

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of June 11, 1996 (61 FR 29481). That document amended the animal drug regulations to reflect approval for use of single ingredient Type A medicated articles to make combination drug Type C medicated broiler chicken feeds containing semduramicin with bacitracin methylene disalicylate and roxarsone. That document failed to designate the approved sources for the drugs. This document amends the regulation to provide that information. In addition, certain cross-references are added in the animal feed regulations.

EFFECTIVE DATE: August 23, 1996.

FOR FURTHER INFORMATION CONTACT:

James F. McCormack, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1607.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 11, 1996 (61 FR 29481), FDA announced the approval of Pfizer, Inc.'s new animal drug application (NADA) 141-058, which provides for use of approved single ingredient Type A medicated articles containing Aviax™ (semduramicin sodium), BMD® (bacitracin methylene disalicylate), and 3-Nitro® (roxarsone), to make combination drug Type C medicated broiler chicken feeds used for the prevention of coccidiosis and improved feed efficiency. That document failed to state the source of the approved Type A medicated articles. It also failed to amend related regulations to provide for cross-references to these uses. This document amends the regulations in 21 CFR 558.76(d)(3)(xiv), 558.530(d)(5)(xxiv), and 558.555(b)(2)(ii) to provide for the cross-references and sources.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.76 is amended by adding new paragraph (d)(3)(xiv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xiv) Semduramicin with roxarsone as in § 558.555.

3. Section 558.530 is amended by adding new paragraph (d)(5)(xxiv) to read as follows:

§ 558.530 Roxarsone.

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(d) * * *

(5) * * *

(xxiv) Semduramicin with bacitracin methylene disalicylate as in § 558.555.

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4. Section 558.555 is amended by adding a sentence at the end of paragraph (b)(2)(ii) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(b) * * *

(2) * * *

(ii) * * * Semduramicin as provided by 000069 in § 510.600(c) of this chapter, bacitracin methylene disalicylate and roxarsone as provided by 046573.

Dated: August 14, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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21 CFR Part 584

[Docket No. 95G-0039]

Food Substances Affirmed As Generally Recognized As Safe In Feed and Drinking Water of Animals; Hydrophobic Silica

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for the listing of specific substances affirmed as generally recognized as safe (GRAS) in the feed and drinking water of animals and to provide that hydrophobic silica be affirmed as GRAS when used as an anticaking/free-flowing agent in vitamin preparations for animal feed. This action is in response to a petition filed by Degussa Corp.

EFFECTIVE DATE: August 23, 1996.

FOR FURTHER INFORMATION CONTACT:

Sharon A. Benz, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1729.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of March 21, 1995 (60 FR 14950), FDA announced that a GRAS affirmation petition for animal use (GRASP 2419) had been filed by Degussa Corp., c/o Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. This petition proposes that part 584 (21 CFR part 584) be amended to provide that hydrophobic silica, prepared by the hydrophobization of silicon dioxide with dichlorodimethylsilane, be affirmed as GRAS as an anticaking/free-flowing agent in vitamin preparations for animal feed. FDA gave interested persons until June 5, 1995, to submit comments. FDA did not receive any comments in response to that notice.

II. Standards for GRAS Affirmation

Under § 570.30 (21 CFR 570.30), general recognition of safety of food ingredients may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of food substances. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 570.30(b)). General recognition of safety through experience based on common use of a substance in food prior to January 1, 1958, may be determined without the quantity or quality of scientific evidence required for approval of a food additive regulation; but ordinarily it is to be based upon generally available data and information concerning its pre-1958 history of use (§ 570.30(c)).

The subject petition relies on scientific procedures evidence to support GRAS affirmation of hydrophobic silica in vitamin preparations for animal feed.

III. Safety Evaluation

A. Manufacturing Process

According to the information in the petition, hydrophobic silica is manufactured from fumed amorphous silicon dioxide or precipitated silica by chemical reaction (methylation) of the

surface of the silicon dioxide particle with the methylating agent, dichlorodimethylsilane. The dichlorodimethylsilane is mixed with a slurry of silicon dioxide and reacts with most of the silanol groups (-Si-OH) on the surface of the particle and converts them to methylsilyl groups (-Si-CH₃). The methylation reaction occurs only at the surface of the silicon dioxide particle leaving 97 to 99 percent of the silicon dioxide intact. Thus, the particle of hydrophobic silica may be viewed as being composed of silicon dioxide with a surface of dimethylpolysiloxane ((CH₃)₂SiOSi(CH₃)₂).

