

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 193

[Docket No.: FAA-2013-0375]

Technical Operations Safety Action Program (T-SAP) and Air Traffic Safety Action Program (ATSAP)

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of Proposed Order Designating Safety Information as Protected from Disclosure.

SUMMARY: The FAA is proposing that safety information provided to it under the T-SAP, established in Notice JO 7210.807 which will be incorporated in FAA Order JO 7200.20, *Voluntary Safety Reporting Programs*, and ATSAP, covered by FAA Order JO 7200.20, be designated by an FAA Order as protected from public disclosure in accordance with the provisions of 14 CFR part 193, *Protection of Voluntarily Submitted Information*. The designation is intended to encourage persons to voluntarily provide information to the FAA under the T-SAP and ATSAP, so the FAA can learn about and address aviation safety hazards of which it was unaware or more fully understand and implement corrective measures for events or safety issues known by it through other means. Under 49 U.S.C. 40123, *Protection of Voluntarily Submitted Information*, the FAA is required to protect information from disclosure to the public, including disclosure under the Freedom of Information Act (5 U.S.C. 552) or other laws, following the issuance of such Order.

DATES: Comments must be received on or before August 19, 2013.

ADDRESSES: You may send comments identified by docket number FAA-2013-0375 using any of the following methods: via mail to U.S. Department of Transportation, Docket Operations,

M-30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington DC 20590-0339; telephone (202) 366-9826. You must identify the FAA Docket No. FAA-2013-0375 at the beginning of your comments. You may also submit comments through this Web site at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Lisbeth Mack—Group Manager, ATO Safety Programs, Federal Aviation Administration, 490 L'Enfant Plaza, Suite 7200, Washington DC 20024 or via email at lisbeth.mack@faa.gov or phone at 202-385-4757.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify docket number FAA 2013-0375 and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2013-0375". The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed Order. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of This Proposed Designation

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rule-making documents can also be accessed through the FAA's Web site at http://www.faa.gov/airports_airtraffic/air_traffic/publications.

1. Background

Under Title 49 of the United States Code (49 U.S.C.), section 40123, certain voluntarily provided safety and security information is protected from disclosure in order to encourage persons to provide the information. The FAA must first issue an Order that specifies why the agency finds that the information should be protected in accordance with 49 U.S.C. 40123. The FAA's rules for implementing that section are in 14 CFR part 193. If the Administrator issues an Order designating information as protected under 49 U.S.C. 40123, that information will not be disclosed under the Freedom of Information Act (Title 5 of the United States Code (5 U.S.C.), section 552) or other laws, except as provided in 49 U.S.C. 40123, 14 CFR part 193, and the Order designating the information as protected. This Order is issued under part 193, section 193.11, which sets out the notice procedure for designating information as protected.

2. Applicability

This proposed designation is applicable to any FAA office that receives information covered under this designation from T-SAP, established in Notice JO 7210.807, and which will be incorporated in FAA Order JO 7200.20, *Voluntary Safety Reporting Programs*, or the ATSAP described in FAA Order JO 7200.20. The proposed designation would also apply to any other government agency that receives such information from the FAA. For any other government agency to receive T-SAP or ATSAP information covered under the proposed designation from the FAA, each such agency must first

stipulate, in writing, that it will abide by the provisions of part 193 and the Order designating T-SAP and ATSAP as protected from public disclosure under 14 CFR part 193.

3. Overview

a. *Qualified Participants.* Technical Operations employees who are covered under the collective bargaining agreement (CBA) between PASS and the FAA effective December 14, 2012, or its successor, and other employees identified in Notice JO 7210.807, which will be incorporated in Order JO 7200.20, are eligible to complete a T-SAP report for events that occur while acting in that capacity. Air Traffic employees who are covered under the CBA between NATCA and the FAA effective October 1, 2009 or its successor, Staff Support Specialists covered under the CBA between NATCA and FAA effective August 1, 2010 or its successor, Flight Services personnel covered under the CBA between NATCA and the FAA effective June 5, 2011, or its successor, employees covered under the CBA between NAGE Local R3-10 and the FAA dated May 24, 2007 or its successor, and others identified in FAA Order JO 7200.20 are eligible to file an ATSAP report for events that occur while acting in that capacity.

b. *Voluntarily-provided Information Protected from Disclosure Under the Proposed Designation.* Except for T-SAP or ATSAP reports that involve possible criminal conduct, substance abuse, controlled substances, alcohol, or intentional falsification, the following information would be protected from disclosure:

(1) The content of any report concerning an aviation safety or security matter that is submitted by a qualified participant under the T-SAP or ATSAP, that is accepted into either program, including the T-SAP or ATSAP report, and the name of the submitter of the report. Notwithstanding the foregoing, mandatory information about occurrences that are required to be reported under FAA Orders, Notices or guidance is not protected under this designation, unless the same information has also been submitted or reported under other procedures prescribed by the Agency. The exclusion is necessary to assure that the information protected under this designation has been voluntarily submitted. It also permits changes to FAA Orders, Notices and guidance without requiring a change to this designation.

