DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2018–F–3230]

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

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to provide for the safe use of vitamin D_2 mushroom powder as a nutrient supplement in specific food categories. This action is in response to a petition filed by Oakshire Naturals, LP.

DATES: This rule is effective July 13, 2020. See section VII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by August 12, 2020.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before August 12, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2020. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–F–3230 for ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_2 Mushroom Powder.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Lauren VieBrock, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 301–796–7454.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 18, 2018 (83 FR 47118), we announced that we filed a food additive petition (FAP 8A4821) submitted by Oakshire Naturals LP (Oakshire), 295 Thompson Road, P.O. Box 388, Kennett Square, PA 19348. The petition proposes that we amend our 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 mushroom powder, produced by exposing homogenized edible mushrooms to ultraviolet (UV) light, as a nutrient supplement in: (1) Foods to which vitamin D_2, vitamin D_3, and vitamin D_2 bakers yeast are currently allowed to be added under §§ 184.1950, 172.379, 172.380, and 172.381 (21 CFR 184.1950, 172.379, 172.380, and 172.381) (excluding cheese and cheese products, foods represented for use as a sole source of nutrition for enteral feeding, infant formula, milk and milk products, and margarine); (2) fruit smoothies; (3) vegetable juices; (4) extruded vegetable snacks; (5) soups and soup mixes (except for those containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act); and (6) plant protein products as defined in 21 CFR 170.3(n)(33).

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. Excessive intake of vitamin D elevates blood plasma calcium levels by increased intestinal absorption or mobilization from the bone that can lead to vascular and tissue calcification, with subsequent damage to the heart, blood vessels, and kidneys (Ref. 1).

To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, we affirmed vitamin D as generally recognized as safe (GRAS) with specific limitations as listed in § 184.1950. Under § 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 requires a food additive regulation.

Vitamin D comprises a group of fat-soluble seco-sterols 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 vitamin D_2, vitamin D_3, or both. Vitamin D is affirmed as GRAS under § 184.1950 for use in food as a nutrient supplement. In accordance with 21 CFR 184.1(b)(2), and as specified in § 184.1950(c)(1), vitamins D_2 and D_3 may be used in food as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served)
Breakfast cereals	350 international units (IU)/100 grams (g).
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 (3), vitamin D is affirmed as GRAS for use in infant formulas and margarine, respectively. Under § 172.379, vitamin D_2 is an approved food additive for use as a nutrient supplement in edible plant-based beverages intended as milk alternatives, edible plant-based yogurt alternatives, soy beverage products, soy-based butter substitute spreads, and soy-based cheese substitutes and soy-based cheese substitute products. Under § 172.380, vitamin D_3 is an approved food additive for use as a nutrient supplement in certain calcium-fortified fruit juices and fruit juice drinks; soy-protein based meal replacement beverages; meal replacement bars and other-type bars represented for special dietary use in reducing or maintaining body weight; some cheese and cheese products; meal replacement beverages not intended for special dietary use in reducing or maintaining body weight; foods represented as a sole source of nutrition for enteral feeding; and some milk. Under § 172.381, vitamin D_2 bakers yeast may be used in foods as a source of vitamin D_2 and as a leavening agent in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods.

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 mushroom powder that is produced by exposing a mushroom homogenate to UV light, resulting in increased conversion of endogenous ergosterol to ergocalciferol. Under section 402(a)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), sources of irradiation, such as UV light, must be used in accordance with a regulation or exemption in effect pursuant to section 409 of the FD&C Act.

To support their petition, Oakshire submitted dietary exposure estimates of vitamin D from the proposed uses of vitamin D_2 mushroom powder, as well as from naturally occurring dietary sources of vitamin D, uses in accordance with our approved food additive regulations (§§ 172.379, 172.380, and 172.381) and our GRAS affirmation regulation (§ 184.1950), and from dietary supplements. Oakshire compared their dietary exposure estimates to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies. Oakshire also submitted a number of publications pertaining to human clinical studies on vitamin D. Oakshire included analyses to determine the presence of lumisterol, tachysterol, and vitamin D_4 that are formed as a result of the UV treatment of the mushroom homogenate. Based on this information, Oakshire concluded that the proposed uses of vitamin D_2 mushroom powder are safe.

