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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2019–F–3519]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3

AGENCY: Food and Drug Administration, 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_3 as a nutrient supplement in breakfast cereals and grain-based bars (*e.g.,* breakfast bars, granola bars, rice cereal bars), and to update the reference for the Vitamin D_3 specifications. We are taking this action in response to a petition filed by Kellogg Company (Kellogg).

DATES: This rule is effective January 5, 2023. The incorporation by reference of certain material listed in the rule is approved by the Director of the Federal Register as of January 5, 2023. See section VIII for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final rule must be submitted by February 6, 2023.

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 February 6, 2023. 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–2019–F–3519 for ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3.'' 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 objections. 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 objections 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: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1204, or Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 12, 2019 (84 FR 39785), we announced that we filed a food additive petition (FAP 9A4823) submitted on behalf of Kellogg by Hogan Lovells US LLP, Columbia Square, 555 Thirteenth St. NW,

Washington, DC 20004. The petition proposed that FDA amend the food additive regulations in § 172.380 (21 CFR 172.380) to provide for the safe use of vitamin D_3 as a nutrient supplement in: (1) breakfast cereals as defined in § 170.3(n)(4) (21 CFR 170.3(n)(4)) at levels up to 560 international units (IU) vitamin D_3 per 100 grams (g) and (2) grain-based nutrition bars at levels up to 400 IU vitamin D_3 per 100 g. (One IU of vitamin D is equivalent to 0.025 micrograms (μg) of vitamin D. We also note that while the petition uses ''grain-based nutrition bars,'' we consider this to refer to the same category of food products as ''grain-based bars'' (*e.g.,* breakfast bars, granola bars, rice cereal bars), which is used elsewhere in existing FDA regulations (see 21 CFR 172.780 and 101.12); therefore, for consistency of terminology, we are using ''grain-based bars.'') FDA is also updating the reference for specifications for vitamin D_3 established in § 172.380(b) by incorporating by reference the most recent edition of the Food Chemicals Codex (FCC). The current food additive regulation for the use of vitamin D_3 (§ 172.380) indicates that the additive must meet the specifications in the 11th edition of the FCC (FCC 11). Since we received the petition, the FCC has been updated to the 13th edition (FCC 13). The specifications for Vitamin D_3 from FCC 11 are identical to those in FCC 13. Therefore, we are amending § 172.380(b) by adopting, and incorporating by reference, the most recent edition of the FCC (FCC 13).

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. 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 and/or mobilization from the bone, and possibly associated with decreased renal function and increased cardiovascular risk (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 § 184.1950 (21 CFR 184.1950). Under § 184.1(b)(2) (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 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 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. Vitamin D is affirmed as GRAS for use in certain foods as a nutrient supplement (as defined under § 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

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 (21 CFR 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; and 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. Vitamin D_2 baker's yeast is an approved food additive under § 172.381 (21 CFR 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 (21 CFR 172.382) for use as a source of vitamin D_2 in foods to which vitamin D_2, vitamin D_3, and vitamin D_2 baker's 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, and margarine; fruit smoothies; vegetable juices; extruded vegetable snacks; certain soups and soup mixes; and plant protein products.

To support their petition, Kellogg submitted dietary exposure estimates of vitamin D from the proposed uses of vitamin D_3, as well as all naturally occurring dietary sources of vitamin D, currently approved and affirmed uses of vitamin D under our food additive and GRAS regulations, and dietary supplements. Kellogg compared these dietary exposure estimates to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies (now the National Academy of Medicine). Kellogg also submitted published scientific literature pertaining to human clinical studies on vitamin D.

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 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 for 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 dietary exposure for the 90th percentile consumer of a food additive as a measure of high chronic dietary exposure (Ref. 3).

A. 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 (DRI) for vitamin D; these DRIs are a family of nutrient reference values that

includes ULs (Ref. 4). Based on this information, the IOM revised the ULs for vitamin D and published a report on their findings (Ref. 5). In their 2011 assessment of vitamin D, the IOM established the following 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, lowest-observed-effect level, 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_3. 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.

B. Dietary Exposure Estimate for Vitamin D

Kellogg provided mean and 90th percentile eaters-only dietary exposure estimates for vitamin D for the overall U.S. population and eight population subgroups from the: (1) proposed uses of vitamin D_3; (2) current food sources of vitamin D (including approved food additive and affirmed GRAS uses as a food ingredient, naturally occurring sources of vitamin D, and dietary supplements); and (3) the combined current and proposed food uses. Kellogg noted that dietary exposure was not estimated for infants 0–6 months as this age group is not expected to consume breakfast cereals or grain-based bars. Additionally, Kellogg indicated that dietary exposure was not estimated for infants 6–12 months for grain-based bars for the same reason; however, they were included in the exposure estimate for breakfast cereals (Ref. 3).

