



3 December 2025

(25-8103)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 3 December 2025, is being circulated at the request of the Delegation of the United States of America.

Listing of Colour Additives Exempt from Certification; Gardenia (Genipin) Blue; Confirmation of Effective Date

The Food and Drug Administration (FDA or we) is confirming the effective date of 29 August 2025 for the order that appeared in the Federal Register of 15 July 2025. The order amends the colour additive regulations to provide for the safe use of gardenia (genipin) blue as a colour additive, at levels consistent with good manufacturing practice (GMP), in sport drinks, flavoured or enhanced non-carbonated water, fruit drinks and ades, ready-to-drink teas, hard candy, and soft candy.

<https://www.federalregister.gov/d/2025-19166>

https://members.wto.org/crnattachments/2025/SPS/USA/25_08466_00_e.pdf

This addendum concerns a:

- ☐ Modification of final date for comments
- ☒ 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): Not applicable

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

For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final order into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Text(s) available from: ☐ 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. 188, page 47229 or on the Internet at:
<https://www.federalregister.gov/d/2025-19166>
