(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2022–21–07 Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH): Amendment 39–22206; Docket No. FAA–2022–0688; Project Identifier MCAI–2022–00409–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 15, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and 328–300 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 11, Placards and markings and 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a safety analysis that lithium batteries installed in personal electronic devices (PED) are a potential risk of an in-flight fire in the flight deck stowage boxes. The PED fire could spread out of the flight deck stowage boxes to the oxygen supply lines and other critical system components. The FAA is issuing this AD to address the potential risk of in-flight fire of lithium batteries installed in PED, which could result in an oxygen fed fire in the flight deck, possibly resulting in an uncontrolled fire.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0050, dated March 22, 2022 (EASA AD 2022–0050).

(h) Exceptions to EASA AD 2022–0050

(1) Where EASA AD 2022–0050 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (2) of EASA AD 2022–0050 specifies to ''inform all flight crews, and, thereafter, operate the aeroplane accordingly,'' this AD does not require those actions as those actions are already required by existing FAA operating regulations (see 14 CFR 121.137, 91.505, and 91.9).

(3) Where paragraph (2) of EASA AD 2022–0050 specifies to amend or use the airplane flight manual (AFM), replace the text ''amend the applicable AFM by incorporating the AFM emergency procedure or use the AFM'' with ''amend the applicable AFM by incorporating the information specified in the AFM emergency procedure.''

(4) The ''Remarks'' section of EASA AD 2022–0050 does not apply to this AD.

(i) No Reporting Requirements

Although the service information referenced in EASA AD 2022–0050 specifies reporting, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Deutsche Aircraft GmbH's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Additional Information

For more information about this AD, contact Todd Thompson, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206 231 3228; email *Todd.Thompson@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0050, dated March 22, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0050, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 3, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–24514 Filed 11–9–22; 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–2020–C–1309]

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 (*Arthrospira platensis*) extract

as a color additive in alcoholic beverages with less than 20 percent alcohol-by-volume content, non-alcoholic beverages, condiments and sauces, dips, dairy product alternatives (identified as non-dairy yogurt alternatives, non-dairy frozen desserts, and non-dairy puddings), salad dressings, and seasoning mixes (unheated). This action is in response to a color additive petition (CAP) filed by GNT USA, Inc. (GNT).

DATES: This rule is effective December 13, 2022. See section X for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final rule must be submitted by December 12, 2022.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 12, 2022. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–C–1309 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, 240–402–7500.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Stephanie A. Hice, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–255), 5001 Campus Dr., College Park, MD 20740, 301–348–1740; or Philip L. Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a document published in the **Federal Register** of May 8, 2020 (85 FR 27340), we announced that we filed a color additive petition (CAP 0C0316) submitted on behalf of GNT by Hogan Lovells US LLP, 555 13th St. NW, Washington, DC 20004. The petition proposed to amend the color additive regulations in § 73.530 *Spirulina extract* (21 CFR 73.530) to provide for the expanded safe use of spirulina extract, prepared from the filtered aqueous extraction of the dried biomass of *A. platensis,* as a color additive in alcoholic beverages with less than 20 percent alcohol-by-volume content (the proposed scope was subsequently amended to include beer), non-alcoholic beverages, condiments and sauces, dips, dairy product alternatives (identified as non-dairy yogurt alternatives, non-dairy frozen desserts, and non-dairy puddings), salad dressings, and seasoning mixes (unheated) at levels consistent with good manufacturing practice (GMP).

II. Background

Spirulina extract is 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), coating formulations applied to dietary supplement tablets and capsules, at levels consistent with GMP, 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 (FD&C Act) (21 U.S.C. 341), unless the use of the added color is authorized by such standards. Spirulina extract also is 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 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 or liquid prepared by the water extraction and filtration of the dried biomass of *A. platensis* (also known as *Spirulina platensis*), an edible blue-green cyanobacterium. The extraction and filtration remove oil, oil soluble substances, and fibers. The color additive contains phycocyanins as the principal coloring components, and consists of proteins, carbohydrates, and minerals. 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 (Refs. 1 and 2).

Spirulina-based ingredients have been the subject of four generally recognized as safe (GRAS) notices (GRNs) filed by FDA (78 FR 49117 at 49118). Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a substance is GRAS if it is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food before January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. Under section 201(s) of the FD&C Act, 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 intended 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)). Importantly, in our response to these GRNs, we indicated that if the substance imparts color to the food, it may be subject to regulation as a color additive (78 FR 49117 at 49118).

III. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the FD&C Act, 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. Our 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 food 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 the estimated daily intake (EDI) of the color additive from all sources to an acceptable daily intake (ADI) level established by toxicological data. The EDI is calculated 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 dietary exposure.

