Issued in Kansas City, Missouri, on March 6, 2007.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–4729 Filed 3–15–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 584

[Docket No. 1995G–0321] (formerly 95G–0321)

Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals: 25-Hydroxyvitamin D_3

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of 25-hydroxyvitamin D_3 is generally recognized as safe (GRAS) as a source of vitamin D_3 activity in broiler chicken feeds and drinking water when used in accordance with certain limitations. This action is in response to a petition filed by Amoco BioProducts Corp. Subsequently, the sponsorship for this petition was changed to IsoGen L.L.C., Monsanto Co., Roche Vitamins, Inc., and lastly, to DSM Nutritional Products, Inc.

DATES: This rule is effective March 16, 2007.

FOR FURTHER INFORMATION CONTACT: Michaela Alewynse, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6866, e-mail: *mika.alewynse@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in 21 CFR 570.35, Amoco BioProducts Corp., P.O. Box 3011, Naperville, IL, 60566, submitted a petition (GRASP 2449) requesting that 25-hydroxyvitamin D_3 (25-OH D_3) be affirmed as GRAS for use as a source of vitamin D_3 activity in broiler chicken feeds. In the original petition, 25-OH D_3 was proposed for use in feed only. The proposed use was amended in a submission dated January 7, 1998, to include administration through drinking water. Furthermore, all data for feed are applicable to water.

FDA published a notice of filing of this petition in the **Federal Register** of October 24, 1995 (60 FR 54505), and gave interested parties an opportunity to submit comments to the agency. FDA did not receive any comments in response to that notice. Subsequent to the filing of the petition, sponsorship was changed to IsoGen L.L.C., Monsanto Co., Roche Vitamins, Inc., and lastly, to DSM Nutritional Products, Inc., 45 Waterview Blvd., Parsippany, NJ, 07054–1298.

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 directly or indirectly added to food. The basis of such views may be either of the following: (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. Ordinarily it is to be based upon generally available data and information (§ 570.30(c)).

The subject petition relies on scientific procedures evidence to support the GRAS affirmation of 25-OH D_3 as a source of vitamin D_3 activity in broiler chicken feeds and drinking water.

III. Safety Evaluation

A. Introduction

25-OH D_3, also called 25-hydroxycholecalciferol, is a normal metabolite of vitamin D_3 in mammals and birds. Chemically, the substance is 9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol. 25-OH D_3 is the principal circulating form of vitamin D_3, which is the primary source of vitamin D activity for livestock animals. The metabolism of vitamin D in animals is well understood and is documented in biochemistry textbooks (for example, Ref. 1). In poultry, vitamin D regulates calcium and phosphorus homeostasis, bone growth, eggshell formation, as well as other endocrine system functions (Ref. 2).

Animals, including poultry, do not have a dietary requirement for vitamin D when sufficient ultraviolet (UV) light is available, because vitamin D is produced through action of UV light on a provitamin present in the skin. This provitamin is synthesized in the body and present in large amounts in skin, intestinal wall, and other tissues (Ref. 2). Vitamin D becomes a nutritionally important factor in the absence of sufficient UV light either from the sun or from an artificial source. Under modern farming conditions, many animals are raised in total confinement with limited exposure to UV light thus creating the need for a dietary supply of vitamin D.

There are two predominant forms of vitamin D for poultry. Vitamin D_2 comes mainly from plants. Vitamin D_3 is produced in a bird's body when sunlight reacts with vitamin D precursors obtained from the bird's diet. Since vitamin D_3 is 30 to 40 times more potent than D_2, plants are considered insignificant sources of vitamin D for birds.

