Name of product/data/publication/information/service	Current fee	New fee
Nightly DMSP–OLS Mosaics, Visible and Thermal Band Data from One Satellite	201.00	223.00
Global DMSP–OLS Nighttime Lights Lunar Cycle Composite from One Satellite	5,624.00	6,020.00
Radiance Calibrated Global DMSP-OLS Nighttime Lights Annual Composite from One Satellite	67,922.00	77,177.00
Research Data Series CD–ROM/DVD	25.00	25.00
Custom Analog Plotter Prints	49.00	60.00
NOS Bathymetric Maps and Miscellaneous Archived Publication Inventory	6.00	7.00
Global DMSP–OLS Annual Composite of Persistent Nighttime Lights on Monthly Increments from One Satellite	.....	7,665.00

* New prices for these products are not included since these products are now available under a different category of NODC products.

[FR Doc. E9–5590 Filed 3–13–09; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2007–F–0274] (formerly Docket No. 2007F–0355)

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_2

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of vitamin D_2 as a nutrient supplement in soy-based food products. This action is in response to a petition filed by Dean Foods Co. (Dean Foods).

DATES: This rule is effective March 16, 2009. Submit written or electronic objections and requests for a hearing by April 15, 2009. See section VII of this document for information on filing objections. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of March 16, 2009.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. FDA–2007–F–0274 (formerly Docket No. 2007F–0355), by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1071.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of October 4, 2007 (72 FR 56768), FDA announced that a food additive petition (FAP 7A4769) had been filed by Dean Foods Co., c/o Hogan and Hartson LLP, 555 13th St., NW., Washington, DC 20004–1109. The petition proposed to amend the food additive regulations in part 172 (21 CFR part 172) *Food Additives Permitted for Direct Addition to Food for Human Consumption* to provide for the safe use of vitamin D_2 as a nutrient supplement in soy-based food products. The petition pertains only to the use of crystalline vitamin D_2 and not the resin form of the vitamin. Foods identified in the petition are soy beverages, soy beverage products, soy-based butter substitute spreads, soy-based cheese substitutes, and soy-based cheese substitute products. The petitioner requested that part 172 be amended to permit the use of crystalline vitamin D_2 as a nutrient supplement at levels not to exceed 50 International Units (IU) per 100 grams (g) of soy beverages, 89 IU per 100 g of soy beverage products, 330 IU per 100 g of soy-based butter substitute spreads, and 270 IU per 100 g of soy-based cheese substitutes and soy-based cheese substitute products.

Vitamin D[1], including vitamin D_2, is affirmed as generally recognized as safe (GRAS) for use in food under 21 CFR 184.1950 (§ 184.1950) with the following specific limitations:

Category of Food	Maximum Levels in Food (as Served)
Breakfast cereals	350 International Units (IU)/100 grams (g)

[1] Vitamin D comprises a group of fat-soluble secosterols and comes in many forms. The two major physiologically relevant forms are vitamin D_2 and vitamin D_3. Vitamin D without a subscript represents either D_2 or D_3. Section 184.1950 includes crystalline vitamin D_2, crystalline vitamin D_3, vitamin D_2 resin, and vitamin D_3 resin. Section 172.379, which is established by this rule, includes only crystalline vitamin D_2.

Category of Food	Maximum Levels in Food (as Served)
Grain products and pasta	90 IU/100 g
Milk	42 IU/100 g
Milk products	89 IU/100 g

Additionally, under § 184.1950(c)(2) and (c)(3), vitamin D is affirmed as GRAS for use in infant formulas and margarine, respectively. Under § 172.380, vitamin D_3 also is approved for use as a nutrient supplement in calcium-fortified fruit juices and fruit juice drinks; meal replacement and other type bars, soy protein-based meal replacement beverages represented for special dietary use in reducing or maintaining body weight; and cheese and cheese products as defined therein.

Vitamin D_2, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. The additive that is the subject of this petition is vitamin D_2 that is produced by ultraviolet irradiation of ergosterol isolated from yeast and is purified by crystallization. In contrast to the description of vitamin D_2 set forth in § 184.1950, this petition does not cover vitamin D_2 that may be produced from ergosterol isolated from fungi other than yeast.

Vitamin D is essential for human health. The major function of vitamin D is the maintenance of blood serum concentrations of calcium and phosphorus by enhancing the absorption of these minerals in the small intestine. Vitamin D deficiency can lead to abnormalities in calcium and bone metabolism such as rickets in children or osteomalacia in adults. High levels of vitamin D may be toxic. Excessive intake of vitamin D elevates blood plasma calcium levels by increased intestinal absorption and/or mobilization from the bone.