B. Safety of Petitioned Use of the Color Additive

During our safety review of this petition (CAP 0C0316), we considered the estimated dietary exposure to spirulina extract and c-phycocyanin (the main coloring component) from the petitioned uses of the subject color additive. GNT provided the eaters-only 90th percentile estimates of dietary exposure for spirulina extract and c-phycocyanin for the petitioned uses for the U.S. population aged 2 years and older, and various subpopulations. Upon further clarification of the proposed uses to include beer (Ref. 3), we amended GNT's dietary exposure estimate to include additional food codes for beer (Ref. 2). We estimated that the petitioned uses of the subject color additive would result in dietary exposures to spirulina extract and c-phycocyanins of 31 grams/person/day (g/p/d) and 0.6 g/p/d, respectively, at the 90th percentile for the U.S. population aged 2 years and older (Ref. 2). GNT cited a cumulative estimated daily intake (CEDI) to phycocyanins of 1.14 g/p/d (Ref. 2). This value has been cited in previous reviews of spirulina extract as an upper bound CEDI for phycocyanins from GRAS-notified uses of spirulina extract in food and is based on uses described in GRN 000424 (see 80 FR 50762 at 50763, August 21, 2015, and Ref. 4). GRN 000424 pertains to the use of a spirulina-based substance similar in chemical composition to the subject color additive but with a higher phycocyanin content and included use in all foods (except infant formula and foods under the U.S. Department of Agriculture's jurisdiction) at levels consistent with GMP (Refs. 2 and 4).

The highest 90th percentile estimate of dietary exposure to phycocyanins (0.7 g/p/d for adults 19 years or older) from the petitioned uses is below the upper-bound CEDI of 1.14 g/p/d phycocyanins from the notified GRAS uses described in GRN 000424 and from the uses approved under § 73.530 (Ref. 2). GNT indicated that, given the high phycocyanin content of the spirulina-based substance described in GRN 000424 (42 to 47 percent) relative to the subject color additive (2 percent) and the multiple uses of spirulina extract addressed previously in GRN 000424, the cited upper-bound CEDI encompasses current and previously petitioned uses of spirulina extract. Based on the data and information reviewed by FDA, the petitioned uses of spirulina extract are not expected to increase the estimated CEDI to phycocyanins in the U.S. diet (Ref. 2).

To support the safety of the petitioned uses of spirulina extract, GNT referenced the safety determinations made by FDA for CAPs 2C0293 (78 FR 49117), 2C0297 (79 FR 20095, April 11, 2014), 4C0300 (80 FR 50762), and 6C0306 (82 FR 30731, July 3, 2017). GNT also conducted an updated search of the peer-reviewed scientific literature on spirulina and submitted the published studies that they identified as being relevant to their petition. GNT concluded that these publications did not reveal any significant new toxicological effects and should not alter the conclusions of FDA's previous reviews on spirulina. Of the publications submitted by the petitioner, some studies had been previously reviewed by FDA. Our review of the new information, the information submitted in previously reviewed publications, as well as our own independent literature search and review of spirulina and phycocyanins, did not reveal any safety concerns relating to spirulina or phycocyanin, nor did it identify any information or data that would change the ADI of 1.0–1.8 g/p/d for phycocyanins (Refs. 5 and 6).

In our most recent evaluation of the use of spirulina extract as a color additive to seasonally color hard-boiled shell eggs (82 FR 30731), we did not have any concerns regarding the safety of the use of spirulina extract and its principal coloring components, phycocyanins. Considering all available safety information and the estimated dietary exposure to phycocyanins from

the petitioned uses, we conclude that the petitioned use of spirulina extract as a color additive 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). 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 spirulina phycocyanins present an insignificant allergy risk to consumers of the color additive. Additionally, after a review of the literature relevant to the potential allergenicity of spirulina, we have determined that spirulina extract as a color additive for both current uses and the petitioned uses in food still presents an insignificant allergy risk for the general population (Ref. 6). We are not aware of any new information that would cause us to change this conclusion.

IV. Comment to the Petition and FDA Response

We received one comment on the petition. The comment asked us to clarify that we interpret ''malted beverages'' to apply to ''what is commonly known in the alcoholic beverage industry and amongst the general public as 'beer.''' GNT included a table of proposed uses in the petition. Under the alcoholic beverages category, GNT included ciders, cocktails and liqueur, ready-to-drink (*e.g.,* daiquiris, schnapps) with less than 20 percent alcohol-by-volume content, malt beverages, wine, and wine coolers. In the proposed amendment to § 73.530 *Spirulina extract,* GNT proposed that the intended uses include alcoholic beverages (with less than 20 percent alcohol-by-volume content, excluding beer).