After further processing, the resulting hydrophobic silica generally contains 97 to 99 percent silicon dioxide. Fumed hydrophobic silicas generally contain greater than 99 percent silicon dioxide and precipitated hydrophobic silica contain greater than 97 percent silicon dioxide.

Silicas used in the production of hydrophobic silica will be food-grade and meet the requirements for purity as defined in the Food Chemical Codex, 3d edition, and the U.S. Pharmacopoeia and National Formulary XVII. The specifications for hydrophobic silica are those for silicon dioxide in the Food Chemical Codex, with the exception of a specification for not more than 50 parts per million (ppm) of dichlorodimethylsilane.

B. Uses of Hydrophobic Silica

The proposed use of hydrophobic silica is as an anticaking/free-flow agent in vitamin preparations for animal feed, as described in 21 CFR 170.3(o)(1). Anticaking agents are processing aids used to impart noncaking, free-flowing properties to dry foods by decreasing adhesion forces between particles of materials to which they are added. Anticaking agents are commonly used in many foods, such as salt, spices, cereals, and sugars, and in complete animal feeds and feed ingredients in a manner similar to human foods.

The methylation of the surface of the silicon dioxide particle only serves to render the particle surface of silicon dioxide hydrophobic. The increased hydrophobicity of the particle surface allows hydrophobic silica to act as anticaking and free-flow agents for hydrophobic substances, such as vitamin A preparations. The individual vitamin particles are coated with silica, which prevents caking and provides free-flow characteristics.

Information supplied by the petitioner evidences that silicas and silicates have been used as direct food and feed ingredients for several decades. Silicon in the form of silicon dioxide is

commonly used as an anticaking agent in various feed ingredients and complete feeds (21 CFR 573.940). Other silicates including silica aerogel (21 CFR 582.1711); aluminum calcium silicate (21 CFR 582.2122); calcium silicate (21 CFR 582.2227); magnesium silicate (21 CFR 582.2437); sodium aluminosilicate (21 CFR 582.2727); hydrated sodium calcium aluminosilicate (21 CFR 582.2729); and tricalcium silicate (21 CFR 582.2906) are recognized as GRAS as anticaking agents and have a history of use in the feed industry as such.

The petition proposes that hydrophobic silica should not be used at levels greater than 5 percent in the vitamin preparation. This would result in no more than 1.5 ppm of hydrophobic silica in the finished feed. Other silicates are commonly used at levels 2 to 2.5 percent or 2,000 ppm in finished feeds. The proposed use of hydrophobic silica is not expected to significantly contribute to the consumption of silicate by animals.

C. General Recognition of Safety of Silicates

The petition provides information to support a determination that the use of hydrophobic silica is GRAS based upon the existence of an expert consensus that the components of hydrophobic silica have been shown to be safe based on scientific procedures and that the safety characteristics of the components can be extended to the product, hydrophobic silica. Foremost in the support of safety is published information indicating that similar silicate compounds are nontoxic at current levels used in food and feed, and that the inherent safety of silicon dioxide is not changed by making the surface portion hydrophobic because the toxicological profile is essentially the same as commonly used silicas.

Both silicon dioxide and dimethylpolysiloxane have been widely used for years in the food, feed, pharmaceutical and dental industries. Information in the petition shows that the food safety of silicas has been evaluated by numerous scientific panels. These panels include the Select Committee on GRAS Substances of the Federation of the American Society for Experimental Biology (the Select Committee) that reviewed the use, exposure, and safety of silicas and silicates in 1979. This committee concluded that the absorption of ingested silicas is limited by its solubility in the contents of the alimentary canal and the absorability of silicon dioxide appears to be slight. Further, the Select Committee concluded that silicon dioxide and

various silicates occur abundantly in the earth's crust and are present in practically all natural waters, animals, and plants; they are part of the normal diet, and silicon compounds consumed as added food ingredients constitute only a minor proportion of the total dietary silicon intake (Ref. 1).

The Select Committee also reviewed the properties, uses, and safety of methylpolysiloxanes for use as direct food ingredients in 1981, and it concluded that methylpolysiloxanes (also called dimethylpolysiloxane) used in food consist of high molecular weight compounds that are not absorbed to any appreciable extent from the gastrointestinal tract and have been demonstrated to be of low acute and chronic toxicity to animals and man. Moreover, the Select Committee also recognized the medical use of dimethylpolysiloxane as dimethicone and simethicone. Simethicone is widely used in over-the-counter drugs as an antifatulence ingredient, and as such, is generally recognized as safe and effective (21 CFR 332.10) (Ref. 2).