Commonly, broiler chickens are grown within the confines of buildings with large numbers of birds per building and are supplied with bulk feed and water for *ad libitum* consumption. Various strains of chicken have been developed for broiler production. They have been bred primarily for rapid weight gain and efficient feed utilization. Typically, broilers are slaughtered at 6 to 7 weeks of age if size and weight requirements are attained. Crumbled starter feed is supplied during weeks 1 to 3, pelletized grower feed during weeks 4 to 6, and finisher feed until slaughter. The major differences among these types of feed are the levels and sources of nutrients provided in the feed, such as amino acids, minerals, and vitamins. The level of vitamin supplementation provided in the broiler industry is based on type of diets fed, species, age of the bird, dietary antagonists, form of vitamin product, requirement status (optimum or minimum requirements), disease status, complexity of the ration, and environmental factors, primarily ambient temperature. Only after all these factors are considered can the optimal vitamin requirements for poultry be estimated (Ref. 2).

The National Research Council's (NRC) recommendation for dietary vitamin D_3 requirement of broiler chickens is 200 International Units (IU) of vitamin D_3 per kilogram (/kg) of feed (Ref. 3). One unit of vitamin D_3 is

defined as the activity of 0.025 microgram (µg) of vitamin D_3. Thus, a supplement of 200 IU/kg of feed is equivalent to 5 µg of vitamin D_3/kg of feed. This requirement is based on diets containing the required amounts of calcium and available phosphorus and is considered by NRC to be the minimum amount required to prevent deficiency signs.

B. Manufacturing and Specifications

According to the petition, the production of 25-OH D_3 uses a bioengineered strain of the yeast *Saccharomyces cerevisiae*. The 25-OH D_3 final product is a white to slightly pink, odorless, crystalline substance. The petition lists the specifications for 25-OH D_3 as: not less than 94.0 percent 25-OH D_3; not more than 1 percent of any individual sterol; not more than 5 percent water; not more than 20 parts per million (ppm) lead; not more than 20 ppm aluminum; not more than 1.0 percent solvents; and non-detectable levels of 2', 4', 5', 7'-tetraiodofluorescin. In order to ensure vitamin potency so that the 25-OH D_3 ''performs an appropriate function in the food,'' an expiration date should be included on feed and water premixes (§ 570.30(f)(2)).

C. Use in Feed and Drinking Water

The petitioner claims that the NRC recommendation of 5 µg of vitamin D_3/kg of feed is virtually never used in the broiler industry because commercial broiler strains currently grow much faster, utilize feed more efficiently, and are reared in confinement with less exposure to UV light than when the NRC made its recommendation. As a result, petitioner claims supplementation of broiler feed with vitamin D_3 is typically at a considerably higher level. A survey of commercial practices in regard to vitamin supplementation of poultry feed supported this argument, i.e., it revealed that the amounts of vitamin D_3 commonly added by the broiler chicken feed companies range from 50.0 to 62.5 parts per billion (ppb) (µg/kg) of finished feed (Ref. 4).

The petitioner proposes that 25-OH $D_3$is GRAS when added to broiler chicken feed at levels not to exceed 69 ppb (µg/kg) of finished feed. Based on the manufacturing and composition of a liquid product and its liquid release and stability data, the petitioner also proposes that 25-OH D_3 is GRAS when added to broiler chickens' drinking water at levels not to exceed 34.5 ppb. This is because it is generally assumed that birds drink approximately twice as much water as the amount of feed consumed on a weight basis. To assure safe use of 25-OH D_3, the label and labeling shall bear adequate mixing directions to ensure that the product (and its premixes) is uniformly blended throughout the feed or drinking water. In addition, since there are no animal consumption data to support the concurrent use of 25-OH D_3 in feed and water, there must be a statement on all premix labeling (feed and drinking water forms) that 25-OH D_3 should not be used concurrently in both feed and water.

D. General Recognition of Safety

The petition provides information to support a determination that the use of 25-OH D_3 in broiler chicken diets or drinking water is GRAS based upon the existence of an expert consensus, based on scientific procedures, that 25-OH D_3 has been shown to be safe. Foremost in the support of the determination is the same kind and quality of safety data as would be required to obtain FDA approval of 25-OH D_3 for use as a food additive. In particular, the majority of the data is published, and there is a consensus among qualified experts, based on the data, that this use of the substance is safe.

