

Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

*For the Center for Drug Evaluation and Research:* Robert E. Osterberg, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2120, or

*For the Center for Biologics Evaluation and Research:* Mercedes A. Serabian, Center for Biologics Evaluation and Research (HFM-760), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6536.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients." This guidance addresses the safety testing of potential excipients to be used in pharmaceutical products. Not all excipients are inert substances; some have been shown to be potential toxicants. The Federal Food, Drug, and Cosmetic Act of 1938 (the act) was enacted after the tragedy of the elixir of sulfanilamide in 1937 in which an untested excipient was responsible for the death of many children who consumed the pharmaceutical. The act required manufacturers to perform safety testing of pharmaceuticals and submit new drug applications (NDAs) demonstrating safety before marketing. Since that time, the agency has become aware that certain other excipients used in commerce can cause serious toxicities in consumers of prescription and over-the-counter (OTC) drug

products in the United States and other countries.

Some of the information used in developing this guidance was obtained during meetings involving the International Pharmaceutical Excipients Council, the United States Pharmacopeia, and the International Conference on Harmonisation. On October 2, 2002 (67 FR 61910), FDA announced the availability of a draft version of this guidance entitled "Nonclinical Studies for Development of Pharmaceutical Excipients." A number of comments were received, and the agency considered them carefully as it finalized the guidance.

This guidance describes the types of toxicity data that the agency uses in determining whether a potential new excipient is safe for use in human pharmaceuticals. It discusses recommended safety evaluations for excipients proposed for use in OTC and generic drug products, and describes testing strategies for pharmaceuticals proposed for short-term, intermediate, and long-term use. It also describes recommended excipient toxicity testing for pulmonary, injectable, and topical pharmaceuticals.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on nonclinical studies for the safety evaluation of pharmaceutical excipients. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 12, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[USCG-2005-21187]

**Identity Security and Modernization of the Merchant Mariner Credential Statutes**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of public meeting and request for comments.

**SUMMARY:** The Coast Guard believes that identity verification is a critical element of port security, recognizing that we must know and trust those who are provided unescorted access to our port facilities and vessels. The Coast Guard will hold a public meeting to accept comments concerning the President's proposal to implement the recommendations of the 9/11 Commission Report in the area of Merchant Mariner Credentials and to modernize these statutes (hereinafter referred to as "the proposal"). The proposal may be viewed in the docket for this notice. The Coast Guard also seeks written comments on the proposal.

**DATES:** The public meeting will be held on Friday, June 17, 2005, from 9 a.m. to 5 p.m. This meeting may close early if all business is finished. Members of the public who desire to make an oral statement may sign up on the day of the meeting. Written comments and related material must reach the Docket Management Facility on or before June 29, 2005.

**ADDRESSES:** The public meeting will be held in the Gallery Ballroom of the Arlington Hilton Hotel, 950 North Stafford Street, Arlington, VA 22203. Further directions regarding the location of the Arlington Hilton may be obtained by phoning (703) 528-6000.

You may submit written comments identified by Coast Guard docket number USCG-2005-21187 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

- (1) Web Site: <http://dms.dot.gov>.
- (2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590-0001.

(3) Fax: 202-493-2251.

(4) Delivery: Room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(5) Federal e-Rulemaking Portal: <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call or e-mail Mark Gould of the Coast Guard at (202) 267-6890

([mgould@comdt.uscg.mil](mailto:mgould@comdt.uscg.mil)) or Gerald Mianite of the Coast Guard at (202) 267-0221 ([gmianite@comdt.uscg.mil](mailto:gmianite@comdt.uscg.mil)). If you have questions on viewing or submitting materials to the docket, call Andrea M. Jenkins, Program Manager, Dockets Operations, telephone 202-366-0271.

**SUPPLEMENTARY INFORMATION:** We encourage you to submit comments concerning identity security and modernization of the Merchant Mariner Credential Statutes in the five areas identified below under Agenda. All comments received will be posted, without change, to <http://www.dms.dot.gov> and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

**Submitting comments:** If you submit a comment, please include your name and address, identify the docket number for this rulemaking (USCG-2005-21187), indicate the specific provision of the proposal to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments received during the comment period.

