



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2024-C-3384]

Listing of Color Additives Exempt from Certification; Spirulina Extract

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the expanded use of spirulina (*Arthrospira platensis*) extract as a color additive in human foods generally (except for infant formula, certain foods subject to regulation by the U.S. Department of Agriculture, and 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) at levels consistent with good manufacturing practice (GMP), to lower the heavy metal specifications for lead, arsenic, and mercury, and to add a specification for cadmium. We are taking this action in response to a color additive petition (CAP) submitted by GNT USA, LLC (GNT or petitioner).

DATES: This order is effective [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section IX of this document for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the order must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 objections until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. 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-2024-C-3384 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: Marissa Santos, Office of Pre-Market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-8160 or Meridith L. Kelsch, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the *Federal Register* of August 5, 2024 (89 FR 63330), FDA announced that we filed a color additive petition (CAP 4C0334) submitted on behalf of GNT by Exponent, 1150 Connecticut Ave. NW, Suite 1100, Washington, DC 20036. The petition proposed that FDA amend the color additive regulations in part 73 (21 CFR 73.530), “Listing of Color Additives Exempt from Certification,” to provide for the expanded safe use of spirulina extract as a color additive at levels consistent with GMP in human foods generally, excluding infant formula and certain foods subject to regulation by the U.S. Department of Agriculture (USDA).

II. Background

Spirulina extract is approved under § 73.530 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 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 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 order 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 current specifications for spirulina extract in §73.530 (Refs. 1 and 2). During the review of the petition, FDA noted that the specifications for heavy metals could be lowered based on the results of the petitioner's batch analyses, and a specification for cadmium should be added. These modifications to the heavy metal specifications would align with FDA's work to reduce dietary exposure to contaminants. Therefore, in addition to expanding the use of spirulina extract, the petitioner proposed to lower the heavy metal specifications for lead (≤ 0.2 mg/kg), arsenic (≤ 0.3 mg/kg), and mercury (≤ 0.1 mg/kg) that are currently in the regulation, and to add a specification for cadmium (≤ 0.3 mg/kg).

There is no generally recognized as safe (GRAS) exception in the definition of a color additive in section 201(t) of the FD&C Act (21 U.S.C. 321(t)), and, therefore, the intended use of a color additive requires our approval. However, we note that spirulina-based ingredients have been the subject of several GRAS notices (GRNs) reviewed by FDA (discussed in 78 FR 49117 at 49118). (Under section 201(s) of the FD&C Act, a substance is GRAS, and excepted from the definition of a food additive, if it is generally recognized, among experts qualified by scientific

training and experience to evaluate its safety, to be safe under the conditions of its intended use.) In particular, the spirulina substance that was the subject of GRN 000424 is similar in chemical composition to the subject color additive, with phycocyanin content ranging from 42 to 47 percent (*id.*). If a substance imparts color to a food, it may be subject to regulation as a color additive even if its use is also considered GRAS.

III. Safety Evaluation

A. Determination of Safety

Under section 721(b) of the FD&C Act (21 U.S.C. 379e(b)), a color additive may not be listed for a proposed use unless the data and other 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 establishing with reasonable certainty that no harm will result from the intended use of the color additive.

To determine whether a color additive is safe under the general safety clause, the FD&C Act requires FDA to conduct a fair evaluation of the available data and consider, among other relevant factors: (1) probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, devices, or cosmetics because of the use of the additive; (2) cumulative effect, if any, of such additive in the diet of man or animals, taking into account chemically or pharmacologically related substance or substances in such diet; and (3) safety factors recognized by experts as appropriate for the use of animal experimentation data (see section 721(b)(5)(A)(i) through (iii) of the FD&C Act).

As part of our safety evaluation to establish with reasonable certainty that a color additive is not harmful under its intended conditions of use, we consider the additive's manufacturing and stability, the projected human dietary exposure to the additive and any impurities resulting from the petitioned use of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare the estimated dietary exposure to the color additive from all sources to an acceptable daily intake (ADI) level

established by toxicological data. The dietary exposure is estimated 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 dietary exposure for the 90th percentile consumer of a color additive as a measure of high chronic dietary exposure.

B. Safety of the Petitioned Use of the Color Additive

During our safety review of this petition (CAP 4C0334), 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. Specifically, the petition sought to expand the intended uses of this color additive to include all foods, except infant formula and certain foods subject to regulation by the USDA (*i.e.*, products subject to regulation by the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)). C-phycocyanin is the predominant phycocyanin present in spirulina, although low levels of allophycocyanin are also present; due to the predominance of c-phycocyanin, the concentration of c-phycocyanin in spirulina extract is assumed to represent all “phycocyanins” in spirulina. The petitioner provided the eaters-only 90th percentile dietary exposure to spirulina extract and c-phycocyanin from the petitioned uses for the U.S. population aged 2 years and older, and various subpopulations.

