Paragraph 6010(a) VOR Federal Airways.

* * * * *

V–129 [Amended]

From Spinner, IL; Peoria, IL; Davenport, IA; Dubuque, IA; INT Dubuque 348° and Nodine, MN, 150° radials; Nodine; Eau Claire, WI; Duluth, MN; Hibbing, MN; to International Falls, MN.

* * * * *

Paragraph 6013 Canadian Area Navigation Routes.

* * * * *

T–797 International Falls, MN (INL) to WUGOR, MN [New]

International Falls, MN (INL)	VOR/DME	(Lat. 48°33′56.87″ N, long. 093°24′20.44″ W)
WUGOR, MN	WP	(Lat. 48°35′58.85″ N, long. 093°25′44.53″ W)

Issued in Washington, DC, on May 6, 2025.

Brian Eric Konie,

Manager (A), Rules and Regulations Group.

[FR Doc. 2025–08230 Filed 5–9–25; 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–2023–C–0544]

Listing of Color Additives Exempt From Certification; Calcium Phosphate

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 safe use of calcium phosphate as a color additive in ready-to-eat chicken products, white candy melts, doughnut sugar, and sugar for coated candies. This action is in response to a color additive petition (CAP) filed by Innophos, Inc. (Innophos or petitioner).

DATES: This order is effective June 26, 2025. See section VIII for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final order must be submitted by June 11, 2025.

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 June 11, 2025. 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–2023–C–0544 for ''Listing of Color Additives Exempt from Certification; Calcium Phosphate.'' 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: Rachel Morissette, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1212; or Barbara Little, 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 a document published in the **Federal Register** of February 27, 2023 (88 FR 12281), we announced that we filed a color additive petition (CAP 3C0324) submitted on behalf of Innophos by Steptoe & Johnson LLP, 1330 Connecticut Avenue NW, Washington, DC 20036–1795. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), *Listing of Color Additives Exempt from Certification,* to provide for the safe use of calcium phosphate as a color additive, by weight of the finished food, in ready-to-eat chicken products; icing; white candy melts; doughnut sugar; and sugar for coated candies. In the petition and filing notice, the color additive was identified as ''tricalcium phosphate.'' During the course of our review, we determined that the correct nomenclature for the color additive is ''calcium phosphate.'' Additionally, during the course of our review and in consultation with FDA, Innophos amended the intended uses to remove icing in order to reduce overall dietary exposure to calcium.

Calcium phosphate is a white, synthetically prepared powder consisting predominantly of precipitated $Ca_5OH(PO_4)_3$. Innophos proposed the following specifications for calcium phosphate: loss on ignition, not more than 10 percent; assay (Ca), 36.0–40.0 percent; fluoride, not more than 75 milligrams/kilogram (mg/kg) (75 parts per million (ppm)); lead, not more than 0.25 mg/kg (0.25 ppm); and arsenic, not more than 3 mg/kg (3 ppm) (Ref. 1).

Calcium phosphate is generally recognized as safe (GRAS) for use as a nutrient or multiple purpose ingredient in food with no limitation other than use in accordance with good manufacturing practice under 21 CFR 182.8217 and 21 CFR 182.1217. Additionally, we have previously evaluated the safety of substances containing calcium and/or phosphate as constituent ions in numerous food and color additive regulations and in GRAS notices.

This final order is expected to result in expanded production options and is considered an E.O. 14192 deregulatory action.

II. Safety Evaluation

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for an intended use unless the data and information available to us establishes that the color additive is safe for that use. Our color additive regulations in § 70.3(i) (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. 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 color additive's manufacturing and stability; the projected human dietary exposure to the color additive and any impurities resulting from the petitioned use of the color additive; the additive's toxicological data; and other relevant information (such as published literature) available to us.