Information in the petition shows that the safety of 25-OH D_3 has been evaluated by an expert panel. The expert panel was convened by the Life Sciences Research Office, Federation of American Societies for Experimental Biology. The expert panel obtained background information, identified and analyzed pertinent literature and experimental studies, and reached an opinion as to whether the available information and data on the health effects of 25-OH D_3 were sufficient to meet the regulatory requirements of safety as a GRAS substance for the intended use. The expert panel concluded that the available information supports a GRAS classification of 25-OH D_3 when supplied as a source of vitamin D activity in broiler feed at the intended level of use of about 69 µg/kg of feed. Corroborating evidence has shown that 25-OH D_3 is a normal metabolite of vitamin D_3 and the principal circulating form of vitamin D_3 in mammals and birds (Ref. 2). In addition, the petitioner provided testimony of a world-renowned expert on vitamin D who concluded that 25-OH D_3 would be a safer dietary ingredient than vitamin D, since it does not accumulate in the body and thus, would not cause toxicity because of accumulation to toxic levels (Ref. 5).

1. Target Animal Safety

The NRC reported that the existing data for broiler chickens do not allow precise estimates to be made for maximum vitamin D (and vitamin D metabolites such as 25-OH D_3) tolerance levels; however, it indicated that under short-term feeding conditions (less than 60 days), most species including chickens, can tolerate as much as 100 times (100 X) their apparent vitamin D dietary requirements, i.e., 500 µg/kg of feed (Ref. 6).

Estimates of the tolerance of 25-OH D_3 by broiler chickens were assessed by the expert panel (Ref. 7) primarily from two field trials conducted for Amoco BioProducts Corp. The aim of these studies was to determine the utility of 25-OH D_3 as a source of vitamin D_3 activity and/or to evaluate whether 25-OH D_3 exhibited toxic effects when added to broiler diets. One of the studies (Ref. 8) was compromised due to the high mortality rate (up to 16 percent) that occurred in all groups including controls. The other study (Ref. 9) was requested by the expert panel and is discussed below.

In addition to the field trials conducted for Amoco BioProducts Corp., the expert panel evaluated information from separate published sources, including the results of several animal feeding studies. Based on its comprehensive review of the literature, the expert panel concluded that dietary levels up to 10 µg of 25-OH D_3/kg of feed are safe for broiler chickens for prolonged feeding. It was noted that broiler chickens fed 100 µg of 25-OH D_3/kg of feed exhibited toxicity signs characterized by epithelial necrosis and mineralization in the distal convoluted tubules of the kidney (Ref. 10). However, a detailed evaluation of the study revealed significant inadequacies in its design and experimental procedures. Thus, the expert panel did not place great weight on this study in its evaluation of safety. Additionally, a number of studies were performed in other poultry species. No signs of toxicity were reported in laying hens when 25-OH D_3 was fed at levels up to 50 µg/kg of feed for periods up to 448 days (Ref. 11). Laying Japanese quail and growing turkeys were fed diets containing up to 16.6 µg of 25-OH D_3/kg of feed for periods up to 42 days with no adverse effects recorded (Refs. 12 and 13).

Because the concentration of 25-OH D_3 in broiler feed that may elicit toxic effects was not known, the expert panel requested that Amoco BioProducts Corp. conduct an additional target animal safety study (Ref. 9). 25-OH D_3

was tested at multiple levels at and above (0, 1, 10, 50, 100, and 200X) the maximum proposed use level. No significant differences in body weight, mortality rate, or treatment-related lesions were observed in the 25-OH D_3 group at the maximum proposed level of 69 µg/kg of feed. However, 35 percent of the birds in the 690 µg 25-OH D_3/kg group (10X) developed renal calcification. In addition, by the end of the study, the body weights of the birds from the 690 µg/kg group fell 12 percent when compared with the birds from the 69 µg/kg group. Data were not collected to determine the level between 69 and 690 µg 25-OH D_3/kg of feed at which toxic effects were seen. High mortality was observed in birds exposed to high levels of 25-OH D_3 (50, 100, and 200X) thus, these treatments were terminated before the end of the study. Based on its review of the available information, including the results of this additional study, the expert panel concluded that the proposed maximum level (69 µg 25-OH D_3/kg of feed) is within the range that growing broilers can tolerate.

