interest because the final rule is merely codifying the new name and expanded function of the advisory committee to reflect the current committee charter.

**List of Subjects in 21 CFR Part 14**

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

## PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264, Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

■ 2. Section 14.100 is amended by revising the heading of paragraph (c)(9) and paragraph (c)(9)(ii) to read as follows:

**§ 14.100 List of standing advisory committees.**

* * * * *

(c) * * *

(9) *Bone, Reproductive and Urologic Drugs Advisory Committee.*

(i) * * *

(ii) Function: Advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

* * * * *

Dated: April 8, 2014.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014–08151 Filed 4–10–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 73

**[Docket No. FDA–2012–C–0900]**

## Listing of Color Additives Exempt From Certification; Spirulina Extract

**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 expanded safe use of spirulina extract as a color additive in food. This action is in response to a petition filed by GNT USA, Inc.

**DATES:** This rule is effective May 13, 2014. See section X for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by May 12, 2014.

**ADDRESSES:** You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2012–C–0900, by any of the following methods:

**Electronic Submissions**

Submit electronic objections in the following way:

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

**Written Submissions**

Submit written objections in the following ways:

- *Mail/Hand Delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA–2012–C–0900 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section.

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

**FOR FURTHER INFORMATION CONTACT:** Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1264.

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

In a document published in the **Federal Register** of September 6, 2012 (77 FR 54862), we announced that GNT USA, Inc., c/o Hogan Lovells US LLP, Columbia Square, 555 Thirteenth St. NW., Washington, DC 20004, had filed a color additive petition (CAP 2C0297). The petition proposed to amend the color additive regulations in part 73 *Listing of Color Additives Exempt From Certification* (21 CFR part 73) to provide for the safe use of spirulina concentrate, prepared from a filtered aqueous extract of the dried biomass of *Arthrospira platensis* (*A. platensis*) (an edible blue-green cyanobacterium also known as *Spirulina platensis*), as a color additive in food.

The spirulina concentrate that is manufactured by the petitioner is a blue colored powder or liquid produced by extracting the water soluble components of *A. platensis,* namely phycocyanins and other proteins, polysaccharides, lipids, and minor amounts of components such as vitamins, minerals, and water, followed by evaporation and the addition of sugars and other food-grade carriers (and water, if liquid form). The principal coloring components in the concentrate are the phycocyanins (not more than 2 percent), with lesser amounts of chlorophyll and carotenoids.

### II. Background

In the **Federal Register** of August 13, 2013, we issued a final rule in response to a color additive petition (CAP 2C0293) approving the use of a filtered aqueous extract of the dried biomass of *A. platensis* as a color additive in candy and chewing gum (78 FR 49117). We established spirulina extract as the common or usual name for the color additive and listed it in § 73.530 (21 CFR 73.530). In addition to the identity of the color additive, the regulation in § 73.530 includes specifications that must be met for lead, arsenic, mercury, and microcystin toxin; however, the regulation does not impose a specific upper limit for spirulina extract in food or for the phycocyanin content of the color additive because FDA determined that the amount of the color additive used in food was self-limiting. Instead, FDA limited the use of spirulina extract in candy and chewing gum to amounts consistent with good manufacturing practice.

The primary difference between the spirulina extract that was the subject of CAP 2C0293 and spirulina concentrate that is the subject of CAP 2C0297 is the concentration of the components. Although spirulina concentrate is produced with an evaporation step to concentrate the components, the color additive has a lower level of phycocyanins (i.e., not more than 2 percent) than the spirulina extract that was the subject of CAP 2C0293 (i.e., not

less than 10 percent) because of a difference in the extraction process. To differentiate its color additive from this other spirulina product, the petitioner proposed that its color additive be listed separately as spirulina concentrate. However, since the regulation in § 73.530 does not have a specification or limit on the phycocyanin content of the color additive, we have determined that the subject color additive meets the specifications of identity for spirulina extract in § 73.530. Therefore, we have concluded that the petitioned uses should be added to § 73.530 for spirulina extract. The subject color additive will be referred hereinafter in this final rule as spirulina extract.

