NOTIFICATION

Addendum

The following communication, received on 2 November 2018, is being circulated at the request of the Delegation of the United States of America.

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| Listing of Color Additives Exempt From Certification; Synthetic Iron Oxide; Notice of Final Rule |
| The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the expanded safe use of synthetic iron oxides as color additives to include use in dietary supplement tablets and capsules. This action is in response to a color additive petition (CAP) filed by Colorcon, Inc.  This rule is effective 4 December 2018.  Text is available at: <https://www.gpo.gov/fdsys/pkg/FR-2018-11-01/pdf/2018-23863.pdf>  <https://members.wto.org/crnattachments/2018/SPS/USA/18_5737_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 final rule by 3 December 2018. |
| **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:** |
| Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, Tel. +1-240- 402-1075For instructions for submiting either electronic or written objections and requests for a hearing, visit [https://www.regulations.gov.](https://www.regulations.gov/) |
| **Text(s) available from: [ ]****National Notification Authority, [ ]** **National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** |
| Text can also be found in the Federal Register, Vol. 83, No. 212, page 54869 or on the internet at: <https://www.gpo.gov/fdsys/pkg/FR-2018-11-01/pdf/2018-23863.pdf>. |

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