Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 comments submitted to the Dockets Management Staff, FDA will post your comment, 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–2011–F–0172 for ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.'' Received comments, 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.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments 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: Felicia B. Billingslea, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 4, 2017, FDA published an interim final rule with a 60-day comment period to request comments on the extension of the compliance date for our final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The interim final rule extended the compliance date from May 5, 2017, to May 7, 2018, and invited comment on several specific questions on how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives to provide consumers with nutrition information so that they can make informed choices for themselves and their families. Comments will inform FDA's regulation for the disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments.

We have received a request for a 60-day extension of the comment period for the interim final rule. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the interim final rule.

FDA has considered the request and is extending the comment period for the interim final rule for 30 days, until August 2, 2017. We believe that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying Agency action on these important issues.

Dated: June 27, 2017.

Anna K. Abram,

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

[FR Doc. 2017–13889 Filed 6–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2016–C–2570]

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 to seasonally color hard-boiled shell eggs at levels consistent with good manufacturing practice (GMP). This action is in response to a color additive petition (CAP) filed by McCormick & Company, Inc. (McCormick).

DATES: This rule is effective August 3, 2017. Submit either electronic or written objections and requests for a hearing on the final rule by August 2, 2017. See section IX for further information on the filing of objections.

ADDRESSES: You may submit either electronic or written 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 August 2, 2017. The *https://www.regulations.gov* electronic filing

system will accept comments until midnight Eastern Time at the end of August 2, 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–2570 for ''Listing of Color Additives Exempt From Certification; Spirulina Extract.'' 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.

- 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 objections 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: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1075.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of September 16, 2016 (81 FR 63728), we announced that we filed a color additive petition (CAP 6C0306) submitted by McCormick & Company, Inc., c/o Exponent, 1150 Connecticut Ave. NW., suite 1100, Washington, DC 20036. The petition proposed to amend the color additive regulations in § 73.530 (21 CFR 73.530) Spirulina extract to provide for the expanded safe use of spirulina extract, prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis,* to seasonally color the shells of hard-boiled eggs. The color additive is intended to be sold as a powder in a packet to consumers at levels consistent with GMP.

II. Background

Spirulina extract is currently approved under § 73.530 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 GMP. Spirulina extract also is currently approved under 21 CFR 73.1530 for coloring coating formulations applied to drug tablets and capsules, at levels consistent with GMP. Spirulina extract is exempt from certification under section 721(c) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(c)) because we previously determined that certification was not necessary for the protection of public health (78 FR 49117 at 49119, August 13, 2013).

The spirulina extract that is the subject of this final rule is a blue-colored powder produced by the filtered aqueous extraction of the dried biomass of *A. platensis* (also known as *Spirulina platensis*), an edible blue-green cyanobacterium. The color additive contains phycocyanins as the principal coloring components. 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-derived ingredients have also been the subject of four notices submitted by firms to FDA informing us of their determinations that certain uses of these substances in food are generally recognized as safe (GRAS) (78 FR 49117 at 49118). Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a substance that is GRAS for a particular use in food is not a food additive, and may lawfully be utilized for that use without our review and approval. There is no GRAS exemption, however, to the definition of color additive in section 201(t) of the FD&C Act). Therefore, we must approve the use of a color additive in food before it is marketed; otherwise the food containing the color additive is adulterated under section 402(c) of the FD&C Act (21 U.S.C. 342(c)). One GRAS

notice (GRN 000424) pertains to the use of a spirulina-derived substance that is similar in chemical composition to the color additive that is the subject of this final rule, but the substance that was the subject of GRN 000424 has a much higher phycocyanin content (Ref. 3). Importantly, in our response to these GRAS notifications, we indicated that if the substances that were the subject of these submissions impart color to the food, they may be subject to regulation as a color additive.

III. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the FD&C Act, 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 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 ingested 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.