A. Estimated Dietary Exposure

To support the safety of the intended use of calcium phosphate, Innophos provided dietary exposure estimates for calcium phosphate, calcium, and phosphorus from the petitioned uses. The petitioned uses included in ready-to-eat chicken products in an amount not exceeding 1.5 percent; in white candy melts in an amount not exceeding 0.25 percent; in doughnut sugar in an amount not exceeding 2.0 percent; and in sugar for coated candies in an amount not exceeding 5.25 percent by weight of the finished food. During review of the petition, Innophos revised the use level in sugar for coated candies from 7.5% to 5.25%. Innophos provided a cumulative dietary exposure for: (1) calcium from background dietary sources, including dietary supplements and drugs, as well as the intended uses of the color additive and (2) for phosphorus based on the intended uses (Ref. 2).

Innophos provided a cumulative dietary exposure to calcium from the intended uses and calcium from background dietary sources, including dietary supplements, by utilizing a simplistic model of the National Cancer Institute (NCI) usual intakes method for estimating dietary exposure (Ref. 2). We noted that Innophos did not include all relevant food codes, may have overestimated exposure by summing the food category exposures, and did not provide a 90th percentile dietary exposure for phosphorus. Therefore, we conducted a dietary exposure estimate and estimated the updated dietary exposure for calcium phosphate, calcium, and phosphorus from the petitioned uses based on the 2015–2020 Nutritional Health and Nutrition Examination Survey (NHANES) to be 535 milligrams (mg)/person (p)/day (d), 214 mg/p/d, and 99 mg/p/d, respectively, at the mean and 1200 mg/p/d, 480 mg/p/d, and 222 mg/p/d, respectively, at the 90th percentile for the U.S. population ages 2 years and older (Ref. 2). Additionally, using 2015–2020 NHANES food consumption data combined with the NCI usual intakes method, we estimated the cumulative dietary exposure to calcium from the background dietary sources, including dietary supplements and drugs, and the petitioned uses to be 1195 mg/p/d at the mean and 1789 mg/p/d at the 90th percentile for the U.S. population ages 2 years and older (Ref. 2). Using 2015–2020 NHANES food consumption data, we also estimated the cumulative dietary exposure to phosphorus from the background dietary sources, including dietary supplements and drugs, and the petitioned uses to be 1330 mg/p/d at the mean and 2010 mg/p/d at the 90th percentile for the U.S. population ages 2 years and older (Ref. 2).

B. Toxicological Considerations

Innophos submitted peer-reviewed published data sourced from a literature review and additional information relevant to the safety of calcium phosphate for the intended use as a color additive. Based on the physiochemical properties of calcium phosphate and the rapid dissolution of the salt into its component ions, the safety conclusion predominantly focuses on the safety of calcium and phosphorus.

Based on the cumulative dietary exposure for calcium from the petitioned uses of calcium phosphate and the contribution of calcium from background dietary sources, including dietary supplements, we concluded that the estimated 90th percentile cumulative dietary exposure for calcium from all dietary calcium sources does not exceed the current Institute of Medicine (IOM) Upper Limit (UL) of 2000 mg/p/d for calcium intake for all assessed populations (Refs. 2 and 3).

Based on the cumulative dietary exposure for phosphorus from the petitioned uses of calcium phosphate and the contribution of phosphorus from background dietary sources, including dietary supplements, we concluded that the estimated 90th percentile cumulative dietary exposure for phosphorus from all dietary phosphorus sources does not exceed the current IOM UL of 3000 mg/p/d for phosphorus intake for all assessed populations (Refs. 2 and 3).

Innophos conducted a comprehensive evaluation of the available literature for information pertinent to the safety of

calcium phosphate, as well as available safety assessments of dietary calcium and phosphorus by other regulatory bodies, including the IOM report on Dietary Reference Intakes (DRI), Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA), and the European Food Safety Authority (EFSA). Innophos provided a safety summary for calcium phosphate and its components, calcium and phosphorus, noting that when used in food, calcium phosphate is expected to dissociate in the gastrointestinal tract to conjugate ionic salts of calcium and inorganic phosphate (phosphorus).

