



4 March 2019

(19-1236)

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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

<b>1. Notifying Member:</b> <u>UNITED STATES OF AMERICA</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Food and Drug Administration (FDA), Health and Human Services (HHS) [1468] <b>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:</b> Please submit comments to: USA WTO TBT Enquiry Point Email: <a href="mailto:usatbtep@nist.gov">usatbtep@nist.gov</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Sunscreen drug products; Domestic safety (ICS 13.120), Products of the chemical industry (ICS 71.100).
<b>5. Title, number of pages and language(s) of the notified document:</b> Sunscreen Drug Products for Over-the-Counter Human Use (72 page(s), in English)
<b>6. Description of content:</b> The Food and Drug Administration (FDA or Agency) is issuing this proposed rule to put into effect a final monograph for nonprescription, over-the-counter (OTC) sunscreen drug products. This proposed rule describes the conditions under which FDA proposes that OTC sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded. It is being published as part of the ongoing review of OTC drug products conducted by FDA. It is also being published to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Sunscreen Innovation Act (SIA).
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety
<b>8. Relevant documents:</b> <ul style="list-style-type: none"><li>• 84 Federal Register (FR) 6204, 26 February 2019; Title 21 Code of Federal Regulations (CFR) Parts 201, 310, 347 and 352. Will appear in the Federal Register when adopted.</li><li>• <a href="#">G/TBT/N/USA/241</a> - Insect Repellent-Sunscreen Drug Products for Over-the-Counter Human Use</li><li>• <a href="#">G/TBT/N/USA/293 and subsequent notifications</a> - Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph</li></ul>

<b>9.</b>	<b>Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> To be determined
<b>10.</b>	<b>Final date for comments:</b> 28 May 2019
<b>11.</b>	<b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b> <a href="https://members.wto.org/crnattachments/2019/TBT/USA/19_1201_00_e.pdf">https://members.wto.org/crnattachments/2019/TBT/USA/19_1201_00_e.pdf</a>