B. Safety of Petitioned Use of the Color Additive

During our safety review of this petition (CAP 6C0306), we considered the projected human dietary exposure to spirulina extract and to phycocyanins (the principal coloring components) from the petitioned use and from currently permitted uses of spirulina extract in foods and ingested drugs. McCormick submitted an exposure estimate for spirulina extract and for phycocyanins for the petitioned use of spirulina extract based on a worst-case scenario that presumed that spirulina extract could potentially migrate from the outside of the egg shell to the edible portion of the egg. McCormick estimated that the petitioned use of spirulina extract to seasonally color the shells of hard-boiled eggs would result in an exposure to spirulina extract of 8.8 milligrams per person per day (mg/p/d) at the 90th percentile for the U.S. population aged 2 years and older (Ref. 2). McCormick also estimated that the petitioned use of spirulina extract would result in an exposure to phycocyanins of 1.9 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older (Ref. 2). Despite providing this worst-case estimate, McCormick noted that egg shells are not consumed and demonstrated that the spirulina extract applied to the outside of an egg shell generally does not migrate through the shell and the outer and inner membranes separating the shell from the edible portion of the egg. For these reasons, McCormick asserted that the amount of spirulina extract that would actually be found on the edible portion of an egg would be negligible, resulting in a 0.17 percent increase of the cumulative estimated daily intake (CEDI) for phycocyanins (Ref. 2). The previously estimated upper bound CEDI for phycocyanins from all GRAS-notified uses of spirulina extract in food is 1,140 mg/p/day or 19 milligrams per kilogram body weight per day (mg/kg bw/d) for a 60 kg individual based on uses addressed in GRN 000424 (Ref. 3). We agree that McCormick's exposure estimate is sufficiently conservative. We conclude that the exposure to spirulina extract and phycocyanins resulting from the petitioned use of spirulina extract to seasonally color the shells of hard-boiled eggs is negligible, and that the petitioned use would not result in a significant contribution to the CEDI for phycocyanins (Ref. 2).

To support the safety of the proposed use of spirulina extract to color the shells of hard-boiled eggs, McCormick referenced the safety determinations made by FDA for CAPs 2C0293 (78 FR 49117, August 13, 2013), 2C0297 (79 FR 20095, April 11, 2014), and 4C0300 (80 FR 50762, August 21, 2015). McCormick 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 were published between January 1, 2014, and July 20, 2016. McCormick submitted to us the published animal and human studies that they identified as being relevant to their petition. We evaluated the submitted safety information and additional studies that we identified as relevant and concluded that this information does not raise any safety concerns (Refs. 4 and 5).

In our previous evaluation of the use of spirulina extract as a color additive in foods (80 FR 50762), we did not have any concerns regarding the safety of the use of spirulina extract and its major coloring components, phycocyanins. Taking into account all the available safety information and the estimated exposure to phycocyanins from the petitioned use, we conclude that the proposed use of spirulina extract to seasonally color the shells of hard-boiled eggs is safe (Ref. 5).

We discussed the potential allergenicity of spirulina phycocyanins in our final rule for the use of spirulina extract as a color additive in candy and chewing gum (78 FR 49117 at 49119). Based on the comparison of the known amino acid sequences of phycocyanins with the sequences of known protein allergens, we determined that there is a low probability that phycocyanins are protein allergens. We therefore concluded that the spirulina phycocyanins present an insignificant allergy risk. Additionally, after a review of the literature relevant to the potential allergenicity of spirulina phycocyanins, we have determined that spirulina phycocyanins still present an insignificant allergy risk (Refs. 4–7). 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 to seasonally color the shells of hard-boiled eggs is safe. We further conclude that the color 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 (21 CFR part 73) as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), we continue to 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. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the September 16, 2016, **Federal Register** notice of petition for CAP 6C0306 (81 FR 63728). 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 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.

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 Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

X. References

The following references 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.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Memorandum from N. Belai, Color Technology Team, Office of Cosmetics and Colors (OCAC), Center for Food Safety and Applied Nutrition (CFSAN), FDA to M. Harry, Division of Petition Review, Office of Food Additive Safety (OFAS), CFSAN, FDA, February 1, 2017.
2. Memorandum from H. Lee, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, February 1, 2017.
3. Letter from D. Keefe, OFAS, 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 L. Rosenfeld, Division of Petition Review, OFAS, CFSAN, FDA to J. Park, Division of Petition Review, OFAS, CFSAN, FDA, January 12, 2017.
5. Memorandum from J. Park, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, February 2, 2017.
6. Memorandum from J. Park, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, April 13, 2017.
7. Memorandum from J. Park, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, April 25, 2017.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 73.530 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), coating formulations applied to dietary supplement tablets and capsules, at levels consistent with good manufacturing practice, and to seasonally color the shells of hard-boiled eggs, 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: June 21, 2017.

Anna K. Abram,

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

[FR Doc. 2017–13867 Filed 6–30–17; 8:45 am]

BILLING CODE 4164–01–P