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§ 584.700 Hydrophobic silicas.

(a) *Product.* Amorphous fumed hydrophobic silica or precipitated hydrophobic silica (CAS Reg. No. 68611-0944-099, silane, dichlorodimethyl-, reaction products with silica).

(b) *Conditions of use.* An anticaking/free-flow agent in vitamin preparations for animal feed.

(c) *Limitations.* Not to exceed 5 percent in the vitamin preparation. It shall be used in accordance with good manufacturing or feeding practices. It must be of purity suitable for intended use, and it must comply with the following specifications:

(i) Amorphous fumed hydrophobic silica: Not less than 99.0 percent silicon dioxide after ignition. Not more than 3 ppm arsenic. Not more than 0.003 percent heavy metals (as lead). Not more than 10 ppm lead. Not more than 2.5 percent loss on drying. Not more than 2 percent loss on ignition after drying. Not more than 1 percent insoluble substances. Not more than 50 parts per million dichlorodimethylsilane.

(ii) Precipitated hydrophobic silica: Not less than 94.0 percent silicon dioxide after ignition. Not more than 3 ppm arsenic. Not more than 0.003 percent heavy metals (as lead). Not more than 10 ppm lead. Not more than 7 percent loss on drying. Not more than 8.5 percent loss on ignition after drying. Not more than 5 percent soluble ionizable salts (as sodium sulfate). Not more than 1 percent insoluble substances. Not more than 50 parts per million dichlorodimethylsilane.

[61 FR 43453, Aug. 23, 1996]

§ 584.725 25-Hydroxyvitamin D₃.

(a) *Product.* 25-Hydroxyvitamin D₃ (9,10-secocholesta-5,7,10(19)-triene-3 β , 25-diol).

(b) *Conditions of use.* This substance is generally recognized as safe as a source of vitamin D₃ activity in feed or drinking water of broiler chickens when used in accordance with the limitations in paragraph (c) of this section.

(c) *Limitations.* (1) Not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water. It shall be used in accordance with good manufacturing and feeding practices.

(2) The product must comply with the following specifications:

(i) Not less than 94.0 percent 25-hydroxyvitamin D₃.

(ii) Not more than 1 percent of any individual sterol.

(iii) Not more than 5 percent water.

(iv) Not more than 20 parts per million (ppm) lead.

(v) Not more than 20 ppm aluminum.

(vi) Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7'-tetraiodofluorescein.

(3) Product labeling shall bear the following:

(i) A statement to indicate that the maximum use level of 25-hydroxyvitamin D₃ must not exceed 69 ppb in feed or 34.5 ppb in drinking water.

(ii) Adequate use directions to ensure that 25-hydroxyvitamin D₃ (and all pre-mixes) is uniformly blended throughout the feed or drinking water.

(iii) An expiration date on all premix labeling.

(iv) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D₃ should not be used simultaneously in both feed and water.

[72 FR 12564, Mar. 16, 2007]

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

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AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371.

Subpart A—General Provisions**§ 589.1 Substances prohibited from use in animal food or feed.**

(a) The substances listed in this part have been prohibited from use in animal food or feed by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in such food or feed. Use of any of these substances in violation of this part causes the animal food or feed involved to be adulterated and in violation of the Act.

(b) This part includes only a partial list of substances prohibited from use in animal food or feed; it is for easy reference purposes and is not a complete list of substances that may not lawfully be used in such animal food or feed. No substance may be used in animal food or feed unless it meets all applicable requirements of the Act.

(c) The Food and Drug Administration either on its own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this part on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, shall be the form set forth in § 571.1 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable ground.

[45 FR 28319, Apr. 29, 1980]

Subpart B—Listing of Specific Substances Prohibited From Use in Animal Food or Feed**§ 589.1000 Gentian violet.**

The Food and Drug Administration has determined that gentian violet has not been shown by adequate scientific data to be safe for use in animal feed. Use of gentian violet in animal feed causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed inves-

tigational exemption for a food additive under § 570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act, or an index listing under section 572 of the act, or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter or § 516.125 of this chapter.

[72 FR 69131, Dec. 6, 2007]

§ 589.1001 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

[61 FR 19544, May 2, 1996]

§ 589.2000 Animal proteins prohibited in ruminant feed.

(a) *Definitions*—(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in § 589.2001; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

(2) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

(3) *Blender* means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.

(4) *Feed manufacturer* includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.

(5) *Nonmammalian protein* includes proteins from nonmammalian animals.

(6) *Distributor* includes persons who distribute or transport feeds or feed ingredients intended for animals.

(7) *Ruminant* includes any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(b) *Food additive status*. The Food and Drug Administration has determined that protein derived from mammalian tissues for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter.

(c) *Requirements for renderers that are not included in paragraph (e) of this section*. (1) Renderers that manufacture products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed shall take the following

measures to ensure that materials identified in paragraph (b) of this section are not used in the feed of ruminants:

(i) Label the materials as follows: “Do not feed to cattle or other ruminants”; and

(ii) Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the copies available for inspection and copying by the Food and Drug Administration.