II. Evaluation of Safety

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, we consider the projected human dietary intake of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated daily intake (EDI) of the additive from all food sources, including dietary supplements, 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. We use the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

A. UV Light Treatment Used To Produce Vitamin D_2 Mushroom Powder

To support the safety of UV treatment to produce vitamin D_2 mushroom powder, Oakshire provided information on the effects of UV light on biological molecules, the safety of UV light for treatment of food, and studies evaluating the bioavailability and safety of vitamin D from the consumption of vitamin D_2 mushroom powder (Ref. 1). Oakshire describes the source of UV radiation as a medium pressure mercury vapor lamp emitting broad-spectrum light (at wavelengths of 250–600 nm), with major intensity peaks in the UVB (280–315 nm) and UVA ranges (315–400 nm). Oakshire also analyzed extracts of mushroom powders from both UV-treated and untreated mushroom homogenate and identified the substances present in the mushroom powders. Oakshire identified tachysterol (a photoisomer resulting from UV light treatment of the vitamin D_2 precursor, previtamin D_2) and lumisterol (typically formed from UV light treatment of previtamin D_2) as present in the mushroom powders derived from UV-treated mushroom homogenate. Oakshire discussed the safety of these substances and we agree that the presence of small amounts of tachysterol and lumisterol do not pose a toxicological concern (Ref. 1).

Agaricus bisporus mushrooms, which Oakshire uses to produce its vitamin D_2 mushroom powder, also contain low levels of 22,23-dihydroergosterol. When treated with UV light, 22,23-dihydroergosterol forms vitamin D_4 ((5*Z*,7*E*)-(3*S*)-9,10-seco-5,7,10(19)-ergostatrien-3-ol). Oakshire analyzed powders from UV-treated mushroom homogenate and found it to contain vitamin D_4 at levels approximately 10 percent of vitamin D_2 levels. Studies have shown that vitamin D_4 that is structurally similar to vitamin D_3 has significantly less biological potency than vitamin D_3 (Ref. 1). We included the contribution of vitamin D_4 in the dietary exposure estimate for vitamin D_2 mushroom powder by presuming that vitamin D_4 was present at a level of 10 percent of vitamin D_2 levels in the vitamin D_2 mushroom powder, and that

vitamin D_4 had equivalent potency to vitamin D_2 (Ref. 2). Oakshire discussed the safety of vitamin D_4, and we agree that the presence of vitamin D_4 in Vitamin D_2 mushroom powder does not pose a toxicological concern (Ref. 1).

B. Acceptable Intake Level for Vitamin D

The IOM considers the UL as the highest daily intake level of a nutrient that poses no risk of adverse effects with chronic consumption of the nutrient (Ref. 3). The UL is determined using a risk assessment model developed specifically for nutrients. 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 application of an uncertainty factor (Ref. 3).

In 2011, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at the IOM conducted an extensive review of relevant published scientific literature on vitamin D to update the nutrient's dietary reference intakes and ULs. Based on this information, the IOM revised the ULs for vitamin D and developed a report on their findings (Ref. 3). The IOM established the following ULs:

- 1,000 IU per person per day (IU/p/d) for infants 0 months to 6 months of age;
- 1,500 IU/p/d for infants 6 months to 12 months of age;
- 2,500 IU/p/d for children 1 year to 3 years of age;
- 3,000 IU/p/d for children 4 years to 8 years of age; and
- 4,000 IU/p/d for children 9 years to 18 years of age and adults.

We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D_2 mushroom powder. We also reviewed published studies on the safety of vitamin D submitted in the petition, as well as other relevant published studies available to us (Ref. 1).

C. Estimated Daily Intake for Vitamin D

Oakshire provided mean and 90th percentile vitamin D exposure estimates for consumers of foods from the: (1) Proposed food uses of vitamin D_2 mushroom powder; (2) current food uses of vitamin D (including authorized uses as a food ingredient, naturally occurring sources of vitamin D, and dietary supplements); and (3) combined current and proposed food uses. Oakshire provided exposure estimates for the overall U.S. population (including infants under 1 year of age) and fourteen population subgroups (Ref. 2).

The exposure estimates provided by Oakshire are appropriate. However, they did not employ the conservative assumptions that we typically use in pre-market exposure estimates. For pre-market exposure estimates, we conservatively assume that all foods for which the use of the additive is approved will contain the additive at the maximum level permitted. In the case of vitamin D exposure estimates presented in the most recent food additive approval for a new use of vitamin D (FAP 3A4801, 81 FR 46578, July 18, 2016), we also included exposure to the vitamin D metabolite 25-hydroxyvitamin D (25(OH)D). For these reasons, we calculated our own exposure estimate for vitamin D_2 mushroom powder, as well as a cumulative exposure estimate for vitamin D from all background sources (approved food uses, dietary supplements, and naturally occurring sources, including 25(OH)D) and the petitioned uses for vitamin D_2 mushroom powder (Ref. 2).

