section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2025–14–04 Airbus Helicopters Deutschland GmbH: Amendment 39–23082; Docket No. FAA–2025–1359; Project Identifier MCAI–2025–00155–R.

(a) Effective Date

This airworthiness directive (AD) is effective July 30, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 D–3 helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6230, Main Rotor Mast/Swashplate.

(e) Unsafe Condition

This AD was prompted by a report of over-torqued swashplate bolts on helicopters in service and in production. The FAA is issuing this AD to detect and correct the condition of the swashplate bolts and damage to the bearing ring and control ring of the swashplate due to over-torquing. The unsafe condition, if not addressed, could result in reduced structural integrity of the swashplate, loss of main rotor control, and consequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2025–0027, dated February 5, 2025 (EASA AD 2025–0027).

(h) Exceptions to EASA AD 2025–0027

(1) Where EASA AD 2025–0027 requires compliance in terms of flight hours, this AD requires using hours time-in-service (TIS).

(2) Where EASA AD 2025–0027 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraphs (2) and (3) of EASA AD 2025–0027 specify ''discrepancy'', this AD requires replacing this text with ''damage to the threads''.

(4) Where paragraph (2) of EASA AD 2025–0027 specifies ''replace that control ring or bearing ring, respectively'', this AD requires replacing that text with ''remove from service and replace that control ring or bearing ring, respectively''.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2025–0027.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2025–0027 specifies to submit certain information to the manufacturer, this AD does not require that action.

(j) Special Flight Permits

Special flight permits are prohibited.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD and email to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(l) Additional Information

For more information about this AD, contact Yves Petiote, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (202) 975–4867; email: *yves.petiote@faa.gov*.

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2025–0027, dated February 5, 2025.

(ii) [Reserved]

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

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on July 10, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–13214 Filed 7–11–25; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2021–C–0522]

Listing of Color Additives Exempt From Certification; Gardenia (Genipin) 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 gardenia (genipin) blue in various foods, at levels consistent with good manufacturing practice (GMP). We are taking this action in response to a color additive petition (CAP) submitted by Exponent, Inc., on behalf of the Gardenia Blue Interest Group (GBIG).

DATES: This order is effective August 29, 2025. See section XI for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the order by August 14, 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 August 14, 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–0522 for ''Listing of Color Additives Exempt from Certification; Gardenia (genipin) 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 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 Pre-market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710; or Deirdre Jurand, 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** on June 30, 2021 (86 FR 34664), we announced that we filed a color additive petition (CAP 1C0319) submitted by GBIG, c/o Exponent, Inc., 1150 Connecticut Ave. 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 gardenia (genipin) blue at levels consistent with GMP in (1) sport drinks, (2) flavored or enhanced non-carbonated water, (3) fruit drinks and ades, (4) ready-to-drink teas, (5) hard candy, and (6) soft candy.

II. Background

Gardenia (genipin) blue is a dark purple or dark blue liquid or powder prepared by the polymerization of genipin obtained from the fruit of *Gardenia jasminoides* Ellis with soy protein hydrolysate. Gardenia (genipin) blue is mainly composed of a genipin-peptide polymer (the principal coloring component), carriers (for powder form), and water (for liquid form).

The color additive is manufactured by sourcing, drying, and crushing the mature fruit of *Gardenia jasminoides* Ellis. The fruit is used to produce the raw material for manufacture of gardenia (genipin) blue because it contains iridoid glycosides, of which 3–8 percent is geniposide. The soluble components are extracted using a mixture of ethanol and water, and the solids are removed by filtration. The extract is further refined to obtain genipin, which is reacted with soy protein hydrolysate, followed by polymerization to produce the liquid form of the principal coloring component (genipin-peptide polymer). Optionally, the finished liquid may be mixed with a food-grade carrier (dextrin or maltodextrin) and the mixture heat-sterilized, spray-dried to powder, and sieved to produce the color additive as a powder (Ref. 1).

The raw material for gardenia (genipin) blue contains carboxymethyl

functional groups, which may hydrolyze into methanol under the aqueous conditions of the manufacturing process. Any methanol formed is likely to be removed along with ethanol during the concentration steps in the manufacturing process, as well as in the final drying step for the powder form.