Kellogg presented the dietary exposure estimates to vitamin D from the proposed and existing uses. However, Kellogg did not provide an overall dietary exposure from all proposed uses, but instead provided separate dietary exposures for each of the petitioned uses of vitamin D_3. Kellogg then estimated a cumulative dietary exposure to vitamin D by adding the dietary exposures from each of the proposed uses and that from the existing uses. While the estimates of dietary exposures to each of the proposed and the existing uses of vitamin D are important to consider, it is not appropriate to estimate a cumulative dietary exposure by summing all the values because the populations of consumers for each of the food uses are not the same. Additionally, since the submission of the current petition by Kellogg, vitamin D_2 mushroom powder was approved under § 172.382 for use as a source of vitamin D_2 in certain foods (see Section I. Background). As a result, Kellogg did not include these uses in its cumulative dietary exposure estimate. Therefore, FDA conducted dietary exposure estimates to determine: (1) the overall dietary exposure to vitamin D_3 from the petitioned uses and (2) a cumulative dietary exposure for vitamin D from all existing sources, including the approved uses of vitamin D_2 in mushroom powder, and the petitioned uses for vitamin D_3 (Ref. 3).

FDA performed the dietary exposure estimate for vitamin D_3 from the proposed uses in breakfast cereals and grain-based bars using the combined 2011–2014 National Health and Nutrition Examination Survey. FDA also estimated a cumulative dietary exposure for vitamin D that includes all existing sources of vitamin D (*i.e.,* naturally occurring sources, approved and affirmed GRAS food uses of vitamin D, and dietary supplements) and Kellogg's proposed uses for vitamin D_3 in breakfast cereals and grain-based bars. Furthermore, FDA also included dietary exposure to the vitamin D metabolite, 25-hydroxyvitamin D, in the cumulative estimate to account for discrepancies seen between dietary intake and blood serum levels of vitamin D (Ref. 3).

For the overall U.S. population 1 year of age and older, we estimated the cumulative dietary exposure at the 90th percentile from all food sources of vitamin D, including the proposed uses and background sources, to be 2,730 IU/p/d. Additionally, the estimated 90th percentile dietary exposure to vitamin D from all food sources for infants 6 to 12 months of age is 1,060 IU/p/d. In summary, the cumulative dietary exposure to vitamin D_3 at the 90th percentile from the petitioned and background sources is below the IOM UL for all population groups for which ULs were established.

C. Safety of the Petitioned Uses of Vitamin D_3

We reviewed and evaluated the information submitted by Kellogg regarding the safety of the dietary exposure to vitamin D_3 from the proposed uses in grain-based bars and breakfast cereals. Kellogg submitted reports of scientific studies published after the 2011 IOM report and concluded that these publications support a conclusion that the proposed uses of vitamin D_3 are safe.

We reviewed the published reports of scientific studies on vitamin D submitted by Kellogg, 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 (85 FR 41916, July 13, 2020; 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 new 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 § 172.382 to allow for the safe use of vitamin D_2 mushroom powder in specific food categories (85 FR 41916). 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_3. Depending on the age group, the IOM ULs for vitamin D for the U.S. population 4 years and older range from 3,000 IU/p/d to 4,000 IU/p/d. FDA's cumulative dietary exposure estimate for 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 no greater than 2,740 IU/p/d, which is below the IOM ULs for all population groups 4 years and above. Estimated dietary exposure to vitamin D from all food sources for infants 6 months to 12 months of age is 1,060 IU/p/d, and for children aged 1 year to 3 years old is 1,730 IU/p/d. These estimates are below the respective IOM UL of 1,500 IU/p/d for infants 6 months to 12 months of age, and 2,500 IU/p/d for children aged older than 1 year to 3 years old (Ref. 6).

Because the estimated 90th percentile dietary exposure to vitamin D from all current and proposed food uses for each population group is less than the corresponding IOM UL for that population group, we conclude that dietary exposure to vitamin D_3 from the proposed uses as a nutrient supplement in breakfast cereals and grain-based bars are safe (Ref. 6).

III. Conclusion

Based on the relevant data available to FDA and information in the petition, we conclude that there is a reasonable certainty that no harm will result from the use of vitamin D_3 as a nutrient supplement in breakfast cereals, as defined in § 170.3(n)(4), at a level up to 560 IU vitamin D_3 per 100 g and in grain-based bars at a level up to 400 IU vitamin D_3 per 100 g. Additionally, we are amending § 172.380(b) by adopting, and incorporating by reference, the most recent edition of the FCC (FCC 13).

