to the list of countries with which DOD has such arrangements. The list is informational only and does not affect any right, duty or prohibition that applies to any person under the DPAS Regulations. DOD would be able to request priority delivery in countries with which it has security of supply arrangements and persons in the United States would be able to request assistance from DOD in obtaining priority delivery even if the list did not appear in the DPAS Regulations.

With the addition of Spain, the list will read: Australia, Finland, Italy, The Netherlands, Spain, Sweden and the United Kingdom.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined not to be significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), unless that collection of information displays a currently valid Office of Management and Budget control number. This rule does not involve a collection of information that is subject to the Paperwork Reduction Act.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. BIS finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice of proposed rulemaking and the opportunity for public comment because it is unnecessary. This rule merely updates the list of countries with which the DOD has entered into security of supply arrangements and thus may seek prioritization of contracts in those countries. Persons in the United States who need such prioritization may request DOD assistance to obtain it. The lists are in the DPAS regulations to inform persons whose need for contract prioritization may extend beyond the United States of where they may be able to obtain assistance. DOD may seek such prioritization and persons in the United States may request DOD assistance regardless whether or not the countries with which DOD has entered into security of supply arrangements are identified in the DPAS Regulations. Listing these countries in the DPAS Regulations does not affect any right, duty or prohibition that applies to any person under those regulations. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. Because neither the Administrative Procedure Act nor any other law requires that notice and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

In addition, the 30-day delay in effectiveness otherwise required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule.

List of Subjects in 15 CFR Part 700

Administrative practice and procedure, Business and industry, Government contracts, National defense, Reporting and recordkeeping requirements, Strategic and critical materials.

For the reasons set forth in the preamble, the Defense Priorities and Allocations System Regulations (15 CFR part 700) are amended as follows:

PART 700—[AMENDED]

■ 1. The authority citation for 15 CFR part 700 continues to read as follows:

Authority: 50 U.S.C. App. 2061, *et seq.;* 42 U.S.C. 5195, *et seq.;* 50 U.S.C. App 468; 10 U.S.C. 2538; 50 U.S.C. 82; E.O. 12656, 53 FR 226, 3 CFR, 1988, Comp. 585; E.O. 12742, 56 FR 1079, 3 CFR, 1991 Comp. 309; E.O. 13603, 77 FR 16651, 3 CFR, 2012 Comp., p. 225.

§ 700.57 [Amended]

■ 2. Section 700.57 is amended by adding ''Spain'' after ''The Netherlands,'' in:

■ a. The last sentence of paragraph (a);

■ b. The italicized heading of paragraph (c);

■ c. Paragraph (c)(1); and

■ d. The first and second sentences of paragraph (c)(2).

Dated: August 17, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–20704 Filed 8–20–15; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2014–C–1552]

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 safe use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules. This action is in response to a petition filed by Colorcon, Inc. (Colorcon).

DATES: This rule is effective September 22, 2015. See section IX for information on the filing of objections. Submit either electronic or written objections and requests for a hearing by September 21, 2015.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2014–C–1552, 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–2014–C–1552 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: Molly A. Harry, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1075.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of October 22, 2014 (79 FR 63062), we announced that we had filed a color additive petition (CAP 4C0300), submitted by Colorcon, Inc. (petitioner), 275 Ruth Rd., Harleysville, PA 19438. The petition proposed to amend the color additive regulations in Title 21, Code of Federal Regulations (CFR) part 73 *Listing of Color Additives Exempt From Certification* to provide for the safe use of spirulina extract, prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis* (*A. platensis*), as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules.

II. Background

In the **Federal Register** of August 13, 2013 (78 FR 49117), 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 at levels consistent with good manufacturing practice (GMP). 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.

In the **Federal Register** of April 11, 2014 (79 FR 20095), we issued a final rule in response to a color additive petition (CAP 2C0297) amending § 73.530 to include the use of spirulina extract as a color additive 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), at levels consistent with GMP.

