(b)(2) of this section, this date will be extended accordingly. If FNS determines that the report in the first sentence of this paragraph (b)(4) does not sufficiently justify the case's pending status, the case shall be considered overdue. Depending upon the number of overdue cases, FNS may find the State agency's QC system to be inefficient or ineffective and suspend and/or disallow the State agency's Federal share of administrative funds in accordance with the provisions of § 276.4.

* * * * *

Cynthia Long,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2021–18743 Filed 9–1–21; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2018–C–4117]

Listing of Color Additives Exempt From Certification; Butterfly Pea Flower Extract

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of an aqueous extract of butterfly pea flower (*Clitoria ternatea*) as a color additive in various food categories at levels consistent with good manufacturing practice. We are taking this action in response to a color additive petition (CAP) submitted by Exponent, Inc., on behalf of Sensient Colors, LLC (Sensient).

DATES: This rule is effective October 5, 2021. See section X for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by October 4, 2021.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before October 4, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 4, 2021. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2018–C–4117 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, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–2710.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notification published in the **Federal Register** of November 13, 2018 (83 FR 56258), we announced that we filed a color additive petition (CAP 8C0313) submitted by Sensient Colors, LLC, c/o Exponent, Inc., 1150 Connecticut Avenue NW, Suite 1100, Washington, DC 20036. 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 an aqueous extract of butterfly pea flower (*Clitoria ternatea*) as a color

additive in: (1) Alcoholic beverages (liquor, liqueurs, and flavored alcoholic beverages); [1] (2) ready-to-drink non-alcoholic beverages; (3) liquid coffee creamers (dairy and non-dairy); (4) ice cream and frozen dairy desserts; (5) fruit preparation in yogurt; (6) chewing gum; (7) coated nuts; (8) hard candy; and (9) soft candy, at levels consistent with good manufacturing practice (GMP).

The petition describes butterfly pea flower extract as a dark blue water-soluble extract derived from the flower petals of *Clitoria ternatea.*

II. Background

The color additive that is 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. The extract also contains flavonols, mainly quercetin and kaempferol derivatives as minor components. These anthocyanins and flavonols are naturally present in various fruits and vegetables commonly consumed in the U.S. diet (Ref. 1).

The color additive is manufactured by sourcing dried flowers of *Clitoria ternatea.* An infusion is prepared by adding demineralized water to the flower petals, which is separated from the plant mass via filtration. The butterfly pea flower extract is further processed by ultrafiltration to remove any residues of plant products greater than 2,500 daltons (Da). The extract is then concentrated to a standardized liquid with an anthocyanin content of approximately 2 percent and pasteurized. Citric acid may be added to control the pH of the extract (Ref. 2).

The petitioner proposed specifications for butterfly pea flower extract of less than 1 milligram per kilogram (mg/kg) (1 part per million (ppm)) of arsenic, less than 1 mg/kg (1 ppm) of cadmium, less than 1 mg/kg (1 ppm) of lead, and less than 1 mg/kg (1 ppm) of mercury, and pH 3.75 ± 0.75 in the butterfly pea flower extract. Upon consideration of the data in the petition and other information available to FDA, we amended the proposed specification for pH to not less than 3.0 and not more than 4.5 at 25 °C (Ref. 2).

The petitioner manufactures the extract starting with butterfly pea flowers grown without the use of added pesticide substances. The petition provides data to support its assertion that no detectable levels of 340 substances commonly used as pesticide are found in the finished extract. The flowers were analyzed using the California Department of Food and Agriculture multi-residue pesticide analysis (Ref. 3).

Currently, there are no residual pesticide tolerance levels for *Clitoria ternatea* codified by the U.S. Environmental Protection Agency in 40 CFR part 180. In cases where no tolerance levels are set, the allowable residual pesticide levels that may remain on the raw agricultural commodity are zero (40 CFR 180.5). Under section 402(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(2)(B)), food is adulterated if it bears or contains pesticide chemical residue that is unsafe within the meaning of section 408(a) of the FD&C Act (21 U.S.C. 346a(a)).

III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act (21 U.S.C. 379e(b)(4)), a color additive may not be listed for a proposed 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 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 or 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) through (C) 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.

