



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2025-C-0380]

Impossible Foods, Inc.; Filing of Color 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 petition, submitted by Impossible Foods, Inc., proposing that the color additive regulations be amended to expand the safe use of soy leghemoglobin as a color additive to include use in plant-based meat, poultry, and fish analogue products (ground and whole cut).

DATES: The color additive petition was filed on March 7, 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.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1309.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 5C0336), submitted on behalf of Impossible Foods, Inc. by Exponent, 1150 Connecticut Ave. NW, Suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in 21 CFR 73.520, “Soy leghemoglobin,” to expand the safe use of soy leghemoglobin to include use in plant-based meat, poultry, and fish analogue products (ground and whole cut).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist (see 21 CFR 25.21). 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: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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