For the overall U.S. population 1 year of age and older, we estimated the cumulative exposure at the 90th percentile from all food sources of vitamin D, including the proposed uses and background sources, to be 2,240 IU/p/d. We estimated the cumulative exposure for infants 0 to 6 months of age and infants 6 to 12 months of age to be 948 IU/p/d and 960 IU/p/d, respectively, for the 90th percentile consumer (Ref. 2).

D. Safety of the Petitioned Uses of Vitamin D_2 Mushroom Powder

We reviewed and evaluated the information submitted by Oakshire regarding the safety of vitamin D_2 mushroom powder, including the safety of using UV light treatment to produce it, and conclude that the use of vitamin D_2 mushroom powder does not pose a safety concern (see section II.A). We also reviewed and evaluated the information submitted by Oakshire regarding the safety of dietary intake of vitamin D_2 from the proposed uses of the vitamin D_2 mushroom powder. Oakshire submitted reports of scientific studies published since our last evaluation of published scientific data in support of safety of the use of vitamin D and issuance of the final rule amending our food additive regulations to allow certain uses of vitamins D_2 and D_3 (81 FR 46578). Oakshire concluded that these studies support a conclusion that the proposed uses of vitamin D_2 mushroom powder are safe.

We reviewed the studies submitted by Oakshire, as well as other relevant published studies available to us since our previous evaluations of food additive petitions for fortifying a variety of foods with vitamin D (81 FR 46578, July 18, 2016; 79 FR 46993, August 12, 2014; 77 FR 52228, August 29, 2012; 74 FR 11019, March 16, 2009; 70 FR 69435, November 16, 2005; 70 FR 37255, June 29, 2005; 70 FR 36021, June 22, 2005; 68 FR 9000, February 27, 2003). These studies did not raise any safety concerns regarding the current or proposed uses of vitamin D. The most recent food additive petition for a new use of vitamin D resulted in our amendment of the food additive regulations in §§ 172.379 and 172.380 to allow for the safe use of vitamin D_2 as a nutrient supplement in edible plant-based beverages intended for use as milk alternatives and in edible plant-based yogurt alternatives, and of vitamin D_3 as a nutrient supplement in milk (81 FR 46578). The earlier food additive petitions also resulted in amendments of the food additive regulations to allow for the safe use of vitamin D as a nutrient supplement in certain foods.

We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D. Depending on the age group, the IOM UL for vitamin D for the U.S. population 1 year of age and older ranges from 2,500 IU/p/d to 4,000 IU/p/d (Ref. 3). The estimated dietary exposure to vitamin D from all food sources, including the proposed uses, at the 90th percentile for the U.S. population 1 year of age and older is estimated to be 2,240 IU/p/d, which is below the lowest IOM UL of 2,500 IU/p/d in the range of ULs for the overall U.S. population 1 year of age and older. Estimated exposure to vitamin D from all food sources, including the proposed uses, for infants 0 months to 6 months of age at the 90th percentile is 948 IU/p/d; for infants 6 months to 12 months of age, estimated exposure to vitamin D is 960 IU/p/d. Both of these estimates are below the IOM UL of 1,000 IU/p/d for infants 0 months to 6 months of age and 1,500 IU/p/d for infants 6 months to 12 months of age. Because the 90th percentile cumulative EDI of vitamin D from all food sources of vitamin D, including the proposed uses and background sources, for each population group is less than the corresponding IOM UL for that population group, we conclude that dietary intake of vitamin D_2 mushroom powder from the proposed uses is safe (Ref. 1).

III. Conclusion

Based on all data relevant to vitamin D_2 mushroom powder we reviewed, we conclude that there is a reasonable certainty that no harm will result from the uses of vitamin D_2 mushroom powder, produced using UV light treatment, as a source of vitamin D_2 in: (1) Foods to which vitamin D_2, vitamin D_3, and vitamin D_2 bakers yeast are allowed under §§ 184.1950, 172.379, 172.380, and 172.381 (excluding cheese and cheese products, foods represented for use as a sole source of nutrition for enteral feeding, infant formula, milk and milk products, and margarine); (2) fruit smoothies; (3) vegetable juices; (4) extruded vegetable snacks; (5) soups and soup mixes (except for those containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act); and (6) plant protein products as defined in 21 CFR 170.3(n)(33). Thus, we are amending our food additive regulations as set forth in this document.

