NOTIFICATION

Addendum

The following communication, received on 14 September 2018, is being circulated at the request of the Delegation of the United States of America.

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| Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Partial withdrawal, Final Rule |
| The Food and Drug Administration (FDA) is removing instruction 13 from the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food) regulation. Instruction 13 directs the Federal Register to remove and reserve as of 17 September 2018, the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Human Food CGMP) regulation. Removal of instruction 13 is necessary because the compliance dates for certain facilities subject to the modernized current good manufacturing practice requirements in the Preventive Controls for Human Food regulation have been extended. Retaining the Human Food CGMP regulation will maintain the status quo while these facilities prepare for compliance with the new CGMP requirements and will avoid an unintended gap in public health protection.  <https://members.wto.org/crnattachments/2018/SPS/USA/18_4868_00_e.pdf> |
| **This addendum concerns a:** |
| [ ] Modification of final date for comments |
| [ ] Notification of adoption, publication or entry into force of regulation |
| [**X**] 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)*: 12 October 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:** |
| For further information contact: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS‑300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, +(1 240) 402 2166 |
| **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. 83, No. 177, page 46104 or on the internet at: <https://www.gpo.gov/fdsys/pkg/FR-2018-09-12/pdf/2018-19855.pdf>. |

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