IV. Safety of Petitioned Use of the Color Additive

A. Exposure Estimate

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 each proposed food use (Ref. 4). The petitioner used food consumption data from the 2011–2014 National Health and Nutrition Examination Survey (NHANES) to estimate exposure to butterfly pea flower extract from the proposed uses. Upon further clarification of the proposed uses to include all alcoholic beverages (Ref. 5), we amended the petitioner's exposure estimate to include all alcoholic beverages (Ref. 4).

Using food consumption data from the 2011–2014 NHANES, we estimated the eaters-only exposure to butterfly pea flower extract to be 198 milligrams per person per day (198 mg/p/d) at the mean and 453 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older and 56 mg/p/d at the mean and 118 mg/p/d at the 90th percentile for children 2 to 5 years of age (Ref. 4).

The petition indicated that butterfly pea flower extract could contain up to 2 percent anthocyanins (by weight). Assuming a maximum of 2 percent, we estimated the dietary exposure to anthocyanins from the proposed uses to be 4 mg/p/d at the mean and 9 mg/p/d at the 90th percentile for the U.S. population 2 years of age and older (Ref. 4). Because delphinidin was stated to be the principal anthocyanin in butterfly pea flower extract, the exposure to anthocyanins represents the exposure to delphinidin from the proposed uses of butterfly pea flower extract.

Similarly, we estimated the dietary exposure to quercetin resulting from the proposed uses of butterfly pea flower extract. The petition indicates that butterfly pea flower contains approximately 3 percent (by weight) of flavonols, which are comprised of various quercetin and kaempferol derivatives. We conservatively presumed that all the flavonols present in butterfly pea flower extract were present as quercetin (see below) and estimated quercetin exposure to be 6 mg/p/d at the mean and 14 mg/p/d at the 90th percentile for the U.S. population 2 years of age and older (Ref. 4).

[1] The proposed scope was subsequently amended to include all alcoholic beverages.

B. Toxicological Considerations

To establish that butterfly pea flower extract is safe for use as a color additive for the proposed uses, the petitioner used a weight-of-evidence approach based on: (1) Toxicological information about the extract's major coloring component, delphinidin, including a 2013 European Food Safety Authority (EFSA) review of anthocyanins (Ref. 6); (2) a 28-day subacute range finding feeding study in rats; (3) a 90-day feeding study in rats; (4) a bacterial reverse mutation test and an in vitro micronucleous test addressing possible mutagenicity and genotoxicity of butterfly pea flower extract; (5) an in vivo somatic mutation and recombination test conducted on the unprocessed butterfly pea flower parts; (6) in vivo genotoxicity data from published literature on anthothyanins (including delphinidin) and flavonol components (Refs. 7 and 8); (7) clinical human studies of anthocyanins (including delphinidin) and spray-dried butterfly pea flower extract; (8) clinical studies of quercetin and kaempferol, the primary flavonols present; (9) a proteomic assessment of butterfly pea flower extract aimed at establishing that cyclotides found in the tissues of *Clitoria ternatea* are not present in the butterfly pea flower extract; and (10) an allergenicity assessment of butterfly pea flower extract.

We reviewed the oral toxicity studies and agree with the petitioner's conclusions that the no observed adverse effect level in the 90-day study is the highest dose tested (3,500 mg/kg/d of butterfly pea flower extract), which is nearly 500-fold of the 90th percentile daily exposure for U.S. population 2 years and older (Ref. 9). While chronic studies were not provided by the petitioner nor available from the published literature, we believe that chronic toxicity from the intended use of butterfly pea flower extract is unlikely because: (1) We did not identify any potential toxicity effects associated with the use of either butterfly pea flower extract or its anthocyanins and flavonol components from literature that warrant further chronic toxicity studies (Refs. 9 and 10); (2) the systemic oral absorption of anthocyanins and flavonols is generally low (Ref. 9); (3) there are available human clinical studies indicating that the main anthocyanins and flavonol components of butterfly pea flower extract are well tolerated in humans (Ref. 9); and (4) anthocyanins and flavonols are naturally present and widely distributed in many plants used as food, and the exposures to anthocyanins and flavonols from the use of butterfly pea flower extract were estimated to be comparable or lower than the exposure from a typical diet (Ref. 11).

