Airway segment		Changeover points	
From	To	Distance	From
§ 95.8005 Jet Routes Changeover Points J2 Is Amended To Add Changeover Point			
MISSION BAY, CA VORTAC	IMPERIAL, CA VORTAC	40	MISSION BAY.
J18 Is Amended To Add Changeover Point			
MISSION BAY, CA VORTAC	IMPERIAL, CA VORTAC	40	MISSION BAY.

[FR Doc. 2026–19722 Filed 9–24–26; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2021–F–1157]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

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 inactive bakers yeast as a source of vitamin D_2 in specific food categories. We are taking this action in response to a food additive petition filed by Lallemand Inc. (Lallemand or petitioner).

DATES: This order is effective September 25, 2026. See section VII for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final order must be submitted by October 26, 2026.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of October 26, 2026. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2021–F–1157 for ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_2 Inactive Bakers Yeast.'' 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, 240–402–7500.

- 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: Sean Fischer, Office of Pre-market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1225; or Meadow Platt, Office

of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 29, 2021 (86 FR 74018), we announced that we filed a food additive petition (FAP 1A4829) submitted by Lallemand Inc. (Lallemand), 1620 rue Préfontaine, Montreal, Quebec, H1W 2N8, Canada. The petition proposed that FDA amend the food additive regulations in 21 CFR part 172 to provide for the safe use of vitamin D_2 inactive bakers yeast, produced by exposing bakers yeast (*Saccharomyces cerevisiae*) to ultraviolet (UV) light and then using heat to inactivate the bakers yeast, as a nutrient supplement in foods. The proposed use would allow for the safe use of vitamin D_2 inactive bakers yeast as a source of vitamin D_2 in the same foods and at the same use levels, on a D_2 basis, for which D_2 mushroom powder is currently authorized under § 172.382.

Vitamin D is essential for human health. Vitamin D comprises a group of fat-soluble seco-sterols and occurs 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. 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. At high levels in the diet, vitamin D may be toxic. Excessive intake of vitamin D elevates blood plasma calcium levels (hypercalcemia) 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 (Refs. 1 and 2).

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 generally recognized as safe (GRAS) with specific limitations as listed in 21 CFR 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 of the ingredient, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires a food additive regulation. Vitamin D is affirmed as GRAS for use in certain foods as a nutrient supplement (as defined under 21 CFR 170.3(o)(20)) under § 184.1950(c)(1), in accordance with § 184.1(b)(2), as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served) (IU/100 g)
Breakfast cereals	350
Grain products and pasta	90
Milk	42
Milk products	89

IU: International Units.

Vitamin D is also affirmed as GRAS under § 184.1950(c)(2) and (3) for use in infant formula and margarine, respectively. Vitamin D_2 is an approved food additive under § 172.379 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. Vitamin D_3 is an approved food additive under § 172.380 for use as a nutrient supplement in certain calcium-fortified 100 percent fruit juices and fruit juice drinks; meal replacement and other-type bars that are represented for special dietary use in reducing or maintaining body weight; soy-protein based meal replacement beverages that are represented for special dietary use in reducing or maintaining body weight; certain cheese and cheese products; certain meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight; foods represented for use as a sole source of nutrition for enteral feeding; milk that contains more than 42 IU vitamin D per 100 g and that meets the requirements for foods named by use of a nutrient content claim and a standardized term in accordance with 21 CFR 130.10; breakfast cereals; grain-based bars; and yogurt and other cultured dairy products fermented with *Lactobacillus delbrueckii,* subspecies *bulgaricus (L. delbrueckii,* subsp. *bulgaricus),* and *Streptococcus thermophilus (S. thermophilus).* Vitamin D_2 bakers yeast is an approved food additive under § 172.381 for use 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 mushroom powder is an approved food additive under § 172.382 for use 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 currently allowed to be added 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, margarine, and grain-based bars; (2) fruit smoothies; (3) vegetable juices; (4) extruded vegetable snacks; (5) certain soups and soup mixes; and (6) plant protein products (see § 172.382(f)).