For the subject petition, spirulina extract is proposed for use in coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, and ready-to-eat cereals (excluding extruded cereals). The petitioner has proposed a phycocyanin limit of 2 percent in the color additive. However, we have determined that because the amount of spirulina extract used in food is self-limiting, there is no need for a specific upper limit for the phycocyanin content or the color additive (Ref. 1). Therefore, we are limiting the use of spirulina extract in the proposed foods to amounts consistent with good manufacturing practice.

## III. Evaluation of Safety

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 may not be listed for a particular use unless the data and information available to FDA establishes that the color additive is safe for that use. Our color additive regulations at 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 food 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 literature) available to us. We compare an individual's estimated daily intake (EDI) of the additive from all food sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all food sources of the additive. We commonly use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic dietary intake.

## IV. Safety of Petitioned Use of the Additive

As part of our safety evaluation, we considered the exposure to phycocyanins from both the petitioned and current uses of spirulina extract as a color additive. We estimated that the petitioned uses of spirulina extract will result in an exposure to phycocyanins of 80 milligrams/person/day (mg/p/d) for the 90th percentile consumer 2 years of age or older. We also estimated the exposure to phycocyanins from the petitioned use of the subject color additive for various age groups, including children 2 to 5 and 6 to 12 years of age, and teenagers 13 to 18 years of age, as these age groups may consume greater amounts of the foods containing spirulina extract. For these population subgroups, we estimated the exposure to phycocyanins at the 90th percentile to be 80 mg/p/d for children 2 to 5 years of age and for teenagers, and 90 mg/p/d for children 6 to 12 years of age (Ref. 2).

Regarding cumulative exposure to phycocyanins from spirulina and spirulina-derived substances, FDA discussed in the final rule for spirulina extract as a color additive in candy and chewing gum that spirulina and spirulina-derived substances have been the subject of four notices submitted by firms to FDA with their determinations that certain uses of spirulina-derived substances are generally recognized as safe (GRAS) (78 FR 49117 at 49118). We evaluated each of these GRAS notices (GRNs) and concluded that we had no reason to question the basis of these GRAS determinations (Refs. 3–6). One of the GRAS notices (GRN 424) pertains to the use of an aqueous extract of powdered *A. platensis* or *A. maxima* as an ingredient for use in all foods at levels consistent with good manufacturing practice, except for infant formula and those food products (e.g., meat, eggs, and catfish) requiring additional review by the U.S. Department of Agriculture. The spirulina substance that was the subject of GRN 424 is similar in chemical composition to the subject color additive, but with a much higher phycocyanin content, ranging from 42 to 47 percent. The notifier (the person who submits a GRAS notice) for GRN 424 estimated a conservative exposure to phycocyanins from the notified uses of a spirulina extract to be 1,140 mg/p/d. This exposure estimate does not include exposure to spirulina and phycocyanins from dietary supplement use due to the notifier's belief that their use is not widespread, and, therefore, would not significantly contribute to the dietary exposure of the wider population (Ref. 7).

We have concluded that the exposure that was estimated for GRN 424 continues to represent the upper bound cumulative exposure to phycocyanins from spirulina-based ingredients in food because of the high phycocyanin content of the substance that is the subject of GRN 424 (i.e., 42 to 47 percent) and its intended use in most foods. Therefore, we conclude that this cumulative exposure estimate of 1,140 mg/p/d for phycocyanins from current and proposed uses of spirulina-derived ingredients is sufficiently conservative (Ref. 2).

Consistent with how we evaluated the petition for the use of spirulina extract as a color additive in candy and chewing gum, we reviewed published animal feeding studies that evaluated the safety of spirulina powder, spirulina extract, and phycocyanins, the main coloring component of spirulina extract. We also evaluated the significance of data findings from human studies that investigated reported therapeutic effects of spirulina supplementation and considered adverse event data from case reports regarding individual humans that ingested spirulina for various time intervals of weeks to several months.

