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 Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for small businesses. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866.

Affirming that the use of HFCS that contains either not less than 42 percent fructose or not less than 55 percent fructose in food is GRAS will expand the formulation possibilities for food manufacturers, including small businesses. Therefore, in accordance with the Regulatory Flexibility Act, FDA has also determined that this rule will have a positive impact on small businesses.

Because no current activity is prohibited by this final rule, the compliance cost to firms is zero. Total costs are also zero because there will be no increase in the health risks faced by consumers resulting from this final rule. Potential benefits include the wider use of these substances to achieve intended technical effects and the savings that will result from not having to prepare any new petitions to affirm that the use of these substances in food is GRAS.

VI. 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)).

VII. References

The following references have been placed on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1.''Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Ingredients'' (SCOGS–50), Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1976.

2.''Evaluation of the Health Aspects of Sucrose as a Food Ingredient'' (SCOGS–69), Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1976.

3. Glinsmann W. H., H. Irausquin, and Y. K. Park, ''Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners,'' Report of Sugars Task Force 1986, *Journal of Nutrition*, 116(11S):S1–S216, 1986.

4. Franz, M. J. et al, ''Nutrition Principles for the Management of Diabetes and Related Complications,'' *Diabetes Care*, 17:490–518, 1994.

5. American Diabetes Association, ''Nutrition Recommendations and Principles for People with Diabetes Mellitus,'' *Diabetes Care*, 17:519–522, 1994.

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follow:

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

§ 182.1866 [Removed]

2. Section 182.1866 *High fructose corn syrup* is removed from subpart B.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 184 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).

4. Section 184.1372 is amended by revising paragraph (a) to read as follows:

§ 184.1372 Insoluble glucose isomerase enzyme preparations.

(a) Insoluble glucose isomerase enzyme preparations are used in the production of high fructose corn syrup described in § 184.1866. They are derived from recognized species of precisely classified nonpathogenic and nontoxicogenic microorganisms, including *Streptomyces rubiginosus, Actinoplanes missouriensis, Streptomyces olivaceus, Streptomyces olivochromogenes, and Bacillus coagulans*, that have been grown in a pure culture fermentation that produces no antibiotics. They are fixed (rendered insoluble) for batch production with GRAS ingredients or may be fixed for further immobilization with either GRAS ingredients or materials approved under § 173.357 of this chapter.

* * * * *

5. Section 184.1866 is added to subpart B to read as follows:

§ 184.1866 High fructose corn syrup.

(a) High fructose corn syrup, a sweet, nutritive saccharide mixture containing either approximately 42 or 55 percent fructose, is prepared as a clear aqueous solution from high dextrose-equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation described in § 184.1372. The product containing more than 50 percent fructose (dry weight) is prepared through concentration of the fructose portion of the mixture containing less than 50 percent fructose.

(b) The ingredient shall conform to the identity and specifications listed in the monograph entitled ''High-Fructose Corn Syrup'' in the Food Chemicals Codex, 4th ed. (1996), pp. 191–192, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

Dated: August 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–21482 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Semduramicin with Bacitracin Methylene Disalicylate and Roxarsone; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

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.

* * * * *

(d) * * *

(5) * * *

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

* * * * *

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.

[FR Doc. 96–21483 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–01–F

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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