To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, FDA affirmed vitamin D as GRAS with specific limitations as listed in § 184.1950. Under 21 CFR 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950.

To support the safety of the proposed uses of vitamin D_2, Dean Foods submitted dietary intake estimates from current and proposed uses and from naturally-occurring sources of vitamin D, and compared these intake estimates to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies. The petitioner also submitted a number of publications pertaining to human clinical studies on vitamin D. Based on this information, which is discussed in section II of this document, the petitioner concluded that the proposed use of vitamin D_2 in soy-based food products is safe.

II. Evaluation of Safety

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive from all food sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all food sources of the additive. The agency commonly uses the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

A. Estimated Daily Intake for Vitamin D

The petitioner provided mean and 90th percentile vitamin D intake estimates for consumers of soy beverages, soy beverage products, soy-based butter substitute spreads, soy-based cheese substitutes, and soy-based cheese substitute products from the following: (1) The proposed food uses; (2) current food uses (including regulated uses, naturally-occurring sources of vitamin D, and dietary supplements); and (3) combined current and proposed food uses. The petitioner provided intake estimates for the overall U.S. population and nine population subgroups. For the purpose of the estimate, Dean Foods assumed that current consumers of dairy products would substitute their consumption of milk and dairy products with the corresponding soy beverages and soy-based dairy alternative products. The agency has determined that the methodology used to calculate these estimates is appropriate.

The petitioner's estimates of intake of vitamin D from all food sources include the proposed food uses, currently-regulated uses in conventional foods (under §§ 184.1950 and 172.380), dietary supplements, and naturally-occurring sources of the vitamin. For the overall U.S. population, including consumers of the soy-based food products identified in the petition, the 90th percentile dietary intake of vitamin D was estimated to be 1,012 IU per person per day (IU/p/d). For the population subgroup of infants less than 12 months of age, including consumers of the soy-based food products identified in the petition, the 90th percentile dietary intake of vitamin D was estimated to be 907 IU/p/d. FDA concurs with these intake estimates.

B. Acceptable Intake Level for Vitamin D

In 1997, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at IOM conducted an extensive review of toxicology and metabolism studies on vitamin D published through 1996. The IOM published a detailed report that included a UL for vitamin D for infants, children, and adults. The IOM UL for vitamin D for children 1 to 18 years of age and adults is 2,000 IU/p/d. The UL for infants is 1,000 IU/p/d.

The IOM considers the UL as the highest usual intake level of a nutrient that poses no risk of adverse effects when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients and considers intake from all sources: food, water, nutrient supplements, and pharmacological agents. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical

substances: No-observed-adverse-effect level, lowest-observed-effect level, and an uncertainty factor.

C. Safety Assessment

To support the safety of the proposed uses for vitamin D_2, Dean Foods submitted 14 scientific articles published subsequent to the IOM report and issuance of the November 2005 final rule (70 FR 69435) for the use of vitamin D_3 in cheese and cheese products. Dean Foods concluded that these recent publications continue to support vitamin D supplementation in humans. FDA concurs with Dean Foods' conclusions.

FDA considered the ULs established by IOM relative to the intake estimates provided by the petitioner as the primary basis for assessing the safety of petitioned uses of vitamin D. FDA also reviewed the scientific articles submitted by the petitioner. Finally, FDA reviewed studies on vitamin D that have published since the IOM report in the agency's evaluation of three previous food additive petitions for fortifying a variety of foods with vitamin D_3. The most recent petition resulted in FDA's amendment of the food additive regulations in § 172.380 to allow for the safe use of vitamin D_3 as a nutrient supplement in cheese and cheese products at levels above those allowed under § 184.1950 (70 FR 69435). The two earlier food additive petitions also resulted in amendments of the food additive regulations to allow for the safe use of vitamin D_3 as a nutrient supplement in certain foods (70 FR 37255; June 29, 2005, 70 FR 36021; June 22, 2005, and 68 FR 9000; February 27, 2003).

