

Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. DHS is claiming exemptions from certain requirements of the Privacy Act for DHS/CBP–022 Electronic Visa Update System (EVUS) System of Records. Some information in DHS/CBP–022 Electronic Visa Update System (EVUS) System of Records relates to official DHS national security, law enforcement, immigration, and intelligence activities. These exemptions are needed to protect information relating to DHS activities from disclosure to subjects or others related to these activities. Specifically, the exemptions are required to preclude subjects of these activities from frustrating these processes. Disclosure of information to the subject of the inquiry could also permit the subject to avoid detection or apprehension.

In appropriate circumstances, when compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case by case basis.

A notice of system of records for DHS/CBP–022 Electronic Visa Update System (EVUS) System of Records is also published in this issue of the **Federal Register**.

List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS proposes to amend chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

- 1. The authority citation for part 5 continues to read as follows:

Authority: Pub. L. 107–296, 116 Stat. 2135; (6 U.S.C. 101 *et seq.*); 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

- 2. In appendix C, add paragraph 74 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

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74. The DHS/CBP–022 Electronic Visa Update System (EVUS) System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/CBP–022 Electronic Visa Update System (EVUS) System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and

proceedings there under; and national security and intelligence activities. The DHS/CBP–022 Electronic Visa Update System (EVUS) System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other Federal, State, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (e)(8), and (g). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2) has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(c) From subsection (g) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Dated: August 29, 2016.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC–2016–0019]

Petition To Amend Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride; Request for Comments

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of petition.

SUMMARY: The United States Consumer Product Safety Commission (CPSC or Commission) received a petition requesting that the Commission amend the agency's 1987 Statement of Interpretation and Enforcement Policy regarding labeling of household products containing methylene chloride (Policy Statement). The petition asks the Commission to expand the Policy Statement to address acute hazards from inhalation of methylene chloride vapors in addition to the chronic hazards addressed by the current Policy Statement. The Commission invites written comments concerning the petition.

DATES: The Office of the Secretary must receive comments on the petition by October 31, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2016–0019, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC–2016–0019, into the “Search” box, and follow the prompts. A copy of the petition is available at <http://www.regulations.gov> under Docket No. CPSC–2016–0019, Supporting and Related Materials.

FOR FURTHER INFORMATION CONTACT:

Todd Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-6833.

SUPPLEMENTARY INFORMATION:

The Commission received a petition from the Halogenated Solvents Industry Alliance, Inc. (Petitioner) requesting that the Commission amend the agency's Statement of Interpretation and Enforcement Policy regarding labeling of household products containing methylene chloride (Policy Statement). The Policy Statement provides the Commission's guidance for labeling of household products containing methylene chloride, focusing particularly on paint strippers. 52 FR 34698 (Sep. 14, 1987). The Policy Statement sets forth general principles and examples for labeling to warn consumers of potential cancer hazards; it does not address acute hazards.

The Petitioner asks the Commission to expand the Policy Statement to address acute hazards from inhalation of methylene chloride vapors. Petitioner notes that the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) issued a Hazard Alert identifying at least 14 deaths associated with use of methylene chloride-containing paint strippers by professional bathtub refinishing operations (https://www.osha.gov/dts/hazardalerts/methylene_chloride_hazard_alert.html). Although the Petitioner refers to incidents involving workers, as the Commission's Policy Statement indicates, methylene chloride paint strippers are household products available for consumers to purchase and use. Petitioner asserts that revising the Policy Statement to give specific guidance on labeling for the acute hazard posed by inhalation of methylene chloride vapors, particularly when used in an enclosed space, such as when refinishing bathtubs, would help to prevent future fatalities.

By this notice, the Commission seeks comments concerning this petition. Interested parties may obtain a copy of the petition from the Commission's Web site: <http://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking/Petitions/> or by writing or calling the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923. A copy of the petition is also available for viewing under "Supporting and Related Materials" in: www.regulations.gov, under Docket No. CPSC-2016-0019.

Dated: August 2, 2016.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2016-N-1149]

Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a 2-day public hearing to obtain input on issues related to communications by manufacturers, packers, and distributors, including their representatives (collectively "firms"), regarding FDA-regulated drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively, "medical products"). FDA is engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved/cleared medical products, and the input from this meeting will inform FDA's policy development in this area. FDA is seeking input on a number of specific questions, but is interested in any other pertinent information participants would like to share.

DATES: The public hearing will be held on November 9 and 10, 2016, from 9 a.m. to 5 p.m. The meeting may be extended or end early depending on the level of public participation. Persons seeking to attend or present at the public hearing must register by October 19, 2016. Electronic or written comments will be accepted after the public hearing until January 9, 2017.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine

security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1149 for "Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at