Calcium is an essential micronutrient necessary for numerous physiological processes, including formation/metabolism of bone, and intracellular signaling related to muscular function, vascular contraction/dilation, nerve transmission, and hormonal secretion. Maintenance of calcium balance in the body within a narrow physiological range is essential for normative function. In 2011, the IOM reassessed the DRI for calcium based on newly available scientific information/data generated since its previous assessment. The IOM panel noted that excess intake of calcium was unlikely related to calcium intake from conventional foods, and higher intake levels often corresponded with use of calcium dietary supplements. The IOM panel specified that the efficiency of calcium absorption is in reverse proportion to the amount of calcium consumed at one time to maintain physiologic calcium balance and may vary based on vitamin D status. The IOM panel identified several potential indicators of adverse outcomes for excess calcium intake, including hypercalcemia, hypercalciuria, vascular and soft tissue calcification, nephrolithiasis (kidney stones), prostate cancer, interactions with iron and zinc, and constipation. As a result, IOM established a calcium UL between 2000 and 3000 mg/d for each DRI life-stage group. Our literature search identified no new publications relevant to the safe use of calcium in food. Therefore, the current state of the science supports the continued use of the IOM UL for calcium intake as a dietary reference value to support public health (Ref. 3).

Phosphorus is ubiquitously present across the food supply as organic phosphorus in various sources, such as dairy, meats, legumes, and nuts, or inorganic phosphorus related to the use of phosphorus salts. Phosphorus is an essential mineral that is a major component of healthy bones and teeth, and critical for numerous physiological functions, including pH homeostasis, energy metabolism, and cellular signaling mediated via phosphorylation and dephosphorylation events. Phosphorus is also a key component of phospholipid membranes and nucleic acids. The IOM panel noted that dietary phosphorus supports tissue growth and replacement of phosphorus lost due to excretion and desquamation of skin cells.

Innophos summarized the scientific literature on the safety of phosphorus and other phosphate salts, including genotoxicity assessments, systemic toxicity studies, carcinogenicity studies, and reproductive and developmental studies, focusing on studies using oral administration. Innophos summarized additional data/studies of various phosphate salts in support of the safety of calcium phosphate. Additionally, Innophos discussed published scientific opinions from JECFA, the EFSA Panel on Food Additives and Flavourings, and the IOM DRI to establish upper limits for phosphorus intake. The IOM panel noted that all adverse effects of excess phosphorous consumption corresponded to elevated inorganic phosphorus in the extracellular fluid. Hyperphosphatemia from dietary sources is a potential concern for individuals diagnosed with end-stage renal disease and is associated with reduced calcium absorption and potential calcification of non-skeletal tissues, particularly the kidney. Based on the weight of evidence, the IOM panel utilized intakes of phosphorus corresponding to normal circulating levels of inorganic phosphate in healthy adults and the application of a factorial approach for other relevant populations to support DRI derivation. The panel recognized the likely need for higher recommended daily allowances of phosphorus during periods of rapid growth in children. As a result, the IOM established a phosphorus UL between 3000 and 4000 mg/d for each DRI life-stage group. Our literature search identified no new publications relevant to the safe use of phosphorous in food. Therefore, the current state of the science supports the continued use of the IOM UL for phosphorus intake as a dietary reference value to support public health (Ref. 3).

Based on the totality of the safety data provided by Innophos and otherwise available to us, including supporting literature on the safety of calcium phosphate and its constituent ions, expert opinions from other regulatory bodies on safe dietary intake levels of calcium and phosphorous, and that the estimated 90th percentile cumulative dietary exposures for calcium and phosphorus from all sources (petitioned intended uses, and background dietary sources, including dietary supplements and drugs) does not exceed the IOM UL established for dietary calcium and phosphorous, we conclude that there is a reasonable certainty of no harm from the intended uses of calcium phosphate as a color additive in ready-to-eat chicken products, white candy melts, doughnut sugar, and sugar for coated candies.

III. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the petitioned use of calcium phosphate as a color additive, by weight of the finished food, in ready-to-eat chicken products in an amount not exceeding 1.5 percent; in white candy melts in an amount not exceeding 0.25 percent; in doughnut sugar in an amount not exceeding 2.0 percent; and in sugar for coated candies in an amount not exceeding 5.25 percent 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 conclude that certification of calcium phosphate is not necessary for the protection of public health.