We also did not find any scientific data suggesting reproductive or developmental toxicity; moreover, the genotoxicity studies demonstrate that butterfly pea flower extract is non-mutagenic and non-genotoxic (Ref. 9).

Based on the totality of evidence and a weight of evidence analysis that considered the lack of overall genotoxicity, mode of action, and the level of exposure, we conclude that butterfly pea flower extract is not likely to pose a carcinogenic risk to humans at its intended use levels (Refs. 9 and 10).

Among the available relevant clinical studies, one study of butterfly pea flower extract indicated no acute adverse effect at doses up to 2 grams per person. Other clinical studies, using either anthocyanins or flavonols, suggested tolerance at doses much higher than the exposure level from the consumption of butterfly pea flower extract under the intended condition of use (Ref. 9).

The petitioner provided analytical evidence demonstrating that the cyclotides identified in butterfly pea flower petals were not detected in the butterfly pea flower extract. Therefore, there is no toxicity concern for cyclotides from the consumption of the extract (Ref. 9).

Although 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, we note that butterfly pea flower extract contains 8 to 12 percent protein by weight. To address the allergenicity potential of butterfly pea flower extract, the petitioner provided bioinformatic analyses of the 193 protein sequences of *Clitoria ternatea* identified in the National Center for Biotechnology Information protein database. These protein sequences were compared for similarity with the known allergenic protein sequences collected in the AllergenOnline database (Ref. 12). The analysis revealed five protein sequence matches (defined as 35 percent or higher identity over an 80-amino-acid sliding window); however, these proteins are expected to be over 5,000 Da and not likely to pass through the 2,500 Da ultrafiltration system used in the manufacturing process. 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. We agree with the petitioner that the totality of the evidence supports the conclusion that it is extremely unlikely that the proteins in butterfly pea flower extract could act as allergens (Ref. 9).

V. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of butterfly pea flower extract as a color additive in: 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 is safe, provided the amount of butterfly pea flower extract does not exceed levels consistent with good manufacturing practice.

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 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), we 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 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VII. Analysis of Environmental Impact

As stated in the November 13, 2018, **Federal Register** notification of filing, 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 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 § 25.32(k). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

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

XI. References

The following references 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 also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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. *Wu, X., G. R. Beecher, J. M. Holden, et al., ''Concentrations of Anthocyanins in Common Foods in the United States and Estimation of Normal Consumption.'' *Journal of Agricultural and Food Chemistry,* 54: 4069–4075, 2006.

2. *Memorandum from B. Petigara Harp, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (CFSAN), FDA, to S. DiFranco, Division of Food Ingredients (DFI), Office of Food Additive Safety (OFAS), CFSAN, FDA, June 4, 2021.

3. Lee, S. M., M. L. Papathakis, H–M. C. Feng, et al., ''Multipesticide Residue Method for Fruits and Vegetables: California Department of Food and Agriculture.'' *Fresenius' Journal of Analytical Chemistry,* 339, 376–383, 1991.

4. *Memorandum from D. Doell, Chemistry Review Team, DFI, OFAS, CFSAN, FDA, to S. DiFranco, DFI, OFAS, CFSAN, FDA, June 7, 2021.

5. *Memorandum of Teleconference from S. DiFranco, Regulatory Review Team, DFI, OFAS, CFSAN, FDA, to the file, April 7, 2020.

6. *EFSA, ''Scientific Opinion on the Re-evaluation of Anthocyanins (E163) as a Food Additive.'' *EFSA Journal,* 11(4): 3145, 2013.

7. *NTP, ''Toxicology and Carcinogenesis Studies of Quercetin (CAS No. 117–39–5) in F344 Rats (Feed Studies).'' NTP Technical Report Series, No. 409, 1992.

8. Hard, G. C., J. C. Seeley, L. J. Betz, et al., ''Re-evaluation of the Kidney Tumors and Renal Histopathology Occurring in a 2-Year Rat Carcinogenicity Bioassay of Quercetin.'' *Food and Chemical Toxicology,* 45: 600–608, 2007.

9. *Memorandum from Y. Zang, Toxicology Review Team, DFI, OFAS, CFSAN, FDA, to S. DiFranco, DFI, OFAS, CFSAN, FDA, June 9, 2021.

