



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2020-C-2131]

Ecoflora SAS; 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 Ecoflora SAS, proposing that the color additive regulations be amended to provide for the safe use of jagua (genipin-glycine) blue in various food categories at levels consistent with good manufacturing practice.

DATES: The color additive petition was filed on July 31, 2020.

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: Richard E. Bonnette, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1235.

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 0C0317), submitted by Ecoflora, SAS, c/o Exponent, Inc., 1150 Connecticut Ave. 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 jagua (genipin-glycine) blue derived from jagua fruit pulp (*Genipa*

*americana*) as a color additive in: (1) flavored milk; (2) dairy drinks and substitutes (milk shakes, milk substitutes, and other dairy drinks); (3) yogurt (dairy and non-dairy); (4) desserts (ice cream and frozen dairy and non-dairy desserts; pudding; gelatins, ices, and sorbets); (5) ready-to-eat cereals; (6) savory snacks (flavored potato chips; tortilla, corn, other chips); (7) candy and chewing gum; (8) non-alcoholic beverages (fruit drinks; nutritional beverages; smoothies); (9) flavored cream cheese-based spread; and (10) jams, syrups, icings, frostings, and fruit toppings and fillings, at levels consistent with good manufacturing practice.

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. 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: November 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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