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 inactive bakers yeast that is produced by exposing bakers yeast 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, Lallemand noted that the petitioned food uses and maximum use levels for vitamin D_2 inactive bakers yeast are the same, on a vitamin D_2 basis, as those for vitamin D_2 mushroom powder approved under § 172.382. Therefore, Lallemand concluded that the petitioned use of vitamin D_2 inactive bakers yeast would not increase the cumulative dietary exposure to vitamin D and referenced FDA's cumulative dietary exposure estimate for vitamin D in FAP 8A4821 (85 FR 41916, July 13, 2020). Lallemand compared the dietary exposure estimate to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) (now the National Academy of Medicine). Lallemand also submitted published scientific literature pertaining to clinical studies on vitamin D.

II. Evaluation of Safety

A. Vitamin D

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the additive, the additive's toxicological data, and other relevant information (such as published scientific literature) available to us. We compare the dietary exposure to the additive from all food sources to an acceptable intake level established by data. The dietary exposure is determined based on the amount of the

additive proposed for specific uses in foods and on data regarding the amount consumed from all food sources of the additive. We commonly use the 90th percentile dietary exposure for the consumer of a food additive as a measure of high chronic dietary exposure.

1. Acceptable Daily Intake for Vitamin D

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 to update established dietary reference intakes (DRIs) for vitamin D; these DRIs are a family of nutrient reference values that includes ULs. Based on this information, the IOM revised the ULs for vitamin D and published a report on their findings (Ref. 3). In their 2011 assessment of vitamin D, the IOM established ULs for different age groups, including total consumption from food (including dietary supplements) and water:

UL IU/per person/day (p/d)	Age group
1,000	infants 0 months to 6 months of age.
1,500	infants 6 months to 12 months of age.
2,500	children 1–3 years of age.
3,000	children 4–8 years of age.
4,000	adolescents aged 9–18 years of age and adults.

The IOM considers the UL as the maximum daily intake level of a nutrient that is likely to pose no health hazard risk for almost all individuals in the general population when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment approach 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 (NOAEL), lowest-observed-effect level (LOEL), and application of an uncertainty factor. We considered the ULs established by the IOM relative to the cumulative dietary exposure estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D_2. We also reviewed published scientific literature on the safety of vitamin D submitted in the petition, as well as other relevant published studies available to FDA (Ref. 4).

2. Dietary Exposure Estimate for Vitamin D

Lallemand stated that the petitioned food uses and maximum use levels for vitamin D_2 inactive bakers yeast are the same, on a vitamin D_2 basis, as those for vitamin D_2 mushroom powder authorized under § 172.382. Lallemand concluded that the petitioned uses of vitamin D_2 inactive bakers yeast would not increase the dietary exposure to vitamin D and therefore, it did not perform a new dietary exposure estimate for vitamin D from the petitioned uses. Because Lallemand considered the petitioned uses as substitutional for those in § 172.382, they referenced FDA's cumulative dietary exposure estimate for vitamin D in FAP 8A4821 (85 FR 41916), which resulted in the promulgation of § 172.382.

We note that the cumulative dietary exposure estimate referenced by Lallemand does not include the contribution to dietary exposure to vitamin D from FAP 9A4823 (88 FR 745, January 5, 2023) for the use of vitamin D_3 as a nutrient supplement in breakfast cereals at levels up to 560 IU/100 g and in grain-based bars at levels up to 400 IU/100 g. This estimate also does not include the contribution to the dietary exposure to vitamin D from the use of vitamin D_3 as a nutrient supplement in yogurt and other cultured dairy products fermented with *L. delbrueckii,* subsp. *bulgaricus,* and *S. thermophilus* at levels up to 178 IU/100 g from FAP 1A4827 (90 FR 42699, September 4, 2025). Furthermore, we note that the cumulative dietary exposure estimate referenced by Lallemand used food consumption data from the 2011–2014 National Health and Nutrition Examination Survey (NHANES), and more recent NHANES food consumption data are available (Ref. 5).