IV. Incorporation by Reference

FDA is incorporating by reference the monograph for vitamin D_3 from the Food Chemicals Codex, 13th ed., 2022, which was approved by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may purchase a copy of the material from the U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852, 1–800–227–8772, *https://www.usp.org/.* You may inspect a copy at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday. On our own initiative, we have revised § 172.380 to state that the referenced material can be found at FDA's Dockets Management Staff instead of FDA's Main Library. This change reflects a recent decision regarding the location of referenced materials cited in FDA regulations.

The FCC monograph sets forth a standard for purity and identity for vitamin D_3. The monograph provides specifications and analytical methodologies to identify the substance and establish acceptable purity criteria. The current food additive regulation for the use of vitamin D_3 (§ 172.380) indicates that the additive must meet the specifications in the FCC 11. The petitioner indicated that the vitamin D_3 petitioned in FAP 9A4823 complies with the specifications in the monograph for vitamin D_3 in FCC 11. Since we received the petition, the FCC has been updated to the 13th edition (FCC 13). The specifications for vitamin D_3 in FCC 13 are identical to those in FCC 11. Therefore, we are amending § 172.380(b) by adopting, and incorporating by reference, the specifications for vitamin D_3 in FCC 13 in place of FCC 11.

V. 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.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the August 12, 2019, **Federal Register** notice of petition for FAP 9A4823 (84 FR 39785). We stated that we had determined, under 21 CFR 25.32(k), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VII. 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.

VIII. 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 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.*

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

Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (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) 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 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.

X. 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. 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. National Institutes of Health, Office of Dietary Supplements, ''Vitamin D—Fact Sheet for Consumers,'' 2021. Available at: *https://ods.od.nih.gov/factsheets/Vitamind-Consumer/.*
2. Pilz, S., W. Marz, K.D. Cashman, et al., ''Rationale and Plan for Vitamin D Food Fortification: A Review and Guidance Paper,'' *Frontiers in Endocrinology,* 9, 2018. Available at: *https://www.frontiersin.org/articles/10.3389/fendo.2018.00373/full.*
* 3. FDA Memorandum from R. Shah, Chemistry Review Branch, Division of Food Ingredients, to L. Highbarger, Regulatory Review Branch, Division of Food Ingredients, October 13, 2022.
* 4. Institute of Medicine Committee to Review Dietary Reference Intakes for Vitamin D and Calcium; Ross, A.C., C.L. Taylor, A.L. Yaktine, et al., editors. ''Dietary Reference Intakes for Calcium and Vitamin D.'' Washington (DC): National Academies Press, 2011. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK56070/.*
5. Taylor, C., K. Patterson, J. Roseland, et al., ''Including Food 25-Hydroxyvitamin D in Intake Estimates May Reduce the Discrepancy between Dietary and Serum Measures of Vitamin D Status.'' *Journal of Nutrition,* 144: 654–659, 2014. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3985821/pdf/nut144654.pdf.*
* 6. FDA Memorandum from S.A. Assimon, Toxicology Review Branch, Division of Food Ingredients, to L. Highbarger, Regulatory Review Branch, Division of Food Ingredients, October 14, 2022.

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, 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. Amend § 172.380 by revising paragraph (b) and adding paragraphs (c)(9) and (10) to read as follows:

§ 172.380 Vitamin D_3.

* * * * *

(b) Vitamin D_3 meets the specifications of ''Vitamin D_3,'' *Food Chemicals Codex,* 13th edition, effective June 1, 2022, which is incorporated by reference. The Director of the Office 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 copies from the U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852; website: *https://www.usp.org.* Copies may be examined at the FDA or the National Archives and Records Administration (NARA). Contact FDA at: the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. For information on inspecting this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.*

(c) * * *

(9) At levels not to exceed 560 IU per 100 g in breakfast cereals (as defined under § 170.3(n)(4) of this chapter).

(10) At levels not to exceed 400 IU per 100 g in grain-based bars (*e.g.,* breakfast bars, granola bars, rice cereal bars).

Dated: December 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28428 Filed 1–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2022–N–3224]

Medical Devices; Neurological Devices; Classification of the Brain Stimulation Programming Planning Software

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying brain stimulation programming planning software into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the brain stimulation programming planning software's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 5, 2023. The classification was applicable on August 23, 2021.

FOR FURTHER INFORMATION CONTACT: Kristen Bowsher, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4210, Silver Spring, MD, 20993–0002, 301–796–6448, *Kristen.Bowsher@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the brain stimulation programming planning software as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an