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.*
- 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–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

have been moved into docket number FDA–2024–C–0971.

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

II. Background

Butterfly pea flower extract is approved under § 73.69 for coloring alcoholic beverages, sport and energy drinks, flavored or carbonated water, fruit drinks (including smoothies and grain drinks), carbonated soft drinks (fruit-flavored or juice, ginger ale, and root beer), fruit and vegetable juice, nutritional beverages, chewing gum, teas, coated nuts, liquid coffee creamers (dairy and non-dairy), ice cream and frozen dairy desserts, hard candy, dairy and non-dairy drinks, fruit preparations in yogurts, and soft candy in amounts consistent with GMP, except that it may not be used for coloring foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the use of added color is authorized by such standards. Butterfly pea flower 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 (86 FR 49230, September 2, 2021).

The color additive that is the subject of this petition is the dark blue liquid produced through the water extraction of the dried flower petals of *Clitoria ternatea,* commonly known as the butterfly pea plant. Butterfly pea flower extract contains 42 to 62 percent water, 22 to 43 percent carbohydrates, and 8 to 12 percent proteins. The principal coloring components in butterfly pea flower extract are anthocyanins, mainly delphinidin derivatives (Ref. 1). The extract also contains flavonols, mainly quercetin and kaempferol derivatives, as minor components. Based on data and information provided in this petition (CAP 4C0328) 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 butterfly pea flower extract in § 73.69 (Ref. 1).

III. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the FD&C Act (21 U.S.C. 379e(b)(4)), 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 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 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 dietary exposure of the color additive from all sources to an acceptable daily intake (ADI) level established by toxicological data. The estimated dietary exposure is based on the amount of the color additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the color additive. We commonly use the estimated dietary exposure 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 4C0328), we considered the estimated dietary exposure to butterfly pea flower extract, anthocyanins (the main coloring component), total flavonols, and quercetin from the petitioned uses of the subject color additive (Ref. 2). The petition provided the eaters-only 90th percentile dietary exposure for butterfly pea flower extract for the petitioned uses for the U.S. population aged 2 years and older, and various subpopulations. From that dietary exposure and compositional information incorporated by reference from CAP 8C0313, the petitioner also estimated the eaters-only 90th percentile dietary exposure to anthocyanins, total flavonols, and quercetin (Ref. 2).

The petitioner requested that butterfly pea flower extract be permitted at levels consistent with GMP and provided the maximum use levels for the color additive, representing GMP, for the petitioned and approved food uses (Ref. 2). Using food consumption data from the 2015–2018 National Health and Nutrition Examination Survey (NHANES), the petitioner estimated the eaters-only cumulative dietary exposure to butterfly pea flower extract to be 215 milligrams/person/day (mg/p/d) at the mean and 467 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older and 94 mg/p/d at the mean and 183 mg/p/d at the 90th percentile for children aged 2–5 years (Ref. 2).

Assuming a maximum content of 2% anthocyanins (the principal coloring component) in butterfly pea flower extract, the petitioner estimated the eaters-only cumulative dietary exposure to anthocyanins to be 4.3 mg/p/d at the mean and 9.3 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older (Ref. 2). The petitioner also indicated that the color additive could contain up to 3% flavonols and assumed that 50% of the flavonol content was quercetin. Based on these assumptions, the petitioner estimated the eaters-only cumulative dietary exposure to flavonols (6.4 mg/p/d at the mean and 14 mg/p/d at the 90th percentile) and to quercetin (3.2 mg/p/d at the mean and 7 mg/p/d at the 90th percentile) for the U.S. population aged 2 years and older (Ref. 2).

To support the safety of the petitioned uses of butterfly pea flower extract, the petitioner referenced the safety determinations made by FDA for CAP 8C0313 (86 FR 49230, September 2, 2021). The petitioner also conducted an updated search of the peer-reviewed scientific literature on butterfly pea flower extract and *Hibiscus sabdariffa* flower extract (a known source of anthocyanins with a high content of delphinidin), as well as on other sources of anthocyanins and delphinidins. The petitioner concluded that these publications did not reveal any significant new toxicological effects and should not alter the conclusions of FDA's previous reviews on butterfly pea flower extract. 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 did not reveal any safety concerns relating to the consumption of butterfly pea flower extract or its major components (Ref. 3).

In our most recent evaluation of the use of butterfly pea flower extract as a color additive in various foods (86 FR 49230, September 2, 2021), we did not have any concerns regarding the safety of the use of butterfly pea flower extract and its principal coloring components, anthocyanins and delphinidins. This finding was based on a weight-of-evidence approach and agreed with the petitioner's conclusion that the no observed adverse effect level (NOAEL) in the submitted 90-day study was the highest dose tested (3,500 mg/kg/d of butterfly pea flower extract), which is nearly 500-fold of the estimated 90th

percentile dietary exposure for the U.S. population aged 2 years and older from the originally petitioned uses. To establish a reasonable certainty of no harm for the petitioned expanded uses of butterfly pea flower extract, we compared the cumulative estimated dietary exposure to the article of commerce and its constituents in the current petition to that of the previous petition, as well as to the petitioner's NOAEL from their previous 90-day study to develop a margin of exposure (MOE) (Ref. 3). Based on the slight increase in the estimated dietary exposure to butterfly pea flower extract and its constituents resulting from the petitioned expanded uses in this petition above those seen in the previous petition, and the high MOE between the observed NOAEL, we conclude that these new uses of the color additive are reasonably safe under the intended conditions of use (Ref. 3).