The estimated intake of vitamin D from all food sources, including the proposed uses, at the 90th percentile for the overall U.S. population is 1,012 IU/p/d, which is below the IOM UL of 2,000 IU/p/d. For infants less than 12 months of age, the estimated intake of vitamin D from all food sources, including the proposed uses, at the 90th percentile is 907 IU/p/d, which is below the IOM UL of 1,000 IU/p/d. Because the 90th percentile EDI of vitamin D from all current and proposed food sources is less than the IOM UL in both cases, the agency concludes that dietary intake of vitamin D_2 from its proposed use as a nutrient supplement in soy beverages, soy beverage products, soy-based butter substitute spreads, soy-based cheese substitutes, and soy-based cheese substitute products will not pose a safety concern.

III. Conclusion

Based on all data relevant to vitamin D_2 reviewed by the agency, FDA concludes that there is a reasonable certainty that no harm will result from the use of vitamin D_2 as a nutrient supplement in soy beverages, soy beverage products, soy-based butter substitute spreads, soy-based cheese substitutes, and soy-based cheese substitute products within the limits proposed by the petitioner. Thus, vitamin D_2 is safe for the proposed use and the agency concludes that the food additive regulations should be amended as set forth in this document. To ensure that only food grade crystalline vitamin D_2 is used in food under this rule, the additive must meet the specifications set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Effects

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 7A4769. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). This final rule is not a statement regarding compliance with other sections of the act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the act to, among other things, add section 301(ll). Section 301(ll) of the act (21 U.S.C. 301(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) through (4) applies. In our review of this petition, FDA did not consider whether section 301(ll) or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll). Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) applies.

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.379 is added to subpart D to read as follows:

§ 172.379 Vitamin D_2.

Vitamin D_2 may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D_2, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. Vitamin D_2 is produced by ultraviolet irradiation of ergosterol isolated from yeast and is purified by crystallization.

(b) Vitamin D_2 meets the specifications of the *Food Chemicals Codex*, 6th ed. (2008), pp. 1013 and 1014, which is incorporated by reference. The Director of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51. You may obtain a copy from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: *http://www.usp.org*). You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1071, 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) The additive may be used as follows:

Category of Food	Maximum Levels in Food (as Served)
Soy beverages	50 International Units (IU)/100 grams (g)
Soy beverage products	89 IU/100 g
Soy-based butter substitute spreads	330 IU/100 g
Soy-based cheese substitutes and soy-based cheese substitute products	270 IU/100 g

Dated: February 23, 2009.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. E9–5549 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4001, 4010, and 4044

RIN 1212–AB09

Annual Financial and Actuarial Information Reporting; Pension Protection Act of 2006

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is a final rule to amend PBGC's regulation on Annual Financial and Actuarial Information Reporting. The amendments implement the provisions of the Pension Protection Act of 2006, Public Law 109–280 (PPA 2006), which changed the standards for determining which persons are required to report under section 4010 (Authority to Require Certain Information) of the Employee Retirement Income Security Act of 1974 and made other changes to the reporting requirements. In addition to providing guidance on implementing the PPA 2006 changes, the final rule waives reporting in certain cases for controlled groups with aggregate plan underfunding of $15 million or less, modifies the standards for determining which plans are exempt from the actuarial information requirements, revises the actuarial information requirements to conform with other PPA 2006 changes, and provides other clarifications.

DATES: Effective April 15, 2009. (See Applicability in **SUPPLEMENTARY INFORMATION**.)

FOR FURTHER INFORMATION CONTACT: John H. Hanley, Director, Legislative and Regulatory Department; or Catherine B. Klion, Manager, or Grace H. Kraemer, Attorney, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Background

Pension Benefit Guaranty Corporation (PBGC) administers the pension insurance programs under Title IV of the Employee Retirement Income Security Act of 1974 (ERISA). In order to give PBGC an opportunity to anticipate and attempt to minimize potential liabilities that may arise from the termination of significantly underfunded plans, ERISA section 4010 requires the reporting of actuarial and financial information by controlled groups with pension plans that have significant underfunding. That information is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552) and may not be made public, except as may be relevant to any administrative or judicial action or proceeding.

Pursuant to ERISA section 4010, PBGC issued its initial regulation on Annual Financial and Actuarial Information Reporting in 1995 (29 CFR part 4010). The regulation specifies the items of identifying, financial, and actuarial information that filers must submit under ERISA section 4010. PBGC reviews the information that is filed and enters it into an electronic database for more detailed analysis. Computer-assisted analysis of this information helps PBGC to anticipate possible major demands on the pension insurance system and to focus PBGC resources on situations that pose the greatest risks to that system. Because other sources of information are usually