4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2018-C-4464]

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 provide for the safe use of soy leghemoglobin as a color additive in plant-based, non-animal derived ground beef analogue products.

DATES: The color additive petition was filed on November 5, 2018.

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, Center for Food Safety and Applied Nutrition, 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 9C0314), submitted by Impossible Foods, Inc., c/o Exponent, Inc., 1150

Connecticut Avenue NW, Suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in part 73 (21 CFR part 73), "Listing of Color Additives Exempt From Certification," to provide for the safe use of soy leghemoglobin as a color additive in plant-based, non-animal derived ground beef analogue products.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because soy leghemoglobin would be added directly to food and 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. 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: December 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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