

(iii) Ipeco SB Number 063–25–10, Revision 00; dated May 31, 2016.

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Issued in Burlington, Massachusetts, on October 19, 2017.

**Karen M. Grant,**

*Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.*

[FR Doc. 2017–24127 Filed 11–6–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA–2016–C–2767]

#### Listing of Color Additives Exempt From Certification; Calcium Carbonate

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum. We are taking this action in response to a color additive petition submitted by the Wm. Wrigley Jr. Company.

**DATES:** This rule is effective December 8, 2017. See section X for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by December 7, 2017. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 7, 2017.

**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 December 7, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 7, 2017. 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–2016–C–2767 for “Listing of Color Additives Exempt from Certification; Calcium Carbonate.” 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 with 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.gpo.gov/fdsys/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.

**FOR FURTHER INFORMATION CONTACT:** Judith Kidwell, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1071.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

In the **Federal Register** on October 7, 2016 (81 FR 69740), we announced that we filed a color additive petition (CAP 6C0307) submitted by Wm. Wrigley Jr. Company (petitioner), c/o Exponent, 1150 Connecticut Ave. NW., Suite 1100, Washington, DC 20036. The petition proposed to amend the color additive

regulations in part 73 (21 CFR part 73) *Listing of Color Additives Exempt from Certification* to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum. The proposed use excludes chocolate or the chocolate portion of candy, as the current standards of identity for chocolate do not allow for the addition of color additives (see 21 CFR 163.123, 163.124, 163.130, 163.135, 163.140, 163.145, 163.153, 163.155). After the petition was filed, the petitioner clarified that calcium carbonate is intended for use only in ink applied to the surface of the chewing gum.

## II. Background

Calcium carbonate is obtained from ground limestone or produced synthetically through a precipitation process using calcium oxide, water, and carbon dioxide. Calcium is abundant in the human body and is an integral component of bones, teeth, and other biological structures. Calcium constantly diffuses in and out of the bone and is resorbed by the kidney. Excess intake of calcium may result in hypercalcemia, hypercalciuria, gastrointestinal issues, kidney stones, interference with iron and zinc absorption, possible vascular and soft tissue calcification, and renal and cardiovascular damage. Carbonate is present in the human body as a critical component of the pH buffering system. The components of carbonate (carbon and oxygen) are ubiquitous in the human diet and body, and carbonate itself does not belong to a class of structures that is associated with any adverse effects or toxicity.

Calcium carbonate that is pharmaceutical grade is currently approved under § 73.1070 for use as a color additive in drugs in amounts consistent with good manufacturing practices (GMP). Additionally, food grade calcium carbonate and ground limestone (consisting of not less than 94 percent calcium carbonate) are affirmed as generally recognized as safe in § 184.1191 and § 184.1409 (21 CFR 184.1191 and 184.1409), respectively. These regulations do not include limitations for use in food other than current GMP. The petitioner proposed that to ensure that only food grade calcium carbonate is used to color hard and soft candy, mints, and chewing gum, the substance must meet the specifications of the Food Chemicals Codex, 10th edition (FCC 10). We have reviewed these specifications and agree that they should be incorporated into the regulation as set forth in this document. The petitioner proposed to use calcium carbonate to color soft and

hard candy, mints, and chewing gum in amounts consistent with GMP. The maximum GMP use level for calcium carbonate in hard and soft candy, mints, and chewing gum will be determined by the desired coloring effect. We have determined that the amount of calcium carbonate used in these foods is self-limiting because the addition of the color additive above a certain level will not achieve the desired coloring effect and negatively interferes with organoleptic properties, such as taste and texture. Because the amount of the color additive used in these foods is self-limiting, we have determined that there is no need for a specific upper limit on the percent by weight of calcium carbonate in hard and soft candy, mints, and chewing gum (Ref. 1).

## III. Safety Evaluation

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. Furthermore, under section 721(b)(4) of the FD&C Act, a color additive is deemed to be suitable and safe for the purpose of listing for use generally in or on food, while there is in effect a published finding declaring such substance exempt from the term “food additive” because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s) of the FD&C Act (21 U.S.C. 321(s)). FDA’s color additive regulations in 21 CFR 70.3(i) define “safe” to mean that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

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

### A. Estimated Dietary Exposure

The petitioner indicated that, given the types of candies to be colored and the variable conditions under which calcium carbonate would be used, the use of the assumption that all candies would contain calcium carbonate at the maximum GMP level would lead to an overestimate of exposure. However, because only hard and soft candy, mints, and chewing gum that are colored white would result in a potential exposure to calcium carbonate from the proposed use, the petitioner reviewed the 2009–2012 National Health and Examination Survey (NHANES) food codes and identified 51 food codes in which calcium carbonate could potentially be used as a color additive that represent the intended use in hard and soft candy, mints, and chewing gum. Although we identified additional food codes that could contain calcium carbonate, these codes were intentionally excluded by the petitioner because there were no associated eating occasions for these additional food codes over the survey years. We agree with the selected 51 food codes and the exclusion of the other food codes (Ref. 2). Furthermore, the petitioner used market data to refine their exposure estimate; however, these data were limited to those products that were introduced in the last 5 years and may not fully represent the market. Therefore, to be conservative, we estimated exposure to calcium carbonate using 2-day food consumption data from the 2009–2012 NHANES for the identified 51 food codes at the GMP use levels and made no adjustment for market data. Exposure to calcium carbonate and to calcium was estimated for the U.S. population 2 years of age and older and children 2 to 5 years of age (Ref. 2).