The spirulina extract used for the purposes of CAP 4C0300 is a blue-colored powder produced by the filtered aqueous extraction of the spray-dried biomass of *A. platensis* (also known as *Spirulina platensis*), an edible blue-green cyanobacterium. The color additive contains phycocyanins as the principal coloring component. The maximum phycocyanin content of the color additive is 28 percent. Based on data and information provided in the petition on the identity, physical and chemical properties, manufacturing process, and composition of the color additive, we have determined that the color additive meets the specifications for spirulina extract in § 73.530 (Ref. 1).

Spirulina extract is intended to be used as a color additive in film coating formulations applied to dietary supplement and drug tablets and capsules in amounts consistent with GMP. The maximum GMP use level for spirulina extract in an individual coating will be determined by the desired coloring effect. Therefore, because the amount of the color additive used in these coatings is self-limiting, we have determined that there is no need for a specific upper limit on the percent by weight of spirulina extract in coating formulations applied to dietary supplement and drug tablets and capsules (Ref. 1).

III. Safety Evaluation

A. Determination 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 establish 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 exposure, or estimated daily intake (EDI), of the 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 additive proposed for use in particular foods or drugs and on data regarding the amount consumed from all ingested sources of the additive. We commonly use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic exposure.

B. Safety of Petitioned Use of the Color Additive

To support the safety of the petitioned use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules, Colorcon submitted an exposure estimate for phycocyanins (the principal coloring component). Colorcon estimated that the petitioned use of spirulina extract in coating formulations applied to dietary supplement and drug tablets and capsules will result in an exposure to phycocyanins of 20.9 milligrams/person/day (mg/p/d) for the 90th percentile consumer (Ref. 2). We agree with Colorcon's exposure estimate for phycocyanins and conclude that it is sufficiently conservative (Ref. 2).[1]

Regarding cumulative exposure (cumulative EDI, or CEDI) to phycocyanins from spirulina and spirulina-derived substances, FDA discussed in the final rule for use of 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 informing us of their determinations that certain uses of spirulina-derived substances are generally recognized as safe (GRAS) (78 FR 49117 at 49118). One of the GRAS notices (GRN 000424) pertains to the use of a spirulina-derived substance similar in chemical composition to the subject color additive but with a much higher phycocyanin content ranging from 42 to 47 percent, and included use in all foods (except infant formula and foods under U.S. Department of Agriculture's jurisdiction) at levels consistent with GMP. The upper bound CEDI for phycocyanins resulting from the notified uses of spirulina extract was estimated to be 1,140 mg/p/d in GRN 000424 based on conservative assumptions (Ref. 3). This exposure estimate does not appear to include exposure to phycocyanins from use of spirulina extract in dietary supplements. Colorcon estimated that the use of spirulina extract in coating formulations applied to dietary supplement and drug tablets and capsules would increase the previously estimated upper bound CEDI of phycocyanins by 1.8 percent. We agree that Colorcon's estimate is conservative, and that the petitioned use of spirulina

[1] The petition referred to both ''drug tablets and capsules'' and ''pharmaceutical tablets and capsules.'' The term ''pharmaceutical tablets and capsules'' was used regarding the exposure assessment (Ref. 2).

extract would not contribute significantly to the previously estimated upper bound CEDI of 1,140 mg/p/d for phycocyanins (Ref. 2).

In support of safety of the use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules in the subject petition, Colorcon referenced the safety determinations made by FDA for CAP 2C0293 (78 FR 49117) and CAP 2C0297 (79 FR 20095). The petitioner also conducted a search of the peer-reviewed scientific literature for animal and human oral consumption studies that tested spirulina, spirulina-derived ingredients, and phycocyanins that have been published since 2011. The petitioner submitted the published animal and human studies that they had identified as being relevant to their petition. We reviewed the relevant studies and determined that these publications did not raise any safety concerns.

In our previous evaluations of the use of spirulina extract as a color additive in food, we had selected as the pivotal safety study a 21-month chronic feeding study that tested spirulina powder in rats at dietary concentrations of 10, 20, or 30 percent (equivalent to 5,000, 10,000, or 15,000 milligrams per kilogram bodyweight per day (mg/kg bw/d)). The results of this study showed that prolonged oral consumption of spirulina powder up to a dietary concentration of 15,000 mg/kg bw/d was without adverse effects. 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 kg person) based on the absence of treatment-related adverse effects at the highest concentration tested in this study. We had also determined the NOEL for phycocyanins for humans to be between 108,000 and 184,500 mg/p/d (78 FR 49117 at 49119). Taking into account all the available safety information, the estimated exposure to phycocyanins from the petitioned use of the spirulina extract, and the margin of safety between the CEDI for phycocyanin (1,140 mg/p/d) and the NOEL for phycocyanin (108,000 to 184,500 mg/p/d), we conclude that the petitioned use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules is safe (Ref. 4).

The potential allergenicity of spirulina phycocyanins was 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). Based on our review of a comparison of the known amino acid sequences of phycocyanins with the sequences of known protein allergens, we had determined that there is a low probability that phycocyanins are protein allergens. We therefore concluded that the spirulina phycocyanins present an insignificant allergy risk to consumers of the color additive. We are not aware of any new information that would cause us to change this conclusion.

IV. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the petitioned use of spirulina extract in coating formulations applied to dietary supplement and drug tablets and capsules 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.

V. 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.

VI. Environmental Impact

We previously considered the environmental effects of this rule, as stated in the October 22, 2014, notice of filing for CAP 4C0300. We stated that we had determined, under 21 CFR 25.32(r), 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. 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, section 301(*ll*) of the FD&C Act (21 U.S.C. 331(*ll*) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(*ll*)(1) to (4) of the FD&C Act applies. In our review of this petition, 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.

IX. 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) of the regulation 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**.

X. 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 address in this reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

1. Memorandum from N. Belai, Color Technology Team, OCAC, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, March 19, 2015.
2. Memorandum from H. Lee, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, January 30, 2015.
3. Letter from D. Keefe, Office of Food Additive Safety, CFSAN, FDA to H. Newman, Desert Lake Technologies, LLC, Agency Response Letter GRAS Notice 000424, December 6, 2012, (*http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm335743.htm*).
4. Memorandum from T. Walker, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, April 2, 2015.

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 re-delegated 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, ready-to-eat cereals (excluding extruded cereals), and coating formulations applied to dietary supplement tablets and capsules, 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.

* * * * *

■ 3. Section 73.1530 is added to subpart B to read as follows:

§ 73.1530 Spirulina extract.

(a) *Identity.* (1) The color additive spirulina extract is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis.* The color additive contains phycocyanins as the principal coloring components.

(2) Color additive mixtures for drug use made with spirulina extract may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* Spirulina extract must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 2 milligrams per kilogram (mg/kg) (2 parts per million (ppm));

(2) Arsenic, not more than 2 mg/kg (2 ppm);

(3) Mercury, not more than 1 mg/kg (1 ppm); and

(4) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring coating formulations applied to drug tablets and capsules, at levels consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall 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: August 14, 2015.

Susan Bernard,

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

[FR Doc. 2015–20676 Filed 8–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2015–0216]

RIN 1625–AA08

Special Local Regulation; Suncoast Super Boat Grand Prix; Gulf of Mexico, Sarasota, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending a special local regulation for the Suncoast Super Boat Grand Prix that occurs on the waters of the Gulf of Mexico near Sarasota, Florida. The event is scheduled to take place annually on the first Friday, Saturday, and Sunday of July from 10 a.m. to 5 p.m. The amendment is needed in order to protect the safety of race participants, participant vessels, spectators, and the general public on the navigable waters of the United States. The amended special local regulation will restrict vessel traffic on the waters near the event by establishing the following three areas: A race area, where all persons and vessels, except those persons and vessels participating in the high speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within; a spectator area, where all vessels must be anchored or operate at No Wake Speed; and an enforcement area where designated representatives may control vessel traffic as determined by prevailing conditions.

DATES: This rule is effective September 21, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2015–0216. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the