10. *Memorandum from S. Mog and S. Francke to Y. Zang. Pathology Consultation Review on Renal Neoplasms in Male F344 rats from National Toxicology Program Technical Report (NTP TR 409) on Quercetin in F344/N Rats (feed studies), October 31, 2019.

11. *USDA. ''Table 1a. Flavonoids from Food and Beverages: Mean Intake (standard error) per Individuals, by Gender and Age, in the United States, What We Eat in America.'' NHANES 2007–2010, 2016.

12. Goodman R. E., M. Ebisawa, F. Ferreira, et al., ''AllergenOnline: A Peer-reviewed, Curated Allergen Database to Assess Novel Food Proteins for Potential Cross-reactivity.'' *Molecular Nutrition and Food Research,* 60(5):1183–1198, 2016.

List of Subjects in 21 CFR Part 73

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

Therefore, 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 § 73.69 to subpart A to read as follows:

§ 73.69 Butterfly pea flower extract.

(a) *Identity.* (1) The color additive butterfly pea flower extract is a dark blue liquid prepared by the aqueous extraction of dried butterfly pea flowers from *Clitoria ternatea.* The extract is further processed by ultrafiltration to remove residues of plant products, followed by concentration and pasteurization. Citric acid may be used to control the pH. The color additive

contains anthocyanins as the principal coloring component.

(2) Color additive mixtures for food use made with butterfly pea flower extract 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.* Butterfly pea flower 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) pH, not less than 3.0 and not more than 4.5 at 25 °C.

(2) Lead, not more than 1 milligram per kilogram (mg/kg) (1 part per million (ppm)).

(3) Arsenic, not more than 1 mg/kg (1 ppm).

(4) Mercury, not more than 1 mg/kg (1 ppm).

(5) Cadmium, not more than 1 mg/kg (1 ppm).

(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, and soft candy in amounts consistent with good manufacturing practice, 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, unless the use of added color is authorized by such standards.

(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 are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: August 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18995 Filed 9–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0426]

RIN 1625–AA00

Special Local Regulation; Swim for Special Operations Forces; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its special local regulations for recurring marine parades, regattas, and other events in Southern California Annual Marine Events for the San Diego Captain of the Port Zone. This final rule will add one new recurring special local regulation. This action is necessary to provide for the safety of life on the navigable waters during the event. This final rule will restrict vessel traffic in the designated areas during the events unless authorized by the Captain of the Port San Diego or a designated representative.

DATES: This rule is effective September 2, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0426 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard; telephone 619–278–7656, email *MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On April 8, 2021, The Honor Foundation notified the Coast Guard that it will be hosting the Honor Foundation Swim for Special Operations Forces annually on a Saturday during the month of September. The regulated area would cover all navigable waters of the San Diego Bay, beginning at Glorietta Bay, continuing to Tidelands Park before proceeding north along the Coronado shoreline, crossing the federal navigable channel at Bayview Park, and finishing at the USS MIDWAY Museum.

In response, on July 2, 2021 the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulations; Swim for Special Operations Forces; San Diego Bay, San Diego, CA (86 FR 35240). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this annual marine event. During the comment period that ended August 2, 2021 we received one comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041 (previously 33 U.S.C. 1231). The Captain of the Port San Diego (COTP) has determined that potential hazards associated with the Honor Foundation Swim for Special Operations Forces annually on a Saturday during the month of September will present a safety of life concern on navigatable waters. The purpose of this rule is to ensure safety of life on the navigable waters in the safety zone before, during, and after the scheduled event. For the reasons stated above, we are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because enforcement of this safety zone is necessary to protect swimmers and vessels from the dangers associated with the swim race events planned for a Saturday in September 2021.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on the NPRM published July 2, 2021. The commentor proposed a method for intercepting and impounding vessels entering the safety zone. The Coast Guard was not proposing to spcecify how on scene representatives must handle situations where vessels enter the safety zone in this rulemaking. The purpose of this rulemaking is to establish the reoccurring annual safety zone and its location. The Coast Guard has existing regulations and policies that cover enforcement and this rulemaking does not intend to deviate from those practices. Accordingly, no changes to the regulatory text were made in response to this comment.