



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2018-C-4117]

Sensient Colors, LLC; 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 Sensient Colors, LLC, proposing that the color additive regulations be amended to provide for the safe use of an aqueous extract of butterfly pea flower (*Clitoria ternatea*) as a color additive in various food categories, at levels consistent with good manufacturing practice.

DATES: The color additive petition was filed on October 4, 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: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710.

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 8C0313) submitted by Exponent, Inc. on behalf of Sensient Colors, LLC, 1150 Connecticut Ave. N.W., Suite 1100, Washington, D.C., 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 an aqueous extract of butterfly pea flower (*Clitoria ternatea*) as a color additive in: (1) alcoholic beverages (liquor, liqueurs, and flavored alcoholic beverages); (2) ready-to-drink non-alcoholic beverages; (3) liquid coffee creamers (dairy and non-dairy); (4) ice cream and frozen dairy desserts; (5) fruit preparation in yogurt; (6) chewing gum; (7) coated nuts; (8) hard candy; and (9) soft candy, 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 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-24662 Filed: 11/9/2018 8:45 am; Publication Date: 11/13/2018]