(2) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section if they:

(i) Use exclusively a manufacturing method that has been validated by the Food and Drug Administration to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) and whose design has been made available to the public;

(ii) Use routinely a test method that has been validated by the Food and Drug Administration to detect the presence of the agent that causes TSE’s and whose design has been made available to the public. Renderers whose products test positive for agents that cause TSE’s must comply with paragraphs (c)(1)(i) and (c)(1)(ii) of this section. Records of the test results shall be made available for inspection by the Food and Drug Administration; or

(iii) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by the Food and Drug Administration.

(3) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraph (c)(1)(ii) of this section if they use a permanent method, approved by FDA, to make a mark indicating that the product contains or may contain protein derived from mammalian tissue. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the Food and Drug Administration and

whose design has been made available to the public.

(4) Renderers shall comply with all applicable requirements under § 589.2001.

(d) *Requirements for protein blenders, feed manufacturers, and distributors that are not included in paragraph (e) of this section.* (1) Protein blenders, feed manufacturers, and distributors that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissues shall comply with paragraph (c)(1) of this section.

(2) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraphs (d)(1) of this section if they:

(i) Purchase animal products from renderers that certified compliance with paragraph (c)(2) of this section or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(2) of this section; or

(ii) Comply with the requirements of paragraph (c)(2) of this section where appropriate.

(3) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraph (c)(1)(ii) of this section if they:

(i) Purchase animal protein products that are marked in accordance with paragraph (c)(3) of this section or purchase such materials from renderers that certified compliance with paragraph (c)(3) of this section, or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(3) of this section; or

(ii) Comply with the requirements of paragraph (c)(3) of this section where appropriate.

(4) Pet food products that are sold or are intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feeds for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in

accordance with paragraph (c) or (d) of this section, as appropriate.

(5) Copies of certifications as described in paragraphs (d)(2) and (d)(3) of this section, shall be made available for inspection and copying by the Food and Drug Administration.

(e) *Requirements for persons that intend to separate mammalian and nonmammalian materials.* (1) Renderers, protein blenders, feed manufacturers, distributors, and others that manufacture, process, blend and distribute both products that contain or may contain protein derived from mammalian tissues or feeds containing such products, and protein products from other animal tissues or feeds containing such products, and that intend to keep those products separate shall:

(i) Comply with paragraphs (c)(1) or (d)(1) of this section as appropriate except that the labeling requirement shall apply only to products that contain or may contain protein derived from mammalian tissues or feeds containing such products;

(ii) In the case of a renderer, obtain nonmammalian or pure porcine or pure equine materials only from single-species slaughter facilities;

(iii) Provide for measures to avoid commingling or cross-contamination;

(A) Maintain separate equipment or facilities for the manufacture, processing, or blending of such materials; or

(B) Use clean-out procedures or other means adequate to prevent carry-over of products that contain or may contain protein derived from mammalian tissues into animal protein or feeds that may be used for ruminants; and

(iv) Maintain written procedures specifying the clean-out procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment.

(2) Renderers, blenders, feed manufacturers, and distributors will be exempted from applicable requirements of paragraph (e)(1) of this section, if they meet the criteria for exemption under paragraphs (c)(2) or (c)(3) of this section, and (d)(2) or (d)(3) of this section.

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(3) Renderers shall comply with all applicable requirements under § 589.2001.

(f) *Requirements for establishments and individuals that are responsible for feeding ruminant animals.* Establishments and individuals that are responsible for feeding ruminant animals shall maintain copies of purchase invoices and labeling for all feeds containing animal protein products received, and make the copies available for inspection and copying by the Food and Drug Administration.

(g) *Adulteration and misbranding.* (1) Animal protein products, and feeds containing such products, that are not in compliance with paragraphs (c) through (f) of this section, excluding labeling requirements, will be deemed adulterated under section 402(a)(2)(C) or 402(a)(4) of the act.

(2) Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of this section will be deemed misbranded under section 403(a)(1) or 403(f) of the act.

(h) *Inspection; records retention.* (1) Records that are to be made available for inspection and copying, as required by this section, shall be kept for a minimum of 1 year.

(2) Written procedures required by this section shall be made available for inspection and copying by the Food and Drug Administration.

[62 FR 30976, June 5, 1997, as amended at 73 FR 22756, Apr. 25, 2008]

EFFECTIVE DATE NOTE: At 62 FR 30976, June 5, 1997, § 589.2000 was added. Paragraph (e)(1)(iv) of this section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.

(a) *Purpose.* The purpose of this section is to prohibit the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of bovine spongiform encephalopathy (BSE) within the United States.

(b) *Definitions*—(1) *Cattle materials prohibited in animal feed* include:

(i) The entire carcass of BSE-positive cattle;

(ii) The brains and spinal cords of cattle 30 months of age and older;

(iii) The entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed;

(iv) Mechanically separated beef as defined in paragraph (b)(3) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section; and

(v) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section.