After evaluating the results of the latter study (Ref. 9), FDA found that, although no toxic effects were observed at the maximum proposed use level (69 µg/kg of feed), significant treatment-related lesions occurred when birds were exposed to 10 times (690 µg/kg of feed) that level. In the absence of key data to determine the level between 69 and 690 µg/kg at which toxicity effects were seen, there was no assurance that toxicity would not occur at levels just above 69 µg/kg. Thus, to identify the margin of safety for the intended use, FDA requested another target animal safety study.

The study (Ref. 14) was designed to show safety to broiler chickens by testing 25-OH D_3 at varying levels between 69 and 690 µg/kg of feed which represented 0 (control), 1, 3, 5, and 10 times the maximum proposed use level. The results of the study corroborated previous findings that 25-OH D_3 supplementation at levels up to the maximum proposed use rate resulted in no toxic effect, and at levels 10 times the proposed use level resulted in renal calcification. The study also found that no treatment-related lesions occurred when broilers were fed at levels up to five times the highest proposed use level.

FDA has determined that the published studies, as corroborated by this unpublished study, provide an adequate basis upon which to conclude that 25-OH D_3 is a safe source of vitamin D_3 activity for broiler chickens when fed at nutritional levels not to exceed 69 µg/kg of finished feed.

2. Consumer Exposure

The safety of 25-OH D_3 has been evaluated to assess its potential toxicity in humans who consume edible tissues derived from broiler chickens fed 25-OH D_3—supplemented feed. The evaluation was based on FDA's review of published and unpublished information provided in the petition, including the safety evaluation performed by the expert panel (Ref. 7). Based on the available information and evaluation of the biological effects of 25-OH D_3, the expert panel concluded that ''The available information supports a Generally Recognized as Safe (GRAS) classification of 25-hydroxyvitamin D_3 when supplied as a source of vitamin D activity in broiler feed at the intended level of use of about 68.8 µg (63.8 to 73.7 µg) per kilogram of feed.''

Having evaluated the data and information contained in the petition, FDA preliminarily found that this use of 25-OH D_3 in broiler feed was safe; however, some concerns regarding the teratogenicity of 25-OH D_3 in the rabbit (the most sensitive species) remained. Specifically, Dutch Belted rabbits dosed at 25 and 50 µg/kg bodyweight (BW)/day by oral intubation from gestation day 6 to day 18 produced pups with skeletal and vascular anomalies. These dose-related effects included domed skulls, enlarged cardiac atria, and dilated pulmonary arteries. None of these abnormalities were noted in the negative controls or the 5 µg/kg BW/day group. This and other toxicity studies were previously reviewed by FDA in support of the use of 25-OH D_3 as the therapeutic drug for humans, calcifediol (Ref. 15).

The petitioner argued that the rabbit's unique calcium metabolism and unusual sensitivity to the effects of vitamin D compounds rendered it too sensitive a model for assessing the teratogenic potential of vitamin D in humans (Ref. 16). In addition, the petitioner provided the testimony of Dr. Hector De Luca, a world-renowned expert (Ref. 5) on vitamin D, who noted that rabbits are extraordinarily sensitive to vitamin D and that they rapidly go into hyperglycemia at low doses of any form of vitamin D. Dr. De Luca stated that in the rabbit, hyperglycemia likely causes the observed teratogenic effects. In the expert's view, the rabbit should not be used as a toxicology model for man for studies of vitamin D compounds, because they almost stand alone in their sensitivity among species used for the safety studies.