**Viewing comments and documents:** To view the proposal, comments, or any other documents mentioned elsewhere in this notice as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in

room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**Privacy Act:** Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

**Agenda of meeting on June 17, 2005:** Under current law, merchant mariners' documents issued by the Coast Guard serve as a form of government issued identification. Yet, some of these credentials contain limited identifying information and are relatively easy to forge. The President's proposal to implement the recommendations of the 9/11 Commission Report in the area of Merchant Mariner Credentials represents an update and rationalization of the Coast Guard's antiquated mariner credentialing and suspension and revocation authorities. It takes into account the findings and recommendations of the 9/11 Commission Regarding the importance of preventing terrorists from obtaining, and using, government identification cards. It is an important component of the Coast Guard's effort to instill a culture of security within a system previously focused almost exclusively on safety efficiency.

This proposal also enhances the Coast Guard's ability to be flexible and agile in establishing appropriate criteria and processes for issuing merchant mariner credentials and in recovering them from unqualified holders or those who present a significant security risk. This public meeting is intended to collect comments from any interested person or organization on the President's proposal (which may be viewed in the docket for this notice).

After a short introduction, the public will be invited to provide oral comments in the following topic areas:

1. **Homeland Security**—The 9/11 Commission found that terrorists used government-issued identification to facilitate their attacks upon the United States. The Commission recommended that the security of such forms of identification be enhanced. Congress responded by enacting laws requiring that security be considered by credentialing agencies, for example, the Maritime Transportation Security Act, Section 102 (46 U.S.C. 70105) and the

Coast Guard and Maritime Transportation Act, Section 407 (46 U.S.C. 7703). This proposal continues to apply those existing authorities in the reorganized new chapters while providing flexibility to respond to developing security threats.

2. **Modernization**—The existing statutes contain numerous outdated, obsolete and confusing provisions, for example, in § 7313 the "coal passer" rating and in § 7306 six separate classifications of "able seaman". The proposal eliminates this antiquated and redundant terminology and improves the Coast Guard's ability to administer the credentialing statutes for the benefit of mariners. As the industry evolves, the proposal will allow us to respond with appropriate training and qualification requirements for mariners in the future.

3. **Organization**—The proposal replaces the current five chapters of Title 46, which randomly intermingle credentialing requirements, with two chapters, one on issuance and one on suspension and revocation of credentials. We believe this will be easier for mariners and other users of the code to understand and apply, as well as easier for the Coast Guard to administer.

4. **Clarification**—With limited exceptions, the proposal does not make substantive changes. It mostly clarifies existing law. At first glance, because of the comprehensive nature of the proposal, the language appears to change much. However, on closer reading, it is clear that the existing authorities are unchanged. For example, at first reading the proposal may appear to eliminate licenses and merchant mariner documents (MMDs) replacing them with "merchant mariner credentials". In fact, however, the proposal defines "merchant mariner credentials" to include both licenses and MMDs thereby preserving the Coast Guard's authority to continue issuing both while adding the flexibility to integrate these documents with the Transportation Workers Identification Credential (TWIC) and other future, secure-credentialing efforts. The Coast Guard did not intend to alter or affect the rights, benefits or duties of any credentialed merchant mariner. Instead, the proposal is intended to clarify, consolidate, add flexibility and increase the effectiveness of the statute. We do not anticipate, or plan to, make any immediate changes to the existing credentials or the regulations, procedures and processes governing merchant mariner credentialing based on the proposal. The Coast Guard will continue working with mariners, industry and the public to improve the

administration of the merchant mariner credentialing program.

5. *Harmonization*—Organizations such as the International Maritime Organization (IMO) have undertaken comprehensive efforts concerning safety and security in the maritime arena. These efforts include the Standards of Training, Certification and Watchkeeping (STCW), and the International Ship and Port Facility Security Code (ISPS). Many of these initiatives have been spearheaded by the United States. The proposal seeks to harmonize the credentialing statutes with these efforts and improve our ability to implement both ongoing and future standards.

*Procedural:* This meeting is open to the public. Please note that the meeting may close early if all business is finished. The facilitator of the meeting has the discretion to limit the amount of time allocated to each commenter based on the total number of persons requesting to make oral comments.

*Information on services for individuals with disabilities:* For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Gould as soon as possible.

Dated: May 6, 2005.

