



27 September 2019

(19-6255)

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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) [1558] 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): Drug substances; Pharmaceuticals (ICS 11.120)
5.	Title, number of pages and language(s) of the notified document: Amendments to the List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act (16 page(s), in English)
6.	Description of content: Proposed rule - The Food and Drug Administration (FDA or Agency) has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs. This proposed rule would amend that list by placing five additional bulk drug substances on the list. This proposed rule also identifies 26 bulk drug substances that FDA has considered and proposes not to include on the list. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.
7.	Objective and rationale, including the nature of urgent problems where applicable: Prevention of deceptive practices and consumer protection; Protection of human health or safety
8.	Relevant documents: <ul style="list-style-type: none">84 Federal Register (FR) 46688, 5 September 2019; Title 21 Code of Federal Regulations (CFR) Part 1 and 216: https://www.govinfo.gov/content/pkg/FR-2019-09-05/html/2019-18951.htm https://www.govinfo.gov/content/pkg/FR-2019-09-05/pdf/2019-18951.pdf

	<ul style="list-style-type: none"> • List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act, Final Rule published 19 February 2019: https://www.govinfo.gov/content/pkg/FR-2019-02-19/html/2019-02367.htm https://www.govinfo.gov/content/pkg/FR-2019-02-19/pdf/2019-02367.pdf • List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act, Proposed Rule published 16 December 2016: https://www.govinfo.gov/content/pkg/FR-2016-12-16/html/2016-30109.htm https://www.govinfo.gov/content/pkg/FR-2016-12-16/pdf/2016-30109.pdf • G/TBT/N/USA/214/Add.3 and G/TBT/N/USA/214/Add.3/Corr.1
9.	<p>Proposed date of adoption: To be determined</p> <p>Proposed date of entry into force: To be determined</p>
10.	<p>Final date for comments: 4 December 2019</p>
11.	<p>Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>https://members.wto.org/crnattachments/2019/TBT/USA/19_5302_00_e.pdf</p>