Based on information provided in the petition, FDA concurs that the rabbit is unusually sensitive to the effects of vitamin D compounds. However, the agency does not have sufficient information to disqualify the rabbit model in toxicity testing. While not disregarding the rabbit study, FDA took into account the high sensitivity of the rabbit model and used a 100-fold safety factor rather than the usual 1000-fold safety factor in calculating an acceptable daily intake (ADI) for 25-OH D_3. Consequently, FDA set the ADI based on current information at 0.05 µg/kg BW/day. The safe concentrations of 25-OH D_3 in chicken tissues based on an ADI of 0.05 µg/kg BW/day is 10 ppb in muscle, 30 ppb in liver, and 60 ppb in skin/fat. These values are well within the estimated safe concentrations for consumers (Ref. 17). Although liver concentrations of 25-OH D_3 were not measured, it is anticipated that these values similarly would be within the calculated acceptable levels. FDA concludes that the available data indicate that residue levels of 25-OH D_3 will not result in any unsafe residues of 25-OH D_3 in edible chicken tissues.

In its evaluation of 25-OH D_3, FDA has reviewed not only the safety of the product itself, but also the safety of the chemical impurities that may be present in the product from the manufacturing process. Residual amounts of reactants and manufacturing aids are commonly found as contaminants in chemical products, including products added to animal feeds.

The biological stain, 2', 4', 5', 7'-tetraiodofluorescin (also known as FD&C Red No. 3 or erythrosin), is used as a photosensitizer in the production of 25-OH D_3. This use of 2', 4', 5', 7'-tetraiodofluorescin may result in unintended residue levels of 50 ppm maximum in the finished 25-OH D_3 product (Ref. 18). At a 50 ppm concentration in the 25-OH D_3 final product, when the 25-OH D_3 is diluted in feed to a concentration of 69 ppb (69 µg/kg), 2', 4', 5', 7'-tetraiodofluorescin would be present at 3.45 parts per trillion (ppt) in finished broiler chicken feed.

FDA used risk assessment procedures to estimate the upper-bound of risk presented by 2', 4', 5', 7'-tetraiodofluorescin, a carcinogenic chemical (21 CFR 81.10(u)), that may be present in the 25-OH D_3 product. Using a worst case estimate, taking into account a bird feed efficiency of approximately 1.9 and 80 percent uptake, the worst case concentration of 2', 4', 5', 7'-tetraiodofluorescin in edible tissue would be 5.2 ppt (3.45 ppt x 1.9 x 0.8 = 5.2 ppt). Therefore, the agency would not expect this impurity to become a component of food at other than minute levels. However, because

2', 4', 5', 7'-tetraiodofluorescin is a carcinogenic chemical, FDA advised that the sponsor should either find a replacement for 2', 4', 5', 7'-tetraiodofluorescin or remove 2', 4', 5', 7'-tetraiodofluorescin from the final product in a consistent manner. Subsequently, the petitioner developed a purification process for complete removal of 2', 4', 5', 7'-tetraiodofluorescin from the final 25-OH D_3 product. The petitioner provided details on the experimental conditions and the supporting analytical data for the analytical method used to quantitate residual 2', 4', 5', 7'-tetraiodofluorescin in the 25-OH D_3 product. FDA found the purification process to be effective based on the analytical work submitted. The analytical method for the detection of the 2', 4', 5', 7'-tetraiodofluorescin has been appropriately validated by the petitioner and FDA found it to be accurate, precise, and acceptable for its purpose.

IV. Conclusion

FDA has determined that the petition provides information to support a determination that the use of 25-OH D_3 is GRAS as a source of vitamin D_3 activity for broiler chicken feeds and drinking water based upon the existence of an expert consensus that 25-OH D_3 has been shown to be safe based on scientific procedures. The determination was based upon published scientific data, corroborating unpublished studies, and other data and information. The agency has reached the following conclusions: (1) 25-OH D_3 is a suitable source of vitamin D_3 activity for broiler chickens; (2) 25-OH D_3 at levels up to 69 ppb in feed, or 34.5 ppb in drinking water, is safe to broiler chickens and to the people consuming the broiler chickens' edible meat products; and (3) an expert panel also concluded that the available information supports a GRAS classification for 25-OH D_3 when supplied as a source of vitamin D activity in broiler feed at the intended level of use of 69 µg/kg of feed.

