., Los Angeles, CA 90036.</td>
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<td>047126</td>
<td>Micro Chemical, Inc., Amarillo, TX 79105.</td>
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<td>Southern Micro-Blenders, Inc., 3801 North Hawshorne St., Chattanooga, TN 37406.</td>
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<td>Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08850–3077.</td>
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<td>050639</td>
<td>I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137.</td>
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<td>Hess &amp; Clark, Inc., Seventh and Orange Sts., Ashland, OH 44805.</td>
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<td>Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709.</td>
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<td>050972</td>
<td>Gossiet Nutrition, Inc., 1767 Cascade Dr., Marion, OH 43302.</td>
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<td>Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052.</td>
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<td>Med-Pharmex, Inc., 2727 Thompson Creek Rd., P.O. Box 698, Mankato, MN 56001.</td>
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<td>051267</td>
<td>Cooperative Research Farms, Box 69, Charlotteville, VA 22915.</td>
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<td>051359</td>
<td>Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44141.</td>
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<td>052339</td>
<td>Orion Corp. ORION-FARMS, P.O. Box 14040 Industrial Rd., Omaha, NE 68137.</td>
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<td>053350</td>
<td>Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501.</td>
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<td>Nutribasics Co., North Highway 71, P.O. Box 1014, Willmar, MN 56201.</td>
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<td>053923</td>
<td>Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524.</td>
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§ 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.

(b) New animal drugs for tests in vivo and in laboratory research animals. (1) A new animal drug for tests in vivo 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 vivo. Not for use in humans.