IV. 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.

V. Analysis of Environmental Impact

As stated in the February 27, 2023 (88 FR 12281) **Federal Register** notification of petition for CAP 3C0324, the petitioner claimed that this action is categorically excluded under 21 CFR 25.32(k) because calcium phosphate added directly to food is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. We further stated that, if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We did not receive 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 21 CFR 25.32(k). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. 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.

VII. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This order 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 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(ll) of the FD&C Act. Furthermore, this language is included in all color additive orders 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.

VIII. 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**.

IX. References

The following references marked with an asterisk (*) 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 J. Barrows, Color Technology Branch, Office of Cosmetics and Colors, Office of the Chief Scientist, FDA to R. Morissette, 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, April 23, 2025.
* 2. Memorandum from T. Todorov, Chemistry Review Branch, DFI, OPMAS, OFCSDSI, FDA to R. Morissette, RMB, DFI, OPMAS, OFCSDSI, HFP, FDA, April 22, 2025.
* 3. Memorandum from T. Hubbard, Toxicology Review Branch, DFI, OPMAS, OFCSDSI, HFP, FDA to R. Morissette, RMB, DFI, OPMAS, OFCSDSI, HFP, FDA, April 22, 2025.

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. Add § 73.80 to read as follows:

§ 73.80 Calcium phosphate.

(a) *Identity.* (1) The color additive calcium phosphate is a white, synthetically prepared powder consisting predominantly of precipitated $Ca_5OH(PO_4)_3$.

(2) Color additive mixtures for food use made with calcium phosphate may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Calcium phosphate 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) Loss on ignition, not more than 10 percent.

(2) Assay (Ca): 36.0–40.0 percent.

(3) Fluoride, not more than 75 milligrams/kilogram (mg/kg) (75 parts per million (ppm)).

(4) Lead, not more than 0.25 mg/kg (0.25 ppm).

(5) Arsenic, not more than 3 mg/kg (3 ppm).

(c) *Uses and restrictions.* Calcium phosphate may be safely used for coloring foods intended for human consumption, subject to the following restrictions:

(1) In ready-to-eat chicken products in an amount not exceeding 1.5 percent by weight of the finished food.

(2) In white candy melts in an amount not exceeding 0.25 percent by weight of the finished food.

(3) In doughnut sugar in an amount not exceeding 2.0 percent by weight of the finished food.

(4) In sugar for coated candies in an amount not exceeding 5.25 percent by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08249 Filed 5–9–25; 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–2024–C–0971]

Listing of Color Additives Exempt From Certification; Butterfly Pea Flower 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 safe use of butterfly pea flower extract as a color additive in ready-to-eat cereals, crackers, snack mixes, hard pretzels, plain potato chips (restructured or baked), and plain corn chips, tortilla chips, and multigrain chips at levels consistent with good manufacturing practice (GMP). This action is in response to a color additive petition (CAP) submitted by Sensient Colors, LLC (Sensient or petitioner).

DATES: This order is effective June 26, 2025. See section X 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 June 11, 2025.

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 June 11, 2025. 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.*
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Written/Paper Submissions

Submit written/paper submissions as follows:

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- 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–0971 for ''Listing of Color Additives Exempt from Certification; Butterfly Pea Flower 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: Stephen DiFranco, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710; or Philip Chao, 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 February 8, 2024 (89 FR 8537), we announced that we filed a color additive petition (CAP 4C0328) submitted by Exponent, Inc., on behalf of Sensient Colors, LLC, 1150 Connecticut Ave. NW, Suite 1100, Washington, DC 20036. The petition proposed to amend the color additive regulations in part 73 (21 CFR 73.69), ''Listing of Color Additives Exempt from Certification'' to provide for the expanded safe use of butterfly pea flower extract to include ready-to-eat cereals, crackers, snack mixes, hard pretzels, plain potato chips (restructured or baked), and plain corn chips, tortilla chips, and multigrain chips, at levels consistent with GMP.

We note that the notification of filing stated that documents related to this petition would be deposited in docket FDA–2018–C–4117. This petition has been reassigned to a new docket, docket number FDA–2024–C–0971. All relevant files from the previous docket