**Howard L. Hime,**

*Acting Director of Standards, Marine Safety, Security and Environmental Protection.*

[FR Doc. 05-9936 Filed 5-18-05; 8:45 am]

BILLING CODE 4910-15-M

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4922-N-08]

### Privacy Act of 1974; Notice of a Computer Matching Program

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice of a computer matching program—HUD and the United States Department of Agriculture (USDA).

**SUMMARY:** In accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988, as amended, (Pub. L. 100-503), and the Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818; June 19, 1989), and OMB Bulletin 89-22, "Instructions on Reporting Computer Matching Programs to the Office of Management (OMB), Congress and the Public," HUD is issuing a public notice of its intent to conduct a recurring

computer matching program with the USDA to utilize a computer information system of HUD, the Credit Alert Interactive Voice Response System (CAIVRS), with USDA's debtor files. In addition to HUD's data, the CAIVRS database includes delinquent debt information from the Departments of Education, Veterans Affairs, Justice and the Small Business Administration. This match will allow prescreening of applicants for debts owed or loans guaranteed by the Federal government to ascertain if the applicant is delinquent in paying a debt owed to or insured by the Federal government for HUD or USDA direct or guaranteed loans.

Before granting a loan, the lending agency and/or the authorized lending institution will be able to interrogate the CAIVRS debtor file which contains the Social Security Numbers (SSNs) of HUD's delinquent debtors and defaulters and defaulted debtor records of the USDA and verify that the loan applicant is not in default or delinquent on direct or guaranteed loans of participating Federal programs of either agency. As a result of the information produced by this match, the authorized users may not deny, terminate, or make a final decision of any loan assistance to an applicant or take other adverse action against such applicant, until an officer or employee of such agency has independently verified such information.

**DATES:** *Effective Date:* Computer matching is expected to begin on June 20, 2005, unless comments are received which will result in a contrary determination, or 40 days from the date a computer matching agreement is signed, whichever is later.

*Comments Due Date:* June 20, 2005.

**ADDRESSES:** Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410.

Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address.

**FOR FURTHER INFORMATION CONTACT:**

*From Recipient Agency:* Jeanette Smith, Departmental Privacy Act Officer, Department of Housing and Urban Development, 451 7th Street, SW., Room P8202, Washington, DC 20410, telephone number (202) 708-2374 or FAX (202) 708-3135. (These are not toll-free numbers.)

*From Source Agency:* Joyce Baumgartner, Debt/Credit Management Coordinator, Department of Agriculture, 14th and Independence Avenue, SW., Washington, DC 20250, telephone number (202) 720-1168. (This is not a toll-free number.)

*Reporting of Matching Program:* In accordance with Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, as amended, and Office of Management and Budget Bulletin 89-22, "Instructions on Reporting Computer Matching Programs to the Office of Management and Budget (OMB), Congress and the Public;" copies of this notice and report are being provided to the Committee on Government Reform of the House of Representatives, the Committee on Homeland Security and Governmental Affairs of the Senate, and the Office of Management and Budget.

*Authority:* The matching program will be conducted pursuant to Public Law 100-503, "The Computer Matching and Privacy Protection Act of 1988," as amended, and Office of Management and Budget (OMB) Circular A-129 (Revised January 1993), Policies for Federal Credit Programs and Non-Tax Receivables. One of the purposes of all Executive departments and agencies—including HUD—is to implement efficient management practices for Federal credit programs. OMB Circular A-129 was issued under the authority of the Budget and Accounting Act of 1921, as amended; the Budget and Accounting Act of 1950, as amended; the Debt Collection Act of 1982, as amended; and, the Deficit Reduction Act of 1984, as amended.

*Objectives To Be Met By The Matching Program:* The matching program will allow USDA access to a system which permits prescreening of applicants for loans owed or guaranteed by the federal government to ascertain if the applicant is delinquent in paying a debt owed to or insured by the Government. In addition, HUD will be provided access to USDA debtor data for prescreening purposes.

*Records To Be Matched:* HUD will utilize its system of records entitled HUD/DEPT-2,

*Accounting Records.* The debtor files for HUD programs involved are included in this system of records. HUD's debtor files contain information on borrowers and co-borrowers who are currently in default) at least 90 days delinquent on their loans; or who have any outstanding claims paid during the last three years on Title II insured or guaranteed home mortgage loans; or individuals who have defaulted on Section 312 rehabilitation loans; or