To support the safety of the proposed use of spirulina extract, the petitioner conducted a search of the peer-reviewed published literature on spirulina and submitted the published animal and human studies that they identified as being relevant to their petition. The petitioner concluded that these publications support the petitioned use of spirulina extract in food. Of the publications submitted by the petitioner, some of the papers had been previously reviewed by FDA. Our review of the new information along with the information submitted in previously reviewed publications did not reveal any new toxicological issues or concerns (Ref. 8).

In our evaluation of the petitioned use of spirulina extract to color candy and chewing gum, we had selected as the pivotal safety study a chronic feeding study that tested spirulina powder in rats for 21 months at concentrations of 10, 20, or 30 percent of the diet (equal to 5,000, 10,000 or 15,000 milligrams per kilogram bodyweight per day (mg/kg bw/day)). We determined that the results of this study showed no

indications of adverse effects in rats with prolonged consumption of the spirulina powder at any of the doses tested. Therefore, we concluded that the no-observed-effect-level (NOEL) for spirulina is 15,000 mg/kg bw/d (900,000 mg/p/d for a 60 kilogram person) based on the absence of any observed treatment-related effects at the highest dose tested in this 21-month study. The phycocyanin content in the spirulina powders that were tested in this study were reported to be in the range of 12 to 20.5 percent and, based on this range, we had determined the NOEL for phycocyanins for humans to be between 108,000 to 184,500 mg/p/d (78 FR 49117 at 49119). Taking into account the available safety information, the estimated exposure to phycocyanins from the petitioned use of the spirulina extract, and the margin of safety between the cumulative EDI and the NOEL, we conclude that the petitioned uses of spirulina extract as a color additive in food is safe.

The potential for spirulina phycocyanins to be allergenic was also discussed in the final rule for the use of spirulina extract as a color additive in candy and chewing gum (78 FR 49117 at 49119). We stated that based on our review of a comparison of the known amino acid sequences of phycocyanins with the sequences of known protein allergens, there is a low probability that the spirulina phycocyanins are protein allergens. Therefore, we concluded that the spirulina phycocyanins present an insignificant allergy risk to consumers of the color additive. We are not aware of any information that would cause us to change this conclusion.

## V. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the petitioned use of spirulina extract in confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, and ready-to-eat cereals (excluding extruded cereals), is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for the petitioned use. Consequently, we are amending the color additive regulations in part 73 as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), we conclude that certification of spirulina extract is not necessary for the protection of the public health.

## 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. Environmental Impact

We previously considered the environmental effects of this rule as stated in the September 6, 2012, notice of filing for CAP 2C0297 (77 FR 54862). 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 FD&C 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, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(*ll*) of the FD&C Act (21 U.S.C. 331(*ll*)). Section 301(ll) of the FD&C Act 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 products containing this color additive. Accordingly, this final rule should not be construed to be a statement that a product 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 Division of Dockets Management (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.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://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 have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to Web sites

after this document publishes in the **Federal Register**.)

1. Memorandum from N. Belai, Color Technology Team, OCAC, CFSAN, FDA to R. Davy, Division of Petition Review, OFAS, CFSAN, FDA, February 6, 2013.

2. Memorandum from H. Lee, Division of Petition Review, CFSAN, FDA to R. Davy, Division of Petition Review, CFSAN, FDA, May 7, 2013.

3. Letter from L. Tarantino, Office of Food Additive Safety, CFSAN, FDA to J. Dore, Cyanotech Corporation, Agency Response Letter GRAS Notice No. GRN 000127, October 6, 2003, (*http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153944.htm*).

4. Letter from D. Keefe, Office of Food Additive Safety, CFSAN, FDA to S. Cho, Nutra Source, Agency Response Letter GRAS Notice No. GRN 000394, June 4, 2012, (*http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm313046.htm*).

5. Letter from D. Keefe, Office of Food Additive Safety, CFSAN, FDA to J. Endres, AIBMR Life Sciences, Inc., Agency Response Letter GRAS Notice No. GRN 000417, August 10, 2012, (*http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm319628.htm*).