For the U.S. population 2 years of age and older, exposure estimates for calcium carbonate at the mean and 90th percentile from the proposed uses were 170 milligrams/person/day (mg/p/d) and 400 mg/p/d, respectively. For children 2 to 5 years of age, exposure estimates for calcium carbonate at the mean and 90th percentile were 125 mg/p/d and 270 mg/p/d, respectively.

Calcium carbonate is a source of calcium for the consumer once ingested and metabolized by the body. Therefore, as part of our evaluation, we also estimated exposure to calcium from the petitioned uses of calcium carbonate by assuming that the amount of calcium provided by calcium carbonate as a color additive is 40 percent of the total weight of calcium carbonate. For the U.S. population 2 years of age and older,

estimated exposure to calcium from the proposed uses of calcium carbonate at the mean and 90th percentile were 70 mg/p/d and 160 mg/p/d, respectively. For children 2 to 5 years of age, estimated exposure to calcium at the mean and 90th percentile were 50 mg/p/d and 110 mg/p/d, respectively.

Additionally, we estimated exposure to calcium from background dietary sources, drugs, and dietary supplements using 2-day food consumption data for all foods and nutrient data for calcium in those foods based on the U.S. Department of Agriculture's National Nutrient Database for Standard Reference. This estimate also included exposure to calcium from dietary supplements (including non-prescription antacids that contain calcium) based on NHANES 2-day survey data (Ref. 2).

For the U.S. population 2 years of age and older, exposure to calcium from background dietary sources, drugs, and dietary supplements at the mean and 90th percentile were estimated to be 1,125 mg/p/d and 1,900 mg/p/d, respectively. For children 2 to 5 years of age, exposure estimates at the mean and 90th percentile were 1,000 mg/p/d and 1,600 mg/p/d, respectively. Because our exposure estimates for dietary supplements include calcium from all sources, not just calcium carbonate, we believe that this exposure estimate is sufficiently conservative to include any exposure to calcium from the use of calcium carbonate to color drugs (Ref. 2).

We estimated exposure to calcium from background dietary sources, drugs, dietary supplements and the proposed uses of calcium carbonate at the mean and 90th percentile for the U.S. population 2 years of age and older and children 2 to 5 years of age. Based on these calculations, exposure estimates for calcium for the U.S. population 2 years of age and older at the mean and 90th percentile were 1,150 mg/p/d and 1,925 mg/p/d, respectively. For children 2 to 5 years of age, exposure estimates for calcium at the mean and 90th percentile were 1,025 mg/p/d and 1,625 mg/p/d, respectively (Ref. 2).

#### *B. Safety of the Petitioned Uses of Calcium Carbonate*

To support the safety of the petitioned use of calcium carbonate, the petitioner referenced safety information on calcium from the 2011 Institute of Medicine (IOM) Report on Dietary Reference Intakes for Calcium and Vitamin D (Ref. 3) and the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies' reevaluation of the safety of

calcium (Ref. 4). In 2011, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board of the IOM conducted an extensive review of relevant published scientific literature on calcium to update current dietary reference intakes and Upper Tolerable Intake Levels (UL). In their 2011 assessment of calcium, the IOM established a UL of 1,000 mg/p/d for infants 0 to 6 months of age and 1,500 mg/p/d for infants 6 to 12 months of age. For children 1 to 8 years of age, IOM did not change the UL of 2,500 mg/p/d from the previous IOM report in 1997. For children 9 to 18 years of age, IOM increased the UL to 3,000 mg/p/d. For adults 19 to 50 years of age, the IOM established a UL of 2,500 mg/p/d; for adults 51 years and older, the IOM established a UL of 2,000 mg/p/d.

The IOM considers the UL as the highest average daily intake level of a nutrient that poses no risk of adverse effects when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients. 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 exposure estimates for calcium as the primary basis for assessing the safety of the petitioned uses of calcium carbonate.

The estimated dietary exposure to calcium from the petitioned uses, dietary sources, and dietary supplements at the 90th percentile for the U.S. population 2 years of age and older is estimated to be 1,925 mg/p/d, which is below the IOM's UL of 2,000–3,000 mg/p/d. For children 2 to 5 years of age, the exposure estimate at the 90th percentile is 1,625 mg/p/d, which also is below the IOM's UL of 2,500 mg/p/d for this age group. Additionally, the body of literature on calcium carbonate and calcium does not present evidence of safety concerns at the expected dietary exposures discussed above. Thus, we conclude that the petitioned use of calcium carbonate as a color additive in soft and hard candy, mints, and chewing gum is safe (Ref. 5).

