



5 August 2025

(25-5002)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>UNITED STATES OF AMERICA</u> If applicable, name of local government involved:
2. Agency responsible: Food and Drug Administration (FDA)
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Food preparations, n.e.s. (HS code(s): 2106); Waters, incl. mineral waters and aerated waters, containing added sugar or other sweetening matter or flavoured, and other non-alcoholic beverages (excl. fruit, nut or vegetable juices and milk) (HS code(s): 2202); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those for transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS code(s): 3004); Food technology (ICS code(s): 67)
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Spoonbill Foundation; Filing of Food Additive Petition; Notification of Petition. Language(s): English. Number of pages: 1 https://www.federalregister.gov/d/2025-14339 https://members.wto.org/crnattachments/2025/SPS/USA/25_05176_00_e.pdf
6. Description of content: The Food and Drug Administration (FDA or we) is announcing that we have filed a food additive petition, submitted by the Spoonbill Foundation, proposing that we amend our food additive regulations to provide for the safe use of 4'-phosphopantetheine (4'-PPT) as a nutrient in medical food. The food additive petition was filed on 3 July 2025.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety , <input type="checkbox"/> animal health , <input type="checkbox"/> plant protection , <input type="checkbox"/> protect humans from animal/plant pest or disease , <input type="checkbox"/> protect territory from other damage from pests.

<p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (dd/mm/yy): No proposed dates of adoption.</p> <p>Proposed date of publication (dd/mm/yy): No proposed dates of publication.</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): No proposed dates of entry into force.</p> <p><input checked="" type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): No final dates for comments.</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.</p>
<p>13. Text(s) available from: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Text can be found in the Federal Register, Vol. 90, No. 143, Page 35645 or on the Internet at: https://www.federalregister.gov/d/2025-14339</p>