The petitioner proposed specifications for gardenia (genipin) blue of not more than 5 milligrams per kilogram (mg/kg) (5 parts per million (ppm)) of unreacted genipin, not more than 80 mg/kg (80 ppm) of geniposide, not more than 6 mg/kg (6 ppm) of methanol, not more than 2 mg/kg (2 ppm) of arsenic, not more than 1 mg/kg (1 ppm) of cadmium, not more than 2 mg/kg (2 ppm) of lead, and not more than 1 mg/kg (1 ppm) of mercury.

III. 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 may not be listed for a particular use unless the data and other information available to FDA establish that the color additive is safe for that use. Our color additive regulations, at 21 CFR 70.3(i), define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive.

To establish with reasonable certainty that a color additive intended for use in foods 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 to the color additive from all dietary sources to an acceptable daily intake (ADI) that is established by toxicological data. The dietary exposure is determined by projections based on the amount of the color additive intended for use in particular foods and on data regarding the amount consumed from all sources of the color additive. We commonly use the dietary exposure for the 90th percentile consumer of a color additive as a measure of high chronic dietary exposure.

IV. Safety of the Petitioned Use of the Color Additive

A. Dietary Exposure Estimate

The petitioner provided information on the proposed food categories and the corresponding maximum use levels of gardenia (genipin) blue as a color additive that represent levels consistent with GMP for each proposed food category (Refs. 2 and 3). The petitioner used food consumption data from the 2013–2016 National Health and Examination Survey (NHANES) to estimate the dietary exposure to gardenia (genipin) blue from the proposed uses. The petitioner estimated the eaters-only dietary exposure to gardenia (genipin) blue to be the following:

- 32 mg/person (p)/day (d) (0.57 mg/kg body weight (bw)/d) at the mean and 72 mg/p/d (1.27 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older; and
- 32 mg/p/d (1.90 mg/kg bw/d) at the mean and 73 mg/p/d (4.60 mg/kg bw/d) at the 90th percentile for children aged 2–5 years.

The petitioner indicated that gardenia (genipin) blue could contain up to 40 percent of the genipin-peptide polymer (the principal coloring component). Assuming a maximum content of 40 percent of the genipin-peptide polymer in the color additive, the petitioner estimated an eaters-only dietary exposure to the principal coloring component from the proposed uses to be 13 mg/p/d at the mean and 29 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older and for children 2–5 years (Ref. 2). We concur with this approach to estimating the dietary exposure to both the color additive and the genipin-peptide polymer content expected in the diet from the petitioned uses (Ref. 2).

B. Toxicological Considerations

To support the safety of the petitioned use of gardenia (genipin) blue, the petitioner provided unpublished safety data, data derived from publicly available databases, and peer-reviewed studies. These data included a mutagenicity and genotoxicity battery composed of (1) a bacterial reverse mutation (Ames) test, (2) an *in vitro* mammalian chromosomal aberration test, (3) an *in vitro* micronucleus test, (4) an *in vivo* micronucleus assay (comet assay), (5) an *in vivo* reverse comet assay, (6) an *in vivo* Pig-a gene mutation assay, and (7) a combined chronic oral toxicity and carcinogenicity study. Data were provided addressing the color additive's absorption, distribution, metabolism, and excretion (ADME) profile, including studies using [^{14}C] radiolabled gardenia (genipin) blue in male and female rats and mice. Further, the petitioner discussed the safety of genipin and geniposide and potential residual impurities from the manufacturing of gardenia (genipin) blue. The petitioner provided published literature on the safety of genipin and genipinoside that addressed the safety of exposure to these impurities. Unreacted genipin was not detected in the final product.

The petitioner found no evidence suggesting that gardenia (genipin) blue has been associated with any allergic or hypersensitivity reactions. The allergenicity potential of gardenia (genipin) blue was assessed via a search of the publicly available databases. The petitioner found no available information that would suggest gardenia (genipin) blue itself has allergenic potential. We concur with this finding and find no additional data suggesting either genipin or gardenia (genipin) blue is associated with allergic or hypersensitivity reactions (Ref. 3).