We discussed the potential allergenicity of butterfly pea flower extract in our previous approval of a petition for its use in various foods (86 FR 49230, September 2, 2021). We stated that there is no evidence in the scientific literature specifically suggesting that either *Clitoria ternatea* flowers or the coloring component delphinidin is associated with allergic or hypersensitive reactions. The petitioner submitted an updated search of the peer-reviewed scientific literature and found no new additional publications which suggested an allergenicity concern. Further, to mitigate the possible risk that allergenic proteins and other large peptides might pose, our regulation at 21 CFR 73.69(a)(1) requires that the aqueous extract used to produce the color additive undergo ultrafiltration. Therefore, we concluded that butterfly pea flower extract presents an insignificant allergy risk to consumers of the color additive (Ref. 4).

V. Conclusion

Based on the data and information in the petition, the referenced material, and other relevant material, we conclude that the petitioned 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 GMP is safe. We further conclude that the color additive will achieve its intended technical effect and is suitable for the petitioned uses. Therefore, 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 batch certification of butterfly pea flower extract is not necessary to protect the public health.

VI. Public Disclosure

In accordance with § 71.15(a) (21 CFR 71.15(a)), 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(b), we will delete from the documents any materials that are not available for public disclosure.

VII. Analysis of Environmental Impact

As stated in the February 8, 2024, **Federal Register** notification of filing for CAP 4C0328, the petitioner claimed that this action is categorically excluded under § 25.32(k) (21 CFR 25.32(k)) because butterfly pea flower extract would be added directly to food and is intended to remain in the food through ingestion by consumers and is not intended to replace nutrients in food (89 FR 8537 at 8538). We further stated that, if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required (id.). 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 § 25.32(k). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. 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.

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 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 orders authorizing new uses of color additives 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 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**.

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 B. Petigara-Harp, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors (OCAC), Office of Commissioner, Office of Chief Scientist, FDA to S. DiFranco, Regulatory Management Branch (RMB), Division of Food Ingredients (DFI), Office of Premarket Additive Safety (OPMAS), HFP, FDA, April 21, 2025.
2. Memorandum from H. Thapa, Chemistry Evaluation Branch, DFI, OPMAS, HFP, FDA to S. DiFranco, RMB, DFI, OPMAS, HFP, FDA, April 21, 2025.
3. Memorandum from T. Thurmond, Toxicology Review Branch (TRB), DFI, OPMAS, HFP, FDA to S. DiFranco, RMB, DFI, OPMAS, HFP, FDA, April 21, 2025.
4. Memorandum from Y. Zang, Toxicology Review Team, DFI, Office of Food Additive Safety (OFAS), Center for Food and Human Nutrition (CFSAN), FDA, to S. DiFranco, DFI, OFAS, CFSAN, FDA, June 9, 2021.

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 73.69 is amended by revising paragraph (c) to read as follows:

§ 73.69 Butterfly pea flower extract.

* * * * *

(c) *Uses and restrictions.* Butterfly pea flower extract may be safely used for coloring alcoholic beverages, sport and energy drinks, flavored or carbonated water, fruit drinks (including smoothies and grain drinks), carbonated soft drinks (fruit-flavored or juice, ginger ale, and root beer), fruit and vegetable juice, nutritional beverages, chewing gum, teas, coated nuts, liquid coffee creamers (dairy and non-dairy), ice cream and frozen dairy desserts, hard candy, dairy and non-dairy drinks, fruit preparations in yogurts, soft candy, ready-to-eat cereals, crackers, snack mixes, hard pretzels, plain potato chips (restructured or baked), and plain corn chips, tortilla chips, and multigrain chips. Amounts must be consistent with good manufacturing practice. Butterfly pea flower extract may not be used for coloring foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

* * * * *

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08248 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–2021–C–0925]

Listing of Color Additives Exempt From Certification; Galdieria Extract Blue

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 galdieria extract blue, derived from unicellular red algae (*Galdieria sulphuraria*), in various food categories at levels consistent with good manufacturing practice (GMP). We are taking this action in response to a color additive petition (CAP) submitted by Fermentalg (Fermentalg or petitioner).

DATES: This order is effective June 26, 2025. See section XI 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 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 objections 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–2021–C–0925 for ''Listing of Color Additives Exempt from Certification; Galdieria Extract Blue.'' 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