(2) Any evidence gathered by the Event Review Committee during its

investigation of a safety- or security-related event reported under T-SAP or ATSAP, including the T-SAP or ATSAP investigative file.

c. *Ways to Participate.* Individuals who are qualified participants register for, and submit a report into, the electronic reporting system.

d. *Duration of Voluntary Safety Reporting Programs.* These programs continue as long as provided for by Order, Notice, policy or a collective bargaining agreement.

4. Findings

The FAA designates information received from a T-SAP or ATSAP submission as protected under 49 U.S.C. 40123 and 14 CFR 193.7, based on the following findings:

a. *Summary of why the FAA finds that the information will be provided voluntarily.* The FAA finds that the information will be provided voluntarily. This finding is supported by the significant increase in reports of safety-related matters since the implementation of T-SAP and ATSAP. No covered individual is required to participate in the T-SAP, ATSAP, or other voluntary safety reporting program.

b. *Description of the type of information that may be voluntarily provided under the program and a summary of why the FAA finds that the information is safety-related.*

(1) The following types of reports are ordinarily submitted under the T-SAP or ATSAP:

i. *Noncompliance reports.* Noncompliance reports identify specific instances of a failure to follow FAA directives.

ii. *Aviation safety concern reports.* Aviation safety concerns that do not involve specific noncompliance with FAA directives. These may include, but are not limited to, potential safety events or perceived problems with policies, procedures, and equipment.

(2) Technical Operations personnel support the delivery and efficiency of flight services through maintenance of the National Airspace System facilities, systems and equipment. Reports submitted by these employees under T-SAP ordinarily involve matters or observations occurring during the performance of their job responsibilities, and therefore the information submitted is inherently safety related. Air Traffic personnel provide and support the provision of air traffic services at FAA facilities throughout the NAS. Reports submitted by these employees under ATSAP ordinarily involve occurrences or problems identified or experienced during the performance of their job

responsibilities which directly affect safety.

c. *Summary of why the FAA finds that the disclosure of the information would inhibit persons from voluntarily providing that type of information.* The FAA finds that disclosure of the information would inhibit the voluntary provision of that type of information. Individuals are unwilling to voluntarily provide detailed information about safety events and concerns, including those that might involve their own failures to follow Agency directives and policies, if such information could be released publicly. If information is publicly disclosed, there is a strong likelihood that the information could be misused for purposes other than to address and resolve the reported safety concern. Unless the FAA can provide assurance that safety-related reports will be withheld from public disclosure, personnel will not participate in the programs.

d. *Summary of why the receipt of that type of information aids in fulfilling the FAA's safety responsibilities.* The FAA finds that receipt of information in T-SAP or ATSAP reports aids in fulfilling the FAA's safety responsibilities. Because of its capacity to provide early identification of needed safety improvements, this information offers significant potential for addressing hazards that could lead to incidents or accidents. In particular, one of the benefits of T-SAP and ATSAP is that they encourage the submission of narrative descriptions of occurrences that provide more detailed information than is otherwise available. The T-SAP and ATSAP produce safety-related data that is not available from any other source. Receipt of this previously unavailable information has provided the FAA with an improved basis for modifying procedures, policies, and regulations to improve safety and efficiency.

e. *Consistencies and inconsistencies with FAA safety responsibilities.* The FAA finds that withholding T-SAP and ATSAP information from public release is consistent with the FAA's safety responsibilities, because it encourages individuals to provide important safety information that it otherwise might not receive.

(1) Withholding T-SAP and ATSAP information from disclosure, as described in this designation, is consistent with the FAA's safety responsibilities. Without the Agency's ability to assure that the detailed information reported under these programs, which often explains why the event occurred or describes underlying problems, will not be disclosed, the

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.

[FR Doc. 2013-17401 Filed 7-18-13; 8:45 am]

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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 provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products.

FOR FURTHER INFORMATION CONTACT:

Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1309.

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 Cosmetic Technologies, 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.

[FR Doc. 2013-17382 Filed 7-18-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172 and 182

[Docket Nos. FDA-2013-F-0700 and FDA-2013-P-0472]

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 (carrageenin) in infant formula.

FOR FURTHER INFORMATION CONTACT:

Molly A. Harry, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1075.

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 food additive regulations in 21 CFR 172.620 and 172.626 to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, Dr. Theuer has submitted a citizen petition, under 21 CFR 10.30, requesting that 21