The petitioner also addressed a potential allergenicity arising from the use of soy protein hydrolysate in the manufacture of the color additive and stated that allergens related to soy protein are not expected to be detected in the final color additive since unreacted protein hydrolysate is removed during manufacturing (Refs. 1, 3). In support of this claim, the petitioner provided results of an enzyme-linked immunoassay test that showed non-detectable levels of soy protein residue in the final article of commerce (Ref. 3). The petitioner included data from a 12-month chronic oral toxicity study that used multiple doses of gardenia (genipin) blue. This study also included an *in utero* exposure phase assessed at interim timepoints to determine if reproductive toxicity hazards existed from the petitioned use levels of gardenia (genipin) blue. We note that this study adheres to the Redbook 2000 guidelines for carcinogenicity or chronic toxicity studies, and that the study reported no adverse effects up to a nominal concentration of 5 percent gardenia (genipin) blue in feed for rats under the conditions of this study. Additionally, we identified no deficiencies that would invalidate the study results for its intended purpose, and no results from this study suggest that gardenia (genipin) blue is a reproductive or developmental toxicant (Ref. 3). From this chronic study, the petitioner determined a no-adverse-effect-level (NOAEL) of 2854.5 and 3465.4 mg/kg bw/d in the parental generation (males and females, respectively), and 3113.5 and 4049.6 mg/kg bw/d in their offspring (males and females, respectively).

FDA searched the publicly available literature to identify any new studies since the submission of the petition that might have examined toxicological effects of gardenia (genipin) blue, or genipin or related compounds. We

found four new relevant publications, two of which reported data that were part of the original submission: (1) the previously reviewed 12-month *in utero* exposure study in rats; (2) the previously reviewed absorption, distribution, metabolism and excretion studies of [^{14}C]Gardenia Blue in rats and mice; (3) an extended one-generation reproductive toxicity study in rats; and (4) a combined 12-month chronic oral toxicity and 24-month carcinogenicity study in rats, which uses the same dosage scheme as the 12-month chronic oral tocicity study with an *in utero* exposure phase that was provided with the petition. The petitioner provided the full study report for the combined 12-month chronic oral toxicity and 24-month carcinogenicity study in rats. We determined that the chronic 24-month carcinogencity study was the most appropriate study for deriving an ADI (Ref. 3). This study establishes a NOAEL of 2175.3 mg/kg bw/day from the highest dose tested. After applying a 100-fold safety factor, we determined the ADI of gardenia (genipin) blue to be 21.75 mg/kg bw/d (Ref. 3).

Based on our review of the safety data provided by the petitioner, including published and unpublished toxicology studies, and our review of the publicly available literature, which do not present evidence of safety concerns for gardenia (genipin) blue or residual impurities at the expected dietary exposures, and given that the estimated 90th percentile exposure for the color additive (1.27 mg/kg bw/d) does not exceed the ADI, we conclude that gardenia (genipin) blue is safe for the petitioned uses.

C. Allergen Labeling

Gardenia (genipin) blue is produced using soy protein hydrolysate. Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) requires that the label of a food that is or contains an ingredient that contains a major food allergen declare the allergen's presence. The FD&C Act defines a ''major food allergen'' as one of nine foods or food groups (*i.e.,* milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame) or a food ingredient that contains protein derived from one of those foods (21 U.S.C. 321(qq)). Because soy protein hydrolysate is used in the manufacturing of gardenia (genipin) blue, this color additive requires allergen labeling under the FD&C Act, unless an exemption from the food allergen labeling requirements is obtained through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act (21 U.S.C. 343(w)(6))). On September 29, 2022, GBIG submitted a petition to FDA seeking a food allergen labeling exemption from the requirements of section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) for gardenia (genipin) blue. The petition is currently under review.

VI. Conclusion

Based on the data and other information in the petition and other available relevant information, we conclude that the petitioned use of gardenia (genipin) blue as a color additive at levels consistent with GMP in (1) sport drinks; (2) flavored or enhanced non-carbonated water; (3) fruit drinks and ades; (4) ready-to-drink teas; (5) hard candy; and (6) soft candy is safe.