As we noted in section I of this document, GNT subsequently expanded the scope of its petition to include beer. Therefore, we consider beer to be within the scope of the amended regulation as an alcoholic beverage with less than 20 percent alcohol-by-volume content.

V. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the petitioned use of spirulina extract as a color additive in alcoholic beverages with less than 20 percent alcohol-by-volume content, non-alcoholic beverages, condiments and sauces, dips, dairy product alternatives (identified as non-dairy yogurt alternatives, non-dairy frozen desserts, and non-dairy puddings), salad dressings, and seasoning mixes (unheated) 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 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 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. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the May 8, 2020, **Federal Register** notice of petition for CAP 0C0316 (85 FR 27340). 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, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) through (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this 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 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**.

XI. References

The following references are on display at 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 website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Memorandum from N. Belai, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors (OCAC), CFSAN, FDA to S. Hice, Regulatory Review Branch (RRB), Division of Food Ingredients (DFI), Office of Food Additive Safety (OFAS), CFSAN, FDA, September 30, 2022.
2. Memorandum from M. Swain, Chemistry Review Branch, DFI, OFAS, CFSAN, FDA to S. Hice, RRB, DFI, OFAS, CFSAN, FDA, October 7, 2022.
3. Memorandum of Telephone Conversation from S. Hice, RRB, DFI, OFAS, CFSAN, FDA, January 26, 2022.
4. Letter from D. Keefe, OFAS, CFSAN, FDA to H. Newman, Desert Lake Technologies, LLC, Agency Response Letter GRAS Notice 000424, December 6, 2012, (*https://wayback.archive-it.org/7993/20171031010129/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm335743.htm*).
5. Memorandum from D. DeGroot, Toxicology Review Branch (TRB), DFI, OFAS, CFSAN, FDA to S. Hice, RRB, DFI, OFAS, CFSAN, FDA, October 8, 2022.
6. Memorandum from D. DeGroot, TRB, DFI, OFAS, CFSAN, FDA to S. Hice, RRB, DFI, OFAS, CFSAN, FDA, October 8, 2022.

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 the authority delegated to the Commissioner of the 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 (including non-dairy frozen dessert), dessert coatings and toppings, beverage mixes and powders, yogurts (including non-dairy yogurt alternatives), custards, puddings (including non-dairy puddings), cottage cheese, gelatin, breadcrumbs, ready-to-eat cereals (excluding extruded cereals), alcoholic beverages with less than 20 percent alcohol-by-volume content, non-alcoholic beverages, seasoning mixes (unheated), salad dressings, condiments and sauces, dips, 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: November 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24429 Filed 11–9–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2022–0528; FRL–10357–02–R3]

Air Plan Approval; West Virginia; 2021 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the State of West Virginia. The revision updates West Virginia's incorporation by reference of EPA's national ambient air quality standards (NAAQS) and the associated monitoring reference and equivalent methods. EPA is approving these revisions to the West Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on December 12, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2022–0528. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Serena Nichols, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1617 John F Kennedy Blvd., Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2053. Ms. Nichols can also be reached via electronic mail at *Nichols.Serena@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 17, 2022 (87 FR 50593), EPA published a notice of proposed rulemaking (NPRM) for the State of West Virginia. In the NPRM, EPA proposed approval of a formal SIP revision submitted on May 11, 2021. The formal SIP revision updates West Virginia's incorporation by reference of the NAAQS promulgated by EPA and found at 40 Code of Federal Regulations (CFR) part 50 and ambient air monitoring reference methods and equivalent methods promulgated by EPA found at 40 CFR part 53 into West Virginia's legislative rules.

II. Summary of SIP Revision and EPA Analysis

West Virginia Department of Environmental Protection (WVDEP) has historically chosen to incorporate by reference the Federal NAAQS, found at 40 CFR part 50, and the associated Federal ambient air monitoring reference methods and equivalent methods for these NAAQS found at 40 CFR part 53. When incorporating by reference these Federal regulations, WVDEP has specified that it is incorporating by reference these regulations as they existed on a certain date. The incorporation by reference of the NAAQS that is currently approved in the West Virginia SIP incorporates by reference 40 CFR parts 50 and 53 as they existed on June 1, 2019. West Virginia's May 11, 2021 SIP revision updates the State's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods, found in 40 CFR parts 50 and 53, respectively, as of June 1, 2020. Since the last West Virginia