The current cumulative eaters-only dietary exposure estimate to vitamin D (*i.e.,* cumulative dietary exposure to vitamin D for consumers of any or all foods petitioned for use) from all existing sources was discussed in FAP 1A4827 (90 FR 42699). Since the uses of vitamin D_2 inactive bakers yeast are substitutional for those in § 172.382, the cumulative eaters-only dietary exposure estimate would not change from that estimated in FAP 1A4827 (90 FR 42699).

For the overall U.S. population 1 year of age and older, the estimated cumulative dietary exposure at the 90th percentile from all food sources of vitamin D, including the proposed uses and background sources, is 3,170 IU/p/d. The estimated 90th percentile cumulative dietary exposure from all food sources of vitamin D is 944 IU/p/d for infants 0 to 6 months, 1230 IU/p/d for infants 6 to 12 months, 1720 IU/p/d for children 1 to 3 years, and 1910 IU/p/d for children 4 to 8 years. Estimated dietary exposures for adolescents, teenagers, and adults ranged from 1960 IU/p/d to 3930 IU/p/d. The estimated cumulative dietary exposure to vitamin D at the 90th percentile from the petitioned uses and background sources is below the IOM ULs for all population groups for which ULs were established (Ref. 5).

B. Safety of the Petitioned Uses of Vitamin D2 Inactive Bakers Yeast

FDA reviewed and evaluated the information submitted by Lallemand regarding the safety of UV light-treated inactive bakers yeast. FDA concludes that the use of UV light to produce vitamin D_2 inactive bakers yeast does not pose a safety concern, since the UV light treatment has been shown not to produce any new components of toxicological concern that could be introduced into the diet (Ref. 4).

In addition, we reviewed and evaluated the information submitted by Lallemand regarding the safety of the dietary exposure to vitamin D_2 from the proposed uses of vitamin D_2 inactive bakers yeast. Lallemand submitted reports of scientific studies published after the 2011 IOM report and issuance of the July 13, 2020, final order (85 FR 41916) for the uses of vitamin D_2 mushroom powder. Lallemand concluded that these publications support a conclusion that the proposed uses of vitamin D_2 are safe.

We reviewed the published reports of scientific studies on vitamin D submitted by Lallemand, 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 (90 FR 42699, September 4, 2025; 88 FR 745, January 5, 2023; 85 FR 41916, July 13, 2020; 81 FR 46578, July 18, 2016; 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; and 68 FR 9000, February 27, 2003). The studies did not raise any new safety concerns regarding the current or proposed uses of vitamin D. The most recent food additive petition concerning vitamin D resulted in our amendment of the food additive regulations in § 172.380 to authorize the use of vitamin D_3 as a nutrient supplement in yogurt and other cultured dairy products

fermented with *L. delbrueckii,* subsp. *bulgaricus,* and *S. thermophilus* at levels up to 178 IU vitamin D_3 per 100 g (90 FR 42699). 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 consider the ULs established by the IOM relative to the dietary exposure estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D_2. The estimated dietary exposure at the 90th percentile to vitamin D from all current and proposed food sources for each population group is less than the corresponding IOM UL for that population group. Considering that the petitioned uses of vitamin D_2 inactive bakers yeast are substitutional on a vitamin D_2 basis for the currently approved uses of vitamin D_2 mushroom powder, FDA concluded that the petitioned uses of vitamin D_2 inactive bakers yeast are not expected to increase the overall dietary exposure to vitamin D. Therefore, we conclude that the proposed uses of vitamin D_2 inactive bakers yeast are safe (Ref. 4).

III. Conclusion

Based on the relevant data available to FDA and information in the petition, we conclude that there is reasonable certainty that no harm will result from the uses of vitamin D_2 inactive bakers yeast, produced using UV light, as a source of vitamin D_2 within the limits proposed by Lallemand.