IV. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **ADDRESSES**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

V. Analysis of Environmental Impacts

As stated in the September 18, 2018 **Federal Register** notification of petition for FAP 8A4821 (83 FR 47118), the petitioners claimed a categorical exclusion from preparing an environmental assessment or environmental impact statement under § 25.32(k) (21 CFR 25.32(k)) because vitamin D_2 mushroom powder is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. We further stated that if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments regarding this claim of categorical exclusion. We have considered the petitioner's claim of categorical exclusion and have determined that this action is categorically excluded under § 25.32(k). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. 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.

VII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

VIII. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 409 of the FD&C Act (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C 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) to (4) of the FD&C Act applies. In our review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act 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) of the FD&C Act. 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) of the FD&C Act applies.

IX. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Memorandum from A. Khan, Toxicology Review Branch, Division of Food Ingredients, to L. VieBrock, Regulatory Review Branch, Division of Food Ingredients, March 18, 2020.*
2. FDA Memorandum from D. Folmer, Safety Assurance Team, Division of Science and Technology, to L. VieBrock, Regulatory Review Branch, Division of Food Ingredients, March 18, 2020.*
3. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine, ''Dietary Reference Intakes for Calcium and Vitamin D,'' National Academies Press, Washington, DC, 2011. Available at *https://www.nap.edu/read/13050/chapter/1* (accessed November 11, 2019).

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 part 172 continues to read as follows:

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

■ 2. Add § 172.382 to subpart D to read as follows:

§ 172.382 Vitamin D_2 mushroom powder.

Vitamin D_2 mushroom powder may be used safely in foods as a source of vitamin D_2 in accordance with the following prescribed conditions:

(a) Vitamin D_2 mushroom powder is the substance produced by exposing an aqueous homogenate of edible cultivars of *Agaricus bisporus* mushrooms to ultraviolet (UV) light, resulting in the photochemical conversion of endogenous ergosterol in the mushrooms to vitamin D_2 (also known as ergocalciferol or [9,10-Seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol]).

(b) The total dose of UV light applied to the mushroom homogenate shall not exceed 12 Joules/square centimeter (J/cm^2).

(c) Vitamin D_2 mushroom powder meets the following specifications:

(1) Moisture, not more than 10 percent.

(2) Negative for *Salmonella, Staphylococcus aureus,* and *Listeria monocytogenes,* and any other recognized microbial pathogen or any harmful microbial toxin.

(3) Standard plate count, not more than 5,000 colony forming units per gram (CFU/g).

(4) Yeasts and molds, not more than 100 CFU/g.

(5) Lead, not more than 0.5 milligrams per kilogram (mg/kg).

(6) Arsenic, not more than 0.3 mg/kg.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (f) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive ''vitamin D_2 mushroom powder,'' in the proper order of decreasing predominance in the finished food.

(f) Vitamin D_2 mushroom powder may be used as a source of vitamin D_2 in food as follows:

TABLE 1 TO PARAGRAPH (f)

Category of food	Maximum level of vitamin D_2
Breakfast cereals	350 IU/100 g.
Edible plant-based beverages marketed as milk alternatives	84 IU/100 g.
Edible plant-based products marketed as yogurt alternatives	89 IU/100 g.
Extruded vegetable snacks	80 IU/28 g.
Fruit smoothies	100 IU/240 mL.
100% fruit juices that are fortified with greater than or equal to 330 mg of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.	100 IU/240 mL.
Fruit juice drinks that are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.	100 IU/240 mL.
Grain products and pastas	90 IU/100 g.
Meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight.	100 IU/40 g.
Meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D provided by the product does not exceed 1,000 IU per day.	500 IU/240 mL.
Plant protein products	80 IU/85 g.
Soups and soup mixes, except for soup and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.	100 IU/245 mL.
Soy-based spreads marketed as butter alternatives	330 IU/100 g.
Soy-based products marketed as cheese and cheese-product alternatives	270 IU/100 g.
Soy beverage products	89 IU/100 g.
Soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight.	140 IU/240 mL.
Vegetable juices	100 IU/240 mL.
Yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods	400 IU/100 g.

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13822 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0150; FRL–10011–22–Region 1]

Air Plan Approval; New Hampshire; Negative Declaration for the Oil and Gas Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of New Hampshire. The revision provides the State's determination, via a negative declaration, that there are no facilities within its borders subject to EPA's 2016 Control Technique Guideline (CTG) for the oil and gas industry. The intended effect of this action is to approve this item into the New Hampshire SIP. This action is being taken under the Clean Air Act.