The petitioner provided information on the proposed expanded food uses of spirulina extract, including food categories in which spirulina extract is intended to be used and the corresponding maximum use levels that represent GMP for the petitioned uses (Ref. 2). The petitioner used food consumption data from the combined 2015-2016 and 2017-2018 National Health and Nutrition Examination Survey (NHANES) to estimate the dietary exposure to spirulina extract from the petitioned uses. The petitioner estimated the eaters-only (*i.e.*, only those individuals in the population that consume the foods of interest) dietary exposure to spirulina extract from the petitioned uses to be 6.3 grams/person/day (g/p/d) at the mean and 14.1

g/p/d at the 90th percentile for the U.S. population aged 2 years and older; and 5.1 g/p/d at the mean and 10.7 g/p/d at the 90th percentile for children aged 2-5 years (Ref. 2). We independently confirmed the petitioner's dietary exposure using food consumption data from the combined 2015-2016 and 2017-2018 NHANES and concur with the petitioner's dietary exposure to spirulina extract (Ref. 2).

The petitioner also estimated the eaters-only dietary exposure to c-phycoyanin from the petitioned uses of spirulina extract to be 0.13 g/p/d at the mean and 0.28 g/p/d at the 90th percentile for the U.S. population aged 2 years and older; and 0.1 g/p/d at the mean and 0.21 g/p/d at the 90th percentile for children aged 2-5 years (Ref. 2).

The petitioner did not provide an updated cumulative dietary exposure estimate for c-phycoyanin in this petition. However, the petitioner indicated that: (1) the overall maximum GMP use level in the current petition is comparable to that in GRN 000424 on a c-phycoyanin basis; GRN 000424 pertains to the use of a spirulina-based substance similar in chemical composition to the subject color additive, but with a higher phycoyanin content; GRN 000424 pertains to the intended use in all foods (except infant formula and foods under the USDA's jurisdiction) (*i.e.*, products subject to regulation by the USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act) at levels consistent with GMP; (2) the petitioner's spirulina extract would not be added to foods already containing other sources of spirulina; (3) the number of servings in the daily diet that could be colored with spirulina extract would reasonably be well below the assumption of 50% of the daily servings in the current cumulative dietary exposure of 1.14 g/p/d from the notified GRAS uses of spirulina; and (4) the current cumulative dietary exposure for c-phycoyanin is inclusive of the dietary exposure to c-phycoyanin from the approved uses of spirulina extract as a color additive under § 73.530 as well as the expanded uses in the current petition. As such, the petitioner concluded that the intended uses of spirulina extract in this petition would be substitutional to other sources of spirulina in foods (on a c-phycoyanin basis), and the dietary exposure to c-phycoyanin from

the petitioned uses would be subsumed by the dietary exposure to c-phyococyanin from the uses in GRN 000424. Therefore, the petitioned uses would not increase the current upper-bound cumulative dietary exposure to c-phyococyanin of 1.14 g/p/d in GRN 000424. We concur with the petitioner's statement regarding the cumulative dietary exposure to c-phyococyanin (Ref. 2).

To support the safety of the petitioned use of spirulina extract, the petitioner referenced the safety determinations made by FDA for spirulina extract in CAPs 2C0293 (78 FR 49117, August 13, 2013), 2C0297 (79 FR 20095, April 11, 2014), 4C0300 (80 FR 50762, August 21, 2015), 6C0306 (82 FR 30731, July 3, 2017), and 0C0316 (87 FR 67785, November 10, 2022). The petitioner 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. The petitioner concluded that these publications did not reveal any significant new toxicological effects and should not alter the conclusion of FDA's previous reviews on spirulina.

FDA's most recent evaluation of the 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 (non-dairy yogurt alternatives, non-dairy frozen desserts, and non-dairy puddings), salad dressings, and unheated seasoning mixes (87 FR 67785, November 10, 2022), included a comprehensive review of studies submitted by the petitioner and a review of all available literature. From our evaluation, we did not have any concerns regarding the safety of the use of spirulina extract and its principal coloring components, phycocyanins.

Of the publications submitted by the petitioner, some studies had been previously reviewed by FDA (Ref. 3), including a chronic toxicity study which identified a NOAEL ("No Observed Adverse Effect Level") of 15,000 mg/kg bw/d of spirulina powder. Our review of the new information submitted by the petitioner, 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 phycocyanins, nor did it

identify any information or data that would change the ADI of 1.8 g/p/d for phycocyanins (Ref. 3).

