AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
055246	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.
055462	Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067.
055529	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.
055882	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy.
057319	Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457.
057561	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503.
057926	Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966.
058034	John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611.
058198	Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419–8300.
058639	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.
058670	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.
058711	Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525.
059079	Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113.
059130	Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457
059258	Rhodia Limited, P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK.
059945	Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167.
059521	Ausa International, Inc., Rt. 8, P.O. Box 324–12, Tyler, TX 75703.
059620	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.Blvd., St. Louis, MO 63167.
060307	Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002.
060594	PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044.
060728	Planalquimica 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.
060951	Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317.
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.
062161	Orphan Medical, Inc., 13911 Ridgedale Dr., Suite 475, Minnetonka, MN 55305.
062240	Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027.
062408	Alstoe, Ltd., Animal Health, Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England.

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
062925	Veterinary Specialties Inc., 387 North Valley Ct., Barrington, Il 60010.
063075	Biopure Corp., 11 Hurley St., Cambridge, MA 02141.
063112	Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.
063238	Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298.
063271	Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067.
063323	American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160.
063604	Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525.
063765	Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden.
064146	Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712.
064288	Peptech Animal Health Pty, Ltd., 35–41 Waterloo Rd., North Ryde, New South Wales 2113, Australia.
064408	Veterinary Research Associates, Inc., 20 Old Dock Rd., Yaphank, NY 11980.
099207	Medicis Dermatologics, Inc., 4343 East Camelback Rd., Suite 250, Phoenix, AZ 85018–2700.

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §510.600, see the List of CFR Sections Affected in the Finding Aids section of this volume.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

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 animal drug will actually be used for tests in animals and is not used in humans.

(3) The person who introduced such shipment or who delivered the new animal drug or animal feed containing a new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the investigator to whom the new animal drug or animal feed containing a 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, such records shall be made available for inspection and copying.

(4) Prior to shipment of the new animal drug for clinical tests in animals, the sponsor of the investigation shall submit in triplicate to the Food and Drug Administration a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' including a signed statement containing the following information:

(i) The identity of the new animal drug.

(ii) All labeling and other pertinent information to be supplied to the investigators. When such pertinent information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(iii) The name and address of each clinical investigator.

(iv) The approximate number of animals to be treated (or if not available, the amount of new animal drug to be shipped).

(v) If the new animal drug is given to food-producing animals, the statement shall contain the following additional information:

(*a*) A commitment that the edible products from such animals shall not be used for food without prior authorization in accordance with the provisions prescribed in this section.

(*b*) Approximate dates of the beginning and end of the experiment or series of experiments.

(*c*) The maximum daily dose(s) to be administered to a given species, the size of animal, maximum duration of administration, method(s) of administration, and proposed withdrawal time, if any.

(vi) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(5) Authorization for use of edible products derived from a treated food-producing animal may be granted under the provisions of this section and when the following specified conditions are met, except that in the case of an animal administered any unlicensed experimental veterinary biological product regulated under the viruses, serums, toxins statute (21 U.S.C., chapter V, sec. 151 *et seq.*) the product shall be exempt from the requirements of this section when U.S. Department of Agriculture approval has been obtained as provided in 9 CFR 103.2. Conditional authorization may be granted in advance of identification of the name(s) and address(es) of the clinical investigator(s) as required by paragraph (b)(4)(iii) of this section. Information required for authorization shall include, in addition to all other requirements of this section, the following:

(i) Data to show that consumption of food derived from animals treated at the maximum levels with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(4)(v)*(c)* of this section, will not be inconsistent with the public health; or

(ii) Data to show that food derived from animals treated at the maximum levels and with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(4)(v)*(c)* of this section, does not contain drug residues or metabolites.

(iii) The name and location of the packing plant where the animals will be processed, except that this requirement may be waived, on request, by the terms of the authorization.

Authorizations granted under this paragraph do not exempt investigational animals and their products from compliance with other applicable inspection requirements. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(6) On written request of the Food and Drug Administration, the sponsor shall submit any additional information reported to or otherwise received by him with respect to the investigation deemed necessary to facilitate a determination whether there are grounds in the interest of public health for terminating the exemption.

(7) The sponsor shall assure himself that the new animal drug is shipped only to investigators who:

(i) Are qualified by scientific training and/experience to evaluate the safety and/or effectiveness of the new animal drug.

(ii) Shall maintain complete records of the investigations, including complete records of the receipt and disposition of each shipment or delivery of the new animal drug under investigation. Copies of all records of the investigation shall be retained by the investigator for 2 years after the termination of the investigation or approval of a new animal drug application.

(iii) Shall furnish adequate and timely reports of the investigation to the sponsor.

(8) The sponsor:

(i) Shall retain all reports received from investigators for 2 years after the termination of the investigation or approval of a new animal drug application and make such reports available to a duly authorized employee of the Department for inspection at all reasonable times.