The evaluation was based on the same type and quality of data as would be required to obtain FDA approval of 25-OH D_3 for use as a food additive. In addition, the majority of the data is published, and there is a consensus among qualified experts, based on the data, that this intended use of the substance is safe. Corroborating evidence has shown that 25-OH D_3 is a normal metabolite of vitamin D_3 and the principal circulating form of vitamin D_3 in mammals and birds. In addition, the petitioner provided testimony of a world-renowned expert on vitamin D who stated that 25-OH D_3 would be a safer dietary supplement than vitamin D, since it does not accumulate in the body and thus, would not cause toxicity because of accumulation to toxic levels. Therefore, the agency is issuing this final rule affirming that 25-OH D_3 is GRAS as a source of vitamin D_3 activity in broiler feeds and drinking water when given to broiler chickens at nutritional levels not to exceed 69 ppb in feed or 34.5 ppb in drinking water and when used in accordance with additional limitations.

V. Environmental Impact

FDA has determined under 21 CFR 25.32(r) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 therefore will be effective immediately (5 U.S.C. 553(d)(1)).

VII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Garret, R. H. and C. M. Grisham, ''The Vitamin D Group,'' in *Biochemistry*, 2d ed., Saunders College Publishing, New York, NY, pp. 604–605, 1999.

2. Ameenuddin, S., M. L. Sunde, E. M. Cook, *World's Poultry Science Journal*, vol. 41, pp. 52–63, 1985 (available in the petition: vol. 17, pp. 4463–4474).

3. National Research Council, ''Vitamins,'' p. 15, and ''Nutrient Requirements of Chickens,'' pp. 19–34, in *Nutrient Requirements of Poultry*, 9th ed., National Academy Press, Washington, DC, 1994.

4. Ward, N. E., *Journal of Applied Poultry Research*, vol. 2, pp. 286–296, 1993 (available in the petition: vol. 19, pp. 5619–5629).

5. GRASP 2449, Amendment C–0032: ''Safety of 25-OH D_3 to Consumers,'' (testimony of Dr. Hector De Luca), November 1999.

6. National Research Council, ''Vitamin D,'' in *Vitamin Tolerance of Animals*, 1st ed., National Academy Press, Washington, DC, pp. 11–22, 1987.

7. GRASP 2449, Appendix E: Expert Panel Report, Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD, 1994.

8. Quarles, C. L., Safety study using 25-OH D_3 in broiler chickens, Colorado AM–1–93, Colorado Quality Research Inc., Fort Collins, CO, 1993, (available in the petition: vol. 11, pp. 02005–02493).

9. Quarles, C. L., Safety study using 25-OH D_3 and vitamin D_3 in broiler chickens, Colorado AM–2–94, Colorado Quality Research, Inc., Fort Collins, CO, 1994, (available in the petition: vol. 12, pp. 2494–2862).

10. Morrissey, J. L., et al., *Journal of Nutrition*, vol. 107, pp. 1027–10324, 1977 (available in the petition: vol. 19, pp. 5220–5227).

11. Janssen, W. M. M. A., H. A. J. Versteegh, P. J. W. Van Schagen, *Archiv fur Geflugelkunde*, vol. 45, pp. 194–200, 1981 (available in the petition: vol. 18, pp. 5018–5024).

12. Kaetzel, D. M., Jr. and J. H. Soares, Jr., *Journal of Nutrition*, vol. 109, pp. 1601–1608, 1979 (available in the petition: vol. 18, pp. 5033–5040).

13. Stevens, V. L. and R. Blair, *Nutrition Reports International*, vol. 35, pp. 755–764, 1987 (available in the petition: vol. 19, pp. 5465–5474).

14. GRASP 2449, Amendment C–0027: Safety Study Using 25-OH D_3 in Broiler Chickens (Project No. ISG–98–2). September 1998 (available in the petition: vol. 31–34).

15. Dutta, S. N., Clinical review and evaluation of NDA 018312 (Organon USA, Inc.'s CALDEROL brand of 25-OH D_3), 1979.

16. GRASP 2449, Amendment C–0028: Human Food Safety of the Use of 25-OH D_3 in Broiler Feed, February 1999.

17. FDA Center for Veterinary Medicine, Guideline for Industry #3: ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals,'' Part 4: ''Guideline for Establishing a Safe Concentration,'' 1994.