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, August 13, 2013). We stated that, based on our review of a comparison of the known amino acid sequences of c-phycocyanin, which is the predominant phycocyanin present in spirulina (Ref. 2), with the sequences of known protein allergens, there is a low probability that the spirulina c-phycocyanin is a protein allergen. Additionally, while allophycocyanin is present at very low levels in spirulina, we consider these levels and any allergenicity risk to be negligible. Therefore, we concluded that spirulina phycocyanins present an insignificant allergy risk to consumers of the color additive. In addition, after a review of all available literature relevant to the potential allergenicity of spirulina, we have determined that while spirulina extract and specifically c-phycocyanin are possible allergens for certain individuals, reactivity is not widespread and spirulina sensitization appears to be rare (Ref. 3). Therefore, we continue to conclude that spirulina extract as a color additive presents an insignificant allergy risk for the general population (Ref. 3). We are not aware of any new information that would cause us to change this conclusion.

Our review considered the safety data provided by the petitioner, including our independent review of the current published literature, which did not present evidence of safety concerns for spirulina extract at the expected dietary exposures. Given that the upper-bound cumulative dietary exposure estimate for c-phycocyanin of 1.14 g/p/d is not expected to increase with the new petitioned uses, exposure remains below the previously determined ADI for phycocyanins of 1.8 g/p/d. Therefore, we conclude that spirulina extract is safe for the petitioned uses (Refs. 2 and 3).

IV. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of spirulina extract as a color additive at levels consistent with GMP (in human foods generally except for infant formula and products subject to regulation by the USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act) is safe.

We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in 21 CFR part 73 to provide for the safe use of this color additive as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b) and consistent with our conclusions in our earlier published approvals of spirulina extract for petitioned uses, we continue to conclude that batch certification of spirulina extract is not necessary to protect 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 order, as stated in the August 5, 2024, *Federal Register* notification of petition for CAP 4C0334 (89 FR 63330 at 63331). The petitioner claimed that this action is categorically excluded under § 25.32(k) (21 CFR 25.32(k)) because the substance is intended to be added directly to food, remain in food through ingestion by consumers, and is not intended to replace macronutrients in food. We have not received any new information or comments regarding this claim of categorical exclusion. We considered the petitioner's claim of categorical exclusion and determined that this action is categorically

excluded under § 25.32(k) (Ref. 4). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This order 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(l) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act (21 U.S.C. 379e). This order is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(l) of the FD&C Act (21 U.S.C. 331(l)) 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(l)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(l) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this order 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(l) of the FD&C Act. Furthermore, this language is included in all color additive final orders that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(l) of the FD&C Act applies.

IX. Objections

This order 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 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>.

1. Memorandum from N. Belai, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors, Office of the Chief Scientist, FDA to M. Santos, Regulatory Management Branch (RMB), Division of Food Ingredients (DFI), Office of Pre-Market Additive Safety (OPMAS), Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI), Human Foods Program (HFP), FDA, February 3, 2026.
2. Memorandum from H. Lee, Chemistry Evaluation Branch, DFI, OPMAS, OFCSDSI, HFP, FDA to M. Santos, RMB, DFI, OPMAS, OFCSDSI, HFP, FDA, February 3, 2026.

3. Memorandum from R. Arechavala, Toxicology Review Branch, DFI, OPMAS, OFCSDSI, HFP, FDA to M. Santos, RMB, DFI, OPMAS, OFCSDSI, HFP, FDA, February 3, 2026.

4. Memorandum from A. Thompson-Woods, Environmental Review Team, OPMAS, OFCSDSI, HFP, FDA to M. Santos, RMB, DFI, OPMAS, OFCSDSI, HFP, FDA, February 3, 2026.

List of Subjects

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 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.

§ 73.530 [Amended]

2. Section 73.530 is amended by revising paragraphs (b) and (c) to read as follows:

§ 73.530 Spirulina extract.

* * * * *

(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 0.2 milligrams per kilogram (mg/kg) (0.2 parts per million (ppm));

(2) Arsenic, not more than 0.3 mg/kg (0.3 ppm);

(3) Mercury, not more than 0.1 mg/kg (0.1 ppm);

(4) Cadmium, not more than 0.3 mg/kg (0.3 ppm); and

(5) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring human foods generally at levels consistent with good manufacturing practice, except that it may not be used to color products that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.); infant formula; or 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.

* * * * *

Lowel M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-02314 Filed: 2/5/2026 8:45 am; Publication Date: 2/6/2026]