



17 December 2018

(18-7973)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>UNITED STATES OF AMERICA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Food and Drug Administration (FDA), Health and Human Services (HHS) [1459] Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Please submit comments to: USA WTO TBT Enquiry Point Email: usatbtep@nist.gov
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Biological product; Vocabularies (ICS 01.040), Pharmaceuticals (ICS 11.120), Microbiology (ICS 07.100).
5. Title, number of pages and language(s) of the notified document: Definition of the Term "Biological Product" (8 page(s), in English)
6. Description of content: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulation that defines "biological product" to incorporate changes made by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and to provide its interpretation of the statutory terms "protein" and "chemically synthesized polypeptide." Under that interpretation, the term protein would mean any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. A chemically synthesized polypeptide would mean any alpha amino acid polymer that is made entirely by chemical synthesis and is greater than 40 amino acids but less than 100 amino acids in size. This proposed rule is intended to clarify the statutory framework under which such products are regulated.
7. Objective and rationale, including the nature of urgent problems where applicable: Cost saving and productivity enhancement
8. Relevant documents: <ul style="list-style-type: none">83 Federal Register (FR) 63817, 12 December 2018; Title 21 Code of Federal Regulations (CFR) Part 600. Will appear in the Federal Register when adopted.
9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined

10. Final date for comments: 25 February 2019

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

https://members.wto.org/crnattachments/2018/TBT/USA/18_6456_00_e.pdf