(vi) Cattle materials prohibited in animal feed do not include:

(A) Tallow derivatives as defined in paragraph (b)(6) of this section;

(B) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(ii) and (b)(1)(iii) of this section and that contains no more than 0.15 percent insoluble impurities. Insoluble impurities must be measured by the method entitled “Insoluble Impurities” (AOCS Method Ca 3a-46), American Oil Chemists’ Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46. You may obtain copies of the method from the AOCS (<http://www.aocs.org>), 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(C) Materials as defined in paragraphs (b)(1)(ii), (b)(1)(iii), (b)(1)(iv) (other than mechanically separated beef from the carcass of a BSE-positive cattle), and (b)(1)(v) of this section from cattle from a country that has been designated under paragraph (f) of this section.

(2) *Cattle not inspected and passed for human consumption* means cattle that did not pass antemortem inspection by the appropriate regulatory authority. This term includes nonambulatory disabled cattle. Nonambulatory disabled cattle are cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(3) *Mechanically separated beef* means a finely comminuted meat food product, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses.

(4) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined in this paragraph) whose intended use for the products may include animal feed, industrial use, or other uses. The term includes renderers that also blend animal protein products.

(5) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues.

(6) *Tallow derivative* means any product obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

(c) *Requirements.* (1) No animal feed or feed ingredient shall be manufactured from, processed with, or otherwise contain, cattle materials prohibited in

animal feed as defined in paragraph (b)(1) of this section.

(2) Renderers that receive, manufacture, process, blend, or distribute cattle materials prohibited in animal feed as defined in paragraph (b)(1) of this section, or products that contain or may contain cattle materials prohibited in animal feed, shall take the following measures to ensure that materials prohibited as defined in paragraph (b)(1) of this section are not introduced into animal feed:

(i) Exclude from use in animal feed the entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section if:

(A) The brain and spinal cord are not effectively removed from such cattle or the brain and spinal cord from such cattle are not otherwise effectively excluded from animal feed; and

(B) Such cattle are 30 months of age or older.

(ii) If renderers remove brain and spinal cord from cattle not inspected and passed for human consumption, or separate such animals based on whether or not they are 30 months of age or older, renderers must maintain adequate written procedures specifying how these processes are carried out.

(iii) Once cattle materials prohibited in animal feed have been separated from other cattle materials, provide for measures to avoid cross-contamination;

(A) Use separate equipment while handling cattle materials prohibited in animal feed; or

(B) Use separate containers that adequately prevent contact with animal feed, animal feed ingredients, or equipment surfaces;

(iv) Label the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed in a conspicuous manner as follows: "Do not feed to animals";

(v) Mark the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed with an agent that can be readily detected on visual inspection; and

(vi) Establish and maintain records sufficient to track cattle materials

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prohibited in animal feed to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by the Food and Drug Administration.

(3) Renderers that receive, manufacture, process, blend, or distribute any cattle materials shall take the following measures to ensure that materials prohibited as defined in paragraph (b)(1) of this section are not used in animal feed:

(i) Establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed and make copies of all records available for inspection and copying by the Food and Drug Administration. With respect to cattle materials obtained from establishments which have segregated cattle materials prohibited in animal feed, such records must demonstrate that establishments supplying cattle materials to the renderers have adequate procedures in place to effectively exclude cattle materials prohibited in animal feed; and these records shall be considered sufficient to meet this requirement if they include either:

(A) Certification or other documentation from the supplier that material supplied to the renderer does not include cattle materials prohibited in animal feed; such certification or documentation is acceptable, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or other documentation; or

(B) Documentation of another method acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded cattle materials prohibited in animal feed.

(ii) Comply with all applicable requirements under § 589.2000 regarding animal proteins prohibited in ruminant feed.

(d) *Adulteration and misbranding.* (1) Failure of a renderer to comply with the requirements in paragraphs (c)(2)(i) through (c)(2)(iii), (c)(2)(v) and

(c)(2)(vi), or (c)(3)(i) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) Animal feed or feed ingredients that are not in compliance with paragraph (c)(1) of this section are adulterated under section 402(a)(2), 402(a)(3), or 402(a)(5) of the act.

(3) Animal feed or feed ingredients that are not in compliance with the labeling requirements of paragraph (c)(2)(iv) of this section are misbranded under section 403(a)(1) or 403(f) of the act.

(4) Failure of a renderer to comply with the requirements in paragraph (e) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the act.

(e) *Inspection; records retention.* Records required to be made available for inspection and copying by the Food and Drug Administration, as required by this section, shall be kept for a minimum of 1 year.

(f) *Process for designating countries.* A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Veterinary Medicine, at the address designated in § 5.1100 of this chapter. The request shall include information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in paragraph (b)(1) of this section. FDA shall respond in writing to any such request and may impose conditions in granting any such request. Any grant by FDA of such a request under this paragraph will be subject to future review by FDA and may be revoked if FDA determines that the granted request is no longer appropriate.

[73 FR 22756, Apr. 25, 2008, as amended at 81 FR 5596, Feb. 3, 2016]

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