4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2025-F-2137]

Spoonbill Foundation; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: 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.

DATES: The food additive petition was filed on July 3, 2025.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Marissa Santos, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-8160.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 5A4842), submitted on behalf of Spoonbill Foundation by Immix Law Group, 500 NW Naito Pkwy, Unit G, Portland, OR 97209. The petition proposes that we amend our food additive regulations in part 172 (21 CFR 172), "Food Additives Permitted For Direct Addition to Food For Human Consumption," to provide for the safe use of 4'-PPT as a nutrient in medical food.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because granting of this petition would become effective "for substances added directly to food that are intended to remain in food through ingestion by consumers and are not intended to replace macronutrients in food." In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: July 25, 2025.

Grace R. Graham

Deputy Commissioner for Policy, Legislation, and International Affairs.

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