18. GRASP 2449, Amendment C–0029: Safety of the Use of Erythrosin in the 25-OH D_3 Final Product, May 1999.

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, and redelegated to

the Center for Veterinary Medicine, 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: 21 U.S.C. 321, 342, 348, 371.

■ 2. Section 584.725 is added to subpart B to read as follows:

§ 584.725 25–Hydroxyvitamin D_3.

(a) *Product.* 25–Hydroxyvitamin D_3 (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(b) *Conditions of use.* This substance is generally recognized as safe as a source of vitamin D_3 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 D_3.

(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'-tetraiodofluorescin.

(3) Product labeling shall bear the following:

(i) A statement to indicate that the maximum use level of 25-hydroxyvitamin D_3 must not exceed 69 ppb in feed or 34.5 ppb in drinking water.

(ii) Adequate use directions to ensure that 25-hydroxyvitamin D_3 (and all premixes) 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 D_3 should not be used simultaneously in both feed and water.

Dated: March 1, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–4796 Filed 3–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 2

RIN 2900–AM18

Delegations of Authority—National Cemetery Administration

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) regulation, ''Secretary's delegations of authority to certain officials.'' The amendment updates the regulation governing certain delegations of authority exercised by the Under Secretary for Memorial Affairs. This minor technical amendment provides delegation of authority from the Secretary of Veterans Affairs to the Under Secretary for Memorial Affairs to accept monetary and/or non-monetary gifts and donations, made in any manner, which are made for the purpose of beautifying or benefiting national cemeteries. The authority to accept offers of land will remain with the Secretary of Veterans Affairs.

DATES: *Effective Date:* March 16, 2007.

FOR FURTHER INFORMATION CONTACT: Patrick Hallinan, Deputy Director, Office of Field Programs (41A), National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; telephone: (202) 273–5229 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The provisions of 38 U.S.C. 2407 authorize the Secretary to ''accept gifts, devises, or bequests from legitimate societies and organizations or reputable individuals, made in any manner, which are made for the purpose of beautifying national cemeteries, or are determined to be beneficial to such cemetery.'' Currently, under 38 CFR 2.6(f)(3), the Secretary has delegated authority to the Under Secretary for Memorial Affairs ''[t]o accept donations of a *minor* nature, such as, individual trees for planting in burial areas and privately purchased grave markers.'' (Emphasis added) The current regulatory language no longer reflects the needs of the agency since the National Cemetery Administration frequently receives offers for donations that may be perceived as more than ''minor in nature.'' Such offers have included heavy equipment, rose gardens, cash, and electric vehicles. Providing authority to the National Cemetery Administration to accept donations, regardless of monetary value, would be commensurate with the authority that has been provided to the Veterans Health Administration and the Veterans Benefits Administration. The Under Secretary for Memorial Affairs will notify the Secretary when making decisions to accept or decline gifts and donations of offers that are unique, unusual or substantial in nature, or that may be of public interest because of the subject of the offer or identity of the donor. The authority to accept land will remain with the Secretary. The Under Secretary for Memorial Affairs will continue to refer all offers of land to the Secretary, with supporting information and a recommendation for action.

This rule revises paragraph (f)(3) to 38 CFR 2.6 by removing the reference ''[t]o accept donations of a minor nature, such as, individual trees for planting in burial areas and privately purchased grave markers'' and adding ''[t]o accept all donations, except offers of land, made in any manner, for the beautification or benefit of national cemeteries.''

Administrative Procedure Act

This final rule states rules of agency procedure or practice and is therefore exempt from the notice and public comment procedures of 5 U.S.C. 553(b). Further, this final rule is not a substantive rule and, consequently, the delayed effective date provisions of 5 U.S.C. 553(d) are not applicable.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule would have no such effect on State, local, or tribal governments, or the private sector.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Executive Order 12866

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 Executive Order classifies a ''significant regulatory action,'' requiring review by