6. Letter from D. Keefe, Office of Food Additive Safety, CFSAN, FDA to H. Newman, Desert Lake Technologies, LLC, Agency Response Letter GRAS Notice No. GRN 000424, December 6, 2012, (*http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm335743.htm*).

7. Memorandum from H. Lee, Division of Petition Review, CFSAN, FDA to R. Davy, Division of Petition Review, CFSAN, FDA, January 15, 2013.

8. Memorandum from J. Park, Division of Petition Review, CFSAN, FDA to F. Ellison, Division of Petition Review, CFSAN, FDA, November 1, 2013.

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

Color additives, Cosmetics, Drugs, 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 21 CFR 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 73.530 is amended by revising paragraph (c) to read as follows:

**§ 73.530 Spirulina extract.**

* * * * *

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, and ready-to-eat cereals (excluding extruded cereals), at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

* * * * *

Dated: April 1, 2014.

**Susan M. Bernard,**

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

[FR Doc. 2014–08099 Filed 4–10–14; 8:45 am]

**BILLING CODE 4160–01–P**

## FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

### 29 CFR Part 2700

### Procedural Rules To Permit Parties To File and Serve Documents Electronically

**AGENCY:** Federal Mine Safety and Health Review Commission.

**ACTION:** Interim rule; extension of comment period.

**SUMMARY:** The Federal Mine Safety and Health Review Commission is extending the comment period for the interim rule entitled, ''Procedural Rules to Permit Parties to File and Serve Documents Electronically,'' that appeared in the **Federal Register** of December 23, 2013. The Commission published a correction to the interim rule in the **Federal Register** on January 17, 2014.

**DATES:** The Commission is extending the comment period on the interim rule published in the **Federal Register** on December 23, 2013 (78 FR 77354). Submit either electronic or written comments on the interim rule by July 31, 2014.

**ADDRESSES:** Electronic comments should state ''Comments on Electronic Rule Changes'' in the subject line and be emailed to *mmccord@fmshrc.gov*. Written comments should be mailed to Michael A. McCord, General Counsel, Office of the General Counsel, Federal Mine Safety and Health Review Commission, 1331 Pennsylvania Avenue NW., Suite 520N, Washington, DC 20004–1710, or sent via facsimile to 202–434–9944.

**FOR FURTHER INFORMATION CONTACT:** Michael A. McCord, General Counsel, Office of the General Counsel, Federal Mine Safety and Health Review Commission, at (202) 434–9935 or *mmccord@fmshrc.gov*.

**SUPPLEMENTARY INFORMATION:** The Commission published in the **Federal Register** on December 23, 2013 (78 FR 77354), an interim rule with a request for comments. In the interim rule, the Commission amended its procedural rules to permit parties to file and serve documents electronically. The Commission is using a new electronic case management system (e-CMS) that will allow parties to file documents electronically with the Commission through a portal which may be accessed on the Commission's Web site (*www.fmshrc.gov*). The Commission expects that the e-CMS will become available for electronic filing in the near future and encourages parties to check the Commission's Web site for more specific information.

The Commission is extending the comment period on the interim rule through July 31, 2014, so that parties may include in their comments any experiences they have had using the e-CMS.

Dated: April 4, 2014.

**Mary Lu Jordan,**

*Chairman, Federal Mine Safety and Health Review Commission.*

[FR Doc. 2014–08078 Filed 4–10–14; 8:45 am]

**BILLING CODE 6735–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R01–OAR–2008–0117; FRL–9908–51-Region 1]**

### Approval and Promulgation of Air Quality Implementation Plans; Connecticut; Reasonable Further Progress Plan and 2002 Base Year Emission Inventory

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Correcting amendments.

**SUMMARY:** The Environmental Protection Agency (EPA) published a final rule regarding reasonable further progress plans and 2002 base year emission inventories for Connecticut in the **Federal Register** on August 22, 2012. A duplicate paragraph letter was