(ii) Shall provide for current monitoring of the investigation by a person qualified by scientific training and experience to evaluate information obtained from the investigation, and shall promptly investigate and report to the Food and Drug Administration and to all investigators any findings associated with use of the new animal drug that may suggest significant hazards pertinent to the safety of the new animal drug.

(iii) Shall not unduly prolong distribution of the new animal drug for investigational use.

(iv) Shall not, nor shall any person acting for or on behalf of the sponsor, represent that the new animal drug is safe or effective for the purposes for which it is under investigation. This requirement is not intended to restrict the full exchange of scientific information.

(v) Shall not commercially distribute nor test-market the new animal drug until a new animal drug application is approved pursuant to section 512(c) of the act.

(9) If the shipment or other delivery of the new animal drug is imported or offered for importation into the United States for clinical investigational use in animals, it shall also meet the following conditions:

(i) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has, prior to such shipments and deliveries, informed the Food and Drug Administration of his intention to import the new animal drug as sponsor in compliance with the conditions prescribed in this subdivision; or

(ii) The new animal drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct laboratory or clinical investigations and is intended solely for use in such institutions and which institution has submitted a statement as sponsor of the investigation.

(10) The sponsor shall submit either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter.

(c) *Withdrawal of eligibility to receive investigational-use new animal drugs.* (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations or has submitted false information either to the sponsor of the investigation or in any required report, the Center for Veterinary Medicine will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on the question of whether the investigator is entitled to receive investigational new animal drugs.

(2) If, after evaluating all available information, including any explanation presented by the investigator, the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational use new animal drugs with a statement of the basis for such determination.

(3) Each ''Notice of Claimed Investigational Exemption for a New Animal Drug'' and each approved new animal drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use new animal drugs will be examined to determine whether he has submitted unreliable data that

are essential to the continuation of the investigation or essential to the approval of any new animal drug application.

(4) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he shall first notify the sponsor, who shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on whether the exemption should be terminated. If a danger to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 (see 42 FR 15675, March 22, 1977) of this chapter on the question of whether the exemption should be reinstated.

(5) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are such that a new animal drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 512(e) of the act.

(6) An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use new animal drugs when the Commissioner determines that he has presented adequate assurance that he will employ such new animal drugs solely in compliance with the exempting regulations in this section for investigational-use new animal drugs.

(d) *Termination of exemption.* If the Commissioner finds that:

(1) The sponsor of the investigation has failed to comply with any of the conditions for the exemption established under this section, or

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is being or has been used for purposes other than bona fide scientific investigation, he shall first notify the sponsor and invite his immediate correction. If the conditions of the exemption are not immediately met, the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant of part 16 of this chapter on whether the exemption should be terminated. If the exemption is terminated the sponsor shall recall or have destroyed the unused supplies of the new animal drug.

(e) *Statements and requests.* ''Notice(s) of Claimed Investigational Exemption for a New Animal Drug'' and requests for authorization to use investigational animals and their products for food should be addressed to the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(f) *Contract research organizations.* (1) For purposes of this part and part 514, *contract research organization* means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

(2) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be in writing and, if not all obligations are transferred, shall describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred.

(3) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to *sponsor* in this part apply to a contract research

organization to the extent that it assumes one or more obligations of the sponsor.

[40 FR 13823, Mar. 27, 1975, as amended at 41 FR 48268, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 8847, Mar. 19, 1987; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992; 62 FR 40599, July 29, 1997]

PART 514—NEW ANIMAL DRUG APPLICATIONS

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514.7 Withdrawal of applications without prejudice.
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AUTHORITY: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

SOURCE: 40 FR 13825, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 514.1 Applications.

(a) Applications to be filed under section 512(b) of the act shall be submitted in the form described in paragraph (b) of this section. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part. Translations of literature printed in a foreign language shall be accompanied by copies of the original publication. The application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of, and must be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States. Pertinent information may be incorporated in, and will be considered as part of, an application on the basis of specific reference to such information, including information submitted under the provisions of § 511.1 of this chapter, in the files of the Food and Drug Administration; however, the reference must be specific in identifying the information. Any reference to information furnished by a person other than the applicant may not be considered unless its use is authorized in a written statement signed by the person who submitted it.

(b) Applications for new animal drugs shall be submitted in triplicate and assembled in the manner prescribed by paragraph (b)(15) of this section, and shall include the following information:

(1) *Identification*. Whether the submission is an original or supplemental application; the name and the address of the applicant; the date of the application; the trade name(s) (if one has been proposed) and chemical name(s) of the new animal drug. Upon receipt, the application will be assigned a number NADA ———, which shall be used for