#### **IV. Incorporation by Reference**

FDA is incorporating by reference the Food Chemicals Codex, 10th ed. (2016), pp. 213–214 (calcium carbonate) and p. 754 (limestone, ground), which was

approved by the Office of the Federal Register. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (<http://www.usp.org>). Copies also may be examined at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039.

The FCC is a compendium of internationally recognized standards for the purity and identity of food ingredients. To ensure that only food grade calcium carbonate and ground limestone (consisting of not less than 94 percent calcium carbonate) are used in hard and soft candy, mints, and chewing gum, the additive must meet the specifications and identity in the appropriate FCC monograph.

#### **V. Conclusion**

FDA reviewed the data and information in the petition and other available relevant material and determined the use of calcium carbonate to color hard and soft candy, mints, and chewing gum at GMP levels is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for the petitioned uses. We note that these uses do not extend to chocolate or the chocolate portion of candy because the standards of identity for chocolate do not allow for the addition of color additives (see 21 CFR 163.123, 163.124, 163.130, 163.135, 163.140, 163.145, 163.153, 163.155). Based on the available information, we are amending the color additive regulations in part 73 as set forth in this document. In addition, based on the factors listed in 21 CFR 71.20(b), we conclude that certification of calcium carbonate to color hard and soft candy, mints, and chewing gum is not necessary for the protection of public health (Ref. 1).

#### **VI. Public Disclosure**

In accordance with § 71.15 (21 CFR 71.15), 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 § 71.15, we will delete from the documents any materials that are not available for public disclosure.

#### **VII. Analysis of Environmental Impact**

We previously considered the environmental effects of this rule, as stated in the October 7, 2016, **Federal Register** notice of petition for CAP 6C0307 (81 FR 69740). 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.

#### VIII. 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.

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

Our review of this petition was limited to section 721 of the FD&C Act. 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 (ll)(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 color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color 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 color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

#### X. Objections

This rule is effective as shown in the DATES section, except as to any provisions that may be stayed by the filing of proper 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 at 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>. We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

#### XI. References

The following references are on display with 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 that are published articles and books are not on display.

1. Memorandum from N. Hepp, Color Technology Team, Office of Cosmetics and Colors (OCAC), CFSAN, FDA to C. Johnston, Division of Petition Review, Office of Food Additive Safety (OFAS), CFSAN, FDA, October 27, 2016.
2. Memorandum from D. Doell, Division of Petition Review, OFAS, CFSAN, FDA to J. Kidwell, Division of Petition Review, OFAS, CFSAN, FDA, February 16, 2017.
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.
4. European Food Safety Authority (EFSA). “Scientific Opinion on the Tolerable Upper Intake Level of Calcium.” *EFSA Journal*, vol. 10(7), p. 2814, 2012.
5. Memorandum from T. Thurmond, Division of Petition Review, OFAS, CFSAN, FDA to J. Kidwell, Division of Petition Review, OFAS, CFSAN, FDA, February 17, 2017.

#### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Incorporation by reference, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

#### PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

- 1. The authority citation for part 73 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

- 2. Section 73.70 is added to subpart A to read as follows:

#### § 73.70 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white powder consisting essentially of calcium carbonate (CaCO<sub>3</sub>) prepared either by grinding naturally occurring limestone or synthetically, by precipitation.

(2) Color additive mixtures for food use made with calcium carbonate may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive meets the specifications of the Food Chemicals Codex, 10th ed. (2016), pp. 213–214 (calcium carbonate) and p. 754 (limestone, ground), 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 United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/cfr/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/cfr/ibr_locations.html).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been promulgated under section 401 of the Federal Food, Drug,

and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: November 1, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-24194 Filed 11-6-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 862

[Docket No. FDA-2017-N-4394]

#### Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Total 25-Hydroxyvitamin D Mass Spectrometry Test System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is classifying the total 25-hydroxyvitamin D mass spectrometry test system 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 total 25-hydroxyvitamin D mass spectrometry test system'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, in part by reducing regulatory burdens.

**DATES:** This order is effective November 7, 2017. The classification was applicable on May 18, 2017.

**FOR FURTHER INFORMATION CONTACT:** Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993-0002, 301-796-5866, [steven.tjoe@fda.hhs.gov](mailto:steven.tjoe@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the total 25-hydroxyvitamin D mass spectrometry test system 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 reducing regulatory burdens 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 action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After

receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

##### II. De Novo Classification

On March 20, 2017, AB Sciex LLC submitted a request for De Novo classification of the Vitamin D 200M Assay for the Topaz System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable