NOTIFICATION

Addendum

The following communication, received on 6 January 2020, is being circulated at the request of the Delegation of the United States of America.

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| Final Rule; Response to Objections and Denial of Public Hearing Requests; Removal of Administrative Stay |
| The Food and Drug Administration (FDA or we) is responding to objections that it received from the Center for Food Safety on the final rule entitled "Listing of Color Additives Exempt from Certification; Soy Leghemoglobin", published on 1 August 2019. The final rule amended the color additive regulations to provide for the safe use of soy leghemoglobin as a color additive in ground beef analogue products. After reviewing the objections, FDA has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking the amendment to the regulations. We are also providing notice that the administrative stay of the effective date for this color additive regulation is now lifted.  The final rule published in the Federal Register of 1 August 2019 (84 FR 37573) with an effective date of 4 September 2019, was administratively stayed by the filing of objections under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(e)(2)) as of 3 September 2019. FDA lifts the administrative stay as of 19 December 2019.  <https://members.wto.org/crnattachments/2020/SPS/USA/20_0023_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)*: 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:** |
| Ellen Anderson, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, Tel: +(1 240) 402 1309 |
| **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. 84, No. 244, page 69620 or on the internet at: <https://www.govinfo.gov/content/pkg/FR-2019-12-19/pdf/2019-27173.pdf> |

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