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 **FOR FURTHER INFORMATION CONTACT**). 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 Impact

As stated in the December 29, 2021 (86 FR 74018) **Federal Register** notification of petition for FAP 1A4829, the petitioner claimed that this action is categorically excluded under 21 CFR 25.32(k) because it is to ''approve a food additive petition for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.'' We further stated that, if FDA determines the categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We did not receive any new information or comments regarding this claim of categorical exclusion. We considered the petitioner's claim of categorical exclusion and determined that this action is categorically excluded under 21 CFR 25.32(k). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This order 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 order 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) through (4) of the FD&C Act applies. In our review of this petition, we 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 order 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 orders 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 in 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 are also 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. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

* 1. Office of Dietary Supplements. ''Vitamin D—Fact Sheet for Consumers.'' *U.S. Department of Health and Human Services, National Institutes of Health,* Nov. 2022, *https://ods.od.nih.gov/factsheets/Vitamind-Consumer/.*

* 2. Pilz, S., et al. ''Rationale and Plan for Vitamin D Food Fortification: A Review and Guidance Paper.'' *Frontiers in Endocrinology,* vol. 9, 2018, article 373, *https://www.frontiersin.org/articles/10.3389/fendo.2018.00373/full.*

* 3. IOM Committee to Review Dietary Reference Intakes for Vitamin D and Calcium. *Dietary Reference Intakes for Calcium and Vitamin D,* edited by A.C. Ross et al., National Academies Press, 2011, *https://www.ncbi.nlm.nih.gov/books/NBK56070/.*

* 4. FDA Memorandum from A. Khan, Toxicology Review Branch, Division of Food Ingredients, to S. Fischer, Regulatory Management Branch,

Division of Food Ingredients, August 25, 2026.

* 5. FDA Memorandum from R. Shah, Chemistry Evaluation Branch, Division of Food Ingredients, to S. Fischer, Regulatory Management Branch, Division of Food Ingredients, August 25, 2026.

6. Parva, N.R., et al. ''Prevalence of Vitamin D Deficiency and Associated Risk Factors in the US Population (2011–2012).'' *Cureus,* vol. 10, no. 6, 2018, article e2741, *https://doi.org/10.7759/cureus.2741.*

7. Corpas, E., et al. ''Vitamin D and Calcium Deficiency in the Elderly.'' *Endocrinology of Aging: Clinical Aspects in Diagrams and Images,* edited by E. Corpas et al., Academic Press, 2021, pp. 103–130, *https://doi.org/10.1016/B978-0-12-819667-0.00004-4.*

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 § 172.383 to subpart D to read as follows:

§ 172.383 Vitamin D_2 Inactive Bakers Yeast.

Vitamin D_2 inactive bakers yeast may be safely used in foods as a source of vitamin D_2 under the following conditions:

(a) Vitamin D_2 inactive bakers yeast is the substance produced by exposing bakers yeast (*Saccharomyces cerevisiae*) to ultraviolet light, resulting in the photochemical conversion of endogenous ergosterol in bakers yeast to vitamin D_2 (also known as ergocalciferol or 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol), and then inactivating the bakers yeast using heat.

(b) Vitamin D_2 inactive bakers yeast can be used alone or in combination with conventional bakers yeast.

(c) Vitamin D_2 inactive bakers yeast meets the following specifications:

(1) Moisture, less than 7 percent.

(2) Negative for *Salmonella, Staphylococcus aureus, Escherichia coli,* and *Pseudomonas aeruginosa.*

(3) Coliforms, less than 10 colony forming units per gram (CFU/g).

(4) Total plate count, less than 3,000 CFU/g.

(5) Yeasts and molds, less than 300 CFU/g.

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

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

(8) Cadmium, not more than 0.5 mg/kg.

(9) Mercury, not more than 0.1 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 (e) of this section.

(e) Vitamin D_2 inactive bakers yeast may be used as a source of vitamin D_2 in food as follows:

TABLE 1 TO PARAGRAPH (e)

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 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19656 Filed 9–24–26; 8:45 am]

BILLING CODE 4164–01–P