WORLD TRADE ORGANIZATION

G/SPS/N/USA/3257/Add.1

16 July 2025

(25-4560)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 16 July 2025, is being circulated at the request of the Delegation of the United States of America.

Listing of Color Additives Exempt From Certification; Gardenia (Genipin) Blue; Final Amendment; Order

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).

This order is effective 29 August 2025.

https://www.federalregister.gov/d/2025-13175
https://members.wto.org/crnattachments/2025/SPS/USA/25_04631_00_e.pdf

This addendum concerns a:

[ ] Modification of final date for comments
[**X**] Notification of adoption, publication or entry into force of regulation
[ ] Modification of content and/or scope of previously notified draft regulation
[ ] Withdrawal of proposed regulation
[ ] Change in proposed date of adoption, publication or date of entry into force
[ ] Other:

Comment period: ***(If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)***

[ ] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: Submit either electronic or written objections and requests for a hearing on the order by 14 August 2025.

Agency or authority designated to handle comments: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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 14 August 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.

Text(s) available from: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Text can be found in the Federal Register, Vol. 90, No. 133, page 31586 or on the Internet at: https://www.federalregister.gov/d/2025-13175