The Scientific Committee for Food of the Commission of European Communities, which reviewed the safety of silicates and silicon dioxides in 1991, concluded that available published data on orally administered silica and silicates, including amorphous silicon dioxide, substantiate the biological inertness of these compounds. It also concluded that silicates and silicones are sufficiently safe so that a restriction on their use is not required nor is the establishment of an acceptable daily intake (Ref. 3).

The Food and Agriculture Organization/World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives reached the same conclusion as the Scientific Committee for the European Communities and also determined that an acceptable daily intake was not necessary (Ref. 4).

D. Corroborating Evidence of Safety of Hydrophobic Silica

The petitioner also submitted relevant toxicological data that supports the safety of hydrophobic silica to man and animals. The submitted information is an article in the published literature entitled "Characterization and Toxicological Behavior of Synthetic Amorphous Hydrophobic Silica" (Ref. 5). The results reported from testing indicate that fumed or precipitated hydrophobic silica does not produce inflammation of the skin or mucous membranes, and acute and chronic oral tests yielded no adverse systemic effects. The submitted information

indicates that hydrophobic silica is nontoxic and the lack of toxicity is related to hydrophobic silica's nonabsorbability. The toxicological profile was essentially the same as similar GRAS silicates.

IV. Conclusion

The agency has determined that the petition provides information to support a determination that the use of hydrophobic silica is GRAS based upon the existence of an expert consensus that the components of hydrophobic silica have been shown to be safe based on scientific procedures and that the safety characteristics of the components apply to the product, hydrophobic silica. Foremost in the support of safety is published information indicating that similar silicate compounds are safe at current levels used in food and feed and that the inherent safety of silicon dioxide is not changed when the particle surface is altered by methylation. Corroborating evidence has shown that the toxicological profile for hydrophobic silica is essentially the same as commonly used silicas. Therefore, the agency is affirming that hydrophobic silica when used as an anticaking/free-flowing agent in vitamin preparations for animal feed is GRAS when used in accordance with good manufacturing or feeding practices at levels not to exceed 5 percent of the vitamin preparation.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. Because no current activity is prohibited by this final rule, the compliance cost to firms is zero. Because no increase in the health risks faced by consumers will result from this final rule, total costs are

also zero. Potential benefits include wider use of this substance because of reduced uncertainty concerning its GRAS status, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this substance for this use. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

VII. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act, 5 U.S.C. 553(d). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. GRASP 2419, Appendix 11, "Evaluation of the Health Aspects of Certain Silicates as Food Ingredients: Report of the Select Committee on GRAS Substances."

2. GRASP 2419, Appendix 12, "Evaluation of the Health Aspects of Methylpolysilicones as Food Ingredients: Report of the Select Committee on GRAS Substances."

3. GRASP 2419, Appendix 10, "Report on Silicates and Silicon Dioxide: The Scientific Committee for Food of the Commission of the European Communities."

4. GRASP 2419, Appendix 13, "Evaluation Status of Silicon Dioxide (JECFA);" "FAO/WHO Food Additives Data System;" "FAO Food and Nutrition Paper," vol. 30/Rev. 1, 1985; "Evaluations of the Joint FAO/WHO Expert Committee on Food Additives," 1956-1984.

5. GRASP 2419, Appendix 6, "Characterization and Toxicological Behavior of Synthetic Amorphous Hydrophobic Silica."

List of Subjects in 21 CFR Part 584

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 584 is amended as follows:

PART 584—FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 584 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 584.700 is added to subpart B to read as follows:

§ 584.700 Hydrophobic silicas.

(a) *Product.* Amorphous fumed hydrophobic silica or precipitated hydrophobic silica (CAS Reg. No. 68611-44-9, 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.

Dated: August 18, 1996.
 Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
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 BILLING CODE 4160-01-F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket number H-033-e]

RIN 1218-AB25

Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule: corrections.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is correcting certain provisions of the final asbestos standards issued August 10, 1994 (59 FR 40964) and corrected and clarified June 29, 1995 (60 FR 33974) and September 29, 1995 (60 FR 50411).

EFFECTIVE DATE: These amendments take effect September 23, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Cyr, Office of Information and Consumer Affairs, OSHA, U. S. Department of Labor, Room N3647, 200 Constitution Avenue, N.W., Washington, DC 20210; telephone: (202) 219-8151.

SUPPLEMENTARY INFORMATION:

1. Background

On August 10, 1994, OSHA issued asbestos standards for general industry, construction work, and shipyard work. 59 FR 40964. On June 29, 1995, and September 29, 1995, OSHA issued notices correcting and clarifying various provisions of those standards. 60 FR 33974; 60 FR 50411. This notice further corrects various provisions of the standards and clarifies the meaning of certain provisions of the standards.

The corrections set forth in this document are based on the existing rulemaking record and are not intended to affect the protection afforded by the standards in a significant way. OSHA therefore finds good cause, pursuant to 29 CFR 1911.15 and the Administrative Procedure Act, for promulgating the corrections without notice and opportunity for public comment.

This preamble will describe the changes to the regulatory text of the standards and will also clarify the meaning of certain existing provisions of the asbestos standards.

2. Respirators

The standards require that engineering and work practice controls be supplemented by respirator use when employees are exposed to asbestos fibers in concentrations exceeding the permissible exposure limit (PEL) and in certain other circumstances. The type of respirator that may be used depends on the amount by which exposures are expected to exceed the PEL. When exposures are less than 10 times the PEL, half-mask air-purifying respirators equipped with high efficiency filters may be used. Full-facepiece air-purifying respirators with high efficiency filters are permissible for exposures up to 50 times the PEL. Higher exposures require the use of positive pressure respirators, either powered air-purifying respirators (for exposures up to 100 times the PEL) or full facepiece supplied-air respirators (for even higher exposures).

Paragraph (h)(2)(iii) of the construction and shipyard standards provides that any employee who must wear a respirator under the standard may require that the employer provide him or her with a powered air-purifying respirator in lieu of a negative pressure respirator. Accordingly, even if the amount of asbestos to which an employee is exposed would permit that employee to be protected by a negative pressure respirator, an employee who wishes to wear a more effective respirator may require the employer to provide a powered air-purifying respirator.

It is important that employees understand that they have this choice. Accordingly, paragraph (h)(2)(iii) of the construction and shipyard standards is being revised to state explicitly that the employer must inform employees of their right to require provision of a powered air-purifying respirator in lieu of a negative pressure respirator. This requirement for employee notification is already implicit in provisions of the standards requiring that employees who perform work that is covered by a standard be trained in the contents of the standard. By stating explicitly that the employer must inform employees who are required to wear respirators that the employee may require the employer to provide a powered air-purifying respirator, the standards will better assure that employees receive the information they need to exercise the option afforded them by paragraph (h)(2)(iii).

3. Signs and Labels

The asbestos standards require that signs and labels be used to warn

employees of the presence of asbestos in buildings and vessels. When the 1994 standards were issued, certain provisions for signs and labels were carried over from earlier standards issued in 1986, and other provisions were added.

In resolving the judicial challenges to the 1986 standards, the court of appeals ordered OSHA to reconsider its determination not to require signs and labels to be in languages other than English. In response to the court's order, OSHA did not require that signs and labels be in languages other than English but did take other steps to assure that employees who were not fluent in English understood the warnings provided by the signs and labels. The agency added a new requirement that the training program specifically cover the contents of signs and labels and also required that the training assure that employees comprehend the warning signs. With these changes, OSHA concluded that the entire hazard communication program required by the standard "will ensure that all exposed employees are effectively warned of the presence and hazards of asbestos-containing material on worksites." 55 FR 3724, 3730 (Feb. 5, 1990).

The 1994 standards carried over the provisions requiring that employees be trained in the contents of signs and labels and that the training be conducted in a manner that the employee can comprehend. To further ensure that workers understand the warnings provided by signs and labels, the June 29, 1995 notice added a requirement to the construction and shipyard standards stating that the employer assure that the signs required at the entrance to regulated areas be comprehensible to employees. The regulated area sign provisions listed foreign languages, pictographs and graphics, as means to promote employee comprehension.

OSHA has determined that language stating the need to promote employee comprehension of signs and labels should be included in all of the sign and label requirements found in the asbestos standards. Accordingly, this notice revises paragraph (j)(3)(v) of the general industry standard, and paragraphs (k)(6) and (k)(8)(vii) of the construction and shipyard standards, to similarly state that employers must assure employee comprehension of the signs and labels. These revisions will provide for consistency in all of the provisions of the standards that require asbestos warning signs and labels and will therefore better assure that workers, particularly those who are not fluent in