We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use (Ref. 1). Therefore, we are amending the color additive regulations in part 73 to provide for the safe use of this color additive. In addition, based on the factors in our regulations, at 21 CFR 71.20(b), we conclude that batch certification of gardenia (genipin) blue is not necessary to protect the public health (Ref. 1).

VII. 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.

VIII. Analysis of Environmental Impact

As stated in the June 30, 2021 **Federal Register** document for CAP 1C0319 (86 FR 34664), the petitioner claimed that this action is categorically excluded under § 25.32(k) (21 CFR 25.32(k)) because the substance 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 § 25.32(k) (Ref. 4). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. 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.

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

Our review of this petition was limited to section 721 of the FD&C Act (21 U.S.C. 379e). This order is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(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 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.

XI. 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**.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Memorandum from N. Belai, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors, Office of the Chief Scientist, FDA to S. DiFranco, Division of Food Ingredients (DFI), Office of Premarket Additive Safety (OPMAS), HFP, FDA, July 1, 2025.
2. Memorandum from H. Lee, Chemistry Evaluation Branch, DFI, OPMAS, HFP, FDA to S. DiFranco, DFI, OPMAS, HFP, FDA, July 1, 2025.
3. Memorandum from J. Gingrich, Toxicology Review Branch, DFI, OPMAS, HFP, FDA to S. DiFranco, DFI, OPMAS, HFP, FDA, July 1, 2025.
4. Memorandum from M. Pfeil, Lead Biologist, Environmental Review Team, OPMAS, HFP, FDA to S. DiFranco, DFI, OPMAS, HFP, FDA, July 1, 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 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 § 73.168 to subpart A to read as follows:

§ 73.168 Gardenia (genipin) blue.

(a) *Identity.* (1) The color additive gardenia (genipin) blue is prepared by reacting genipin extracted from the fruit of *Gardenia jasminoides* Ellis with soy protein hydrolysate. The color additive contains a genipin-peptide polymer as the principal coloring component.

(2) Color additive mixtures for food use made with gardenia (genipin) blue 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.* Gardenia (genipin) blue 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) Genipin, not more than 5 milligram per kilogram (mg/kg) (5 part per million (ppm)).

(2) Geniposide, not more than 80 mg/kg (80 ppm).

(3) Methanol, not more than 6 mg/kg (6 ppm).

(4) Lead, not more than 2 mg/kg (2 ppm).

(5) Arsenic, not more than 2 mg/kg (2 ppm).

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

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

(c) *Uses and restrictions.* Gardenia (genipin) blue may be safely used in amounts consistent with good manufacturing practice for coloring sport drinks, flavored or enhanced noncarbonated water, fruit drinks and ades, ready-to-drink teas, hard candy, and soft candy, 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. The label of the powdered form of the additive must also declare any additional ingredients used in its manufacture.

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

Dated: July 9, 2025.

Martin A. Makary,

Commissioner of Food and Drugs.

[FR Doc. 2025–13175 Filed 7–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1300

RIN 2127–AM81

Technical Amendment to the Uniform Procedures for State Highway Safety Grant Programs

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule makes technical amendments to the Uniform Procedures for State Highway Safety Grant Programs to remove references to rescinded Executive Orders.

DATES: This final rule is effective on July 15, 2025.

ADDRESSES: This document may be viewed online through the Federal eRulemaking portal at *www.regulations.gov* using the RIN number listed above. Electronic retrieval help and guidelines are available on the website. An electronic copy of this document may be downloaded by accessing the Office of the Federal Register's website at: *www.federalregister.gov* and the U.S. Government Publishing Office's website at: *www.GovInfo.gov.*

FOR FURTHER INFORMATION CONTACT:

Program issues: Barbara Sauers, Associate Administrator, Regional Operations and Program Delivery, National Highway Traffic Safety Administration; Email: *barbara.sauers@dot.gov;* Phone: (202) 366–1810.

Legal issues: Megan Brown, Attorney-Advisor, Office of the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; Email: *megan.brown@dot.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents