information will not be provided to the FAA. Individuals are concerned that public release of the information could result in potential misuses of the information that could affect them negatively. If the FAA does not receive the information, the FAA and the public will be deprived of the opportunity to make the safety improvements that receipt of the information otherwise enables. Corrective action under T–SAP and ATSAP can be accomplished without disclosure of protected information. For example, for acceptance under each program, the reporting individual must comply with ERC recommendations for corrective action, such as additional training. If the individual fails to complete corrective action in a manner satisfactory to all members of the ERC, the event may be referred to an appropriate office within the FAA for any additional investigation, reexamination, and/or action, as appropriate.

(2) The FAA may release T–SAP and ATSAP information submitted to the agency, as specified in Part 193 and this proposed Order. For example, to explain the need for changes in FAA policies, procedures, and regulations, the FAA may disclose de-identified, summarized information that has been derived from T–SAP and ATSAP reports or extracted from the protected information listed under paragraph 4b. The FAA may disclose de-identified, summarized T–SAP and ATSAP information that identifies a systemic problem in the National Airspace System, when a party needs to be advised of the problem in order to take corrective action. Under the current version of FAA Order JO 7200.20, reported events and possible violations may be subject to investigation, reexamination, and/or action. Although the report itself and the content of the report are not used as evidence, the FAA may use the knowledge of the event or possible violation to generate an investigation, and, in that regard, the information is not protected from disclosure. To withhold information from such limited release would be inconsistent with the FAA’s safety responsibilities. In addition, reports that appear to involve possible criminal activity, substance abuse, controlled substances, alcohol, or intentional falsification will be referred to an appropriate FAA office for further handling. The FAA may use such reports for enforcement purposes, and will refer such reports to law enforcement agencies, if appropriate. To withhold information in these circumstances would be inconsistent with the agency’s safety responsibilities because it could prevent, or at least diminish, the FAA’s ability to effectively address egregious misconduct.

f. Summary of how the FAA will distinguish information protected under part 193 from information the FAA receives from other sources.

(1) All T–SAP and ATSAP reports are clearly labeled as such. Each individual must submit their own report.

5. Designation

The FAA designates the information described in paragraph 4b to be protected from disclosure in accordance with 49 U.S.C. 40123 and 14 CFR part 193.

Issued in Washington, DC, on July 10, 2013.

Michael P. Huerta,
Administrator, Federal Aviation Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–1998–C–0381] (Formerly Docket No. 98C–0676)

Sensient Technologies Corporation;
Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 8C0261) proposing that the color additive regulations be amended to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, the petitioner has submitted a citizen petition, under FDA regulations, requesting that we amend the generally recognized as safe (GRAS) regulations to prohibit the use of Chondrus extract (carrageeinn) in infant formula.


SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that Richard C. Theuer, Ph.D., 7904 Sutterton Ct., Raleigh, NC 27615, has filed a food additive petition (FAP 3A4798; Docket No. FDA–2013–F–0700). The petition proposes to amend the color additive regulations in 21 CFR part 74 Listing of Color Additives Subject to Certification to provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products. Sensient Technologies Corporation has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: July 16, 2013.

Dennis M. Keefe,
Director, Office of Food Additive Safety.
Center for Food Safety and Applied Nutrition.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Parts 172 and 182


Richard C. Theuer; Filing of Food Additive Petition and Citizen Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that Richard C. Theuer, Ph.D., has filed a petition proposing that the food additive regulations be amended to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, the petitioner has submitted a citizen petition, under FDA regulations, requesting that we amend the generally recognized as safe (GRAS) regulations to prohibit the use of Chondrus extract (carrageeinn) in infant formula.


SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 24, 1998 (63 FR 45073), FDA announced that a color additive petition (CAP 8C0261) had been filed by Warner-Jenkinson Co., Inc. (now part of Sensient Technologies Corporation, a unit of Sensient Technologies Corporation), 107 Wade Ave., South Plainfield, NJ 07080. The petition proposed to amend

the color additive regulations in 21 CFR part 74 Listing of Color Additives Subject to Certification to provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products. Sensient Technologies Corporation has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: July 16, 2013.

Dennis M. Keefe,
Director, Office of Food Additive Safety.
Center for Food Safety and Applied Nutrition.