

that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 26 and 27, 2009, there will be a discussion of different types of prescription drug information currently available to patients in the form of Medication Guides, Patient Package Inserts (PPIs), and Consumer Medication Information (CMI).

CMI is information developed by the private sector and distributed with each prescription at the pharmacy, as provided by law. On August 6, 1996, Public Law 104-180 was enacted and adopted the following goals with regard to CMI: 75 percent of people receiving new prescriptions would receive "useful" written patient information with their prescriptions by 2000, and 95 percent of people receiving new prescriptions would receive "useful" written patient information with their prescriptions by 2006. The committee will review and discuss a recently completed survey designed to assess whether the year 2006 goal was achieved (for results, see committee background, to be posted as described in this document). The committee will also discuss possible next steps for assuring that consumers receive useful written information with their prescriptions.

The survey is a followup to the year 2001 evaluation of the quality of consumer medication information dispensed in community pharmacies (<http://www.fda.gov/cder/reports/prescriptionInfo/default.htm>). To assist the private sector in meeting the year 2006 goal, FDA published a guidance on producing "Useful Written Consumer Medication Information (CMI)" (<http://www.fda.gov/cder/guidance/7139fnl.htm>).

In 1998, FDA published a final rule that required the development of a Medication Guide for a small number of drugs that the agency considered posed a serious and significant health concern (63 FR 66378, December 1, 1998). A Medication Guide is produced by the drug sponsor, reviewed and approved by FDA and is a component of the approved professional product labeling. An FDA public meeting was held in June 2007 to obtain feedback on the development, distribution, comprehensibility and accessibility of Medication Guides. At that meeting, stakeholders voiced a concern that for prescription drugs with both a

Medication Guide and CMI, patients would be getting unnecessarily duplicative information (meeting summary: <http://www.fda.gov/cder/meeting/SummaryPublicHearingMedicationGuides.htm>).

Finally, PPIs are also required for some drugs and are considered part of the approved product labeling, for example, for estrogens and oral contraceptives.

FDA will seek the advice of the advisory committee, and commentary from stakeholders and from the public, for consideration as it considers appropriate next steps to improve the communication of information about prescription drugs to patients.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is or will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 19, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on February 26 and between approximately 10:30 a.m. and 11:30 a.m. on February 27. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 19, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 20, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 26, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-28887 Filed 12-5-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Privacy Act of 1974; Establishment of a New System of Records

AGENCY: Office of the Secretary, Interior.

ACTION: Proposed establishment of a new Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Office of the Secretary of the Department of the Interior is issuing public notice of its intent to establish a new Privacy Act system of records, DOI-84, "National Business Center Datamart."

DATES: Comments must be received by January 20, 2009.

ADDRESSES: Any persons interested in commenting on this new, proposed system of records may do so by submitting comments in writing to the Office of the Secretary Acting Privacy Act Officer, Linda S. Thomas, U.S. Department of the Interior, MS-116 SIB, 1951 Constitution Avenue NW., Washington, DC 20240, or by e-mail to Linda_Thomas@nbc.gov.

FOR FURTHER INFORMATION CONTACT:

Mark Stover, Chief, Applications Management and Technology Branch, National Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, Denver, CO 80235-2230 or by e-mail at Mark_A_Stover@nbc.gov.

SUPPLEMENTARY INFORMATION: The information contained in Datamart is derived from two existing systems

covered by Privacy Act Systems of Records Notices: Federal Personnel and Payroll System (FPPS) covered by DOI-85, "Payroll, Attendance, Retirement, and Leave Records" and Federal Financial System (FFS) covered by DOI-90, "Federal Financial System," as well as associated systems. The purpose of the Datamart is to provide a data warehouse that allows appropriate users to access FPPS and FFS data through a core reporting tool, Hyperion. The reports may be pre-formatted or ad hoc, and are available to appropriate users from the Department of the Interior or appropriate individuals from other Federal agencies, as detailed in the routine uses. This notice will be effective as proposed at the end of the comment period unless comments are received which would require a contrary determination. The Department will publish a revised notice if changes are made based upon a review of comments received.

Dated: December 3, 2008.

Linda S. Thomas,

Office of the Secretary Acting Privacy Act Officer.

SYSTEM NAME:

Interior, National Business Center Datamart, DOI-84.

SYSTEM LOCATION:

Records are located at the National Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, Denver, CO 80235.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEMS:

(1) Current and former employees of the Department of the Interior.

(2) Current and former emergency workers of the Department of the Interior.

(3) Current and former volunteers within the Department of the Interior (volunteers).

(4) Current and former contractors within the Department of the Interior (contractors).

(5) Individuals identified as emergency contacts for the above employees, emergency workers, and volunteers.

(6) Individual and corporate vendors who do business with the Department of Interior. (Only records containing personal information relating to individuals are subject to the Privacy Act.)

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee (and emergency worker, volunteer, contractor and vendor) name, address, phone numbers, birth date;

employee (and emergency worker and volunteer) emergency contact information (including name, address, phone numbers and relationship to individual), Social Security Number and organizational code; employee common identifier (ECI); vendor Taxpayer Identification Number; vendor code or number; employee ethnicity/race, pay rate, grade, length of service, individual's pay and leave records; time and attendance records, leave request records, allowances and cost distribution records; employee deductions for Medicare, Old Age Survivor and Disability Insurance (OASDI), bonds, Federal Employees' Group Life Insurance (FGLI), union dues, taxes, allotments, quarters, retirement, charities, health benefits, Flexible Spending Account, Long Term Care, and Thrift Savings Fund contributions; employee awards, shift schedules, pay differentials, tax lien data, commercial garnishments and child support and/or alimony wage assignments; related payroll and personnel data. Also included is information on debts owed to the government as a result of overpayment, refunds owed or a debt referred for collection on an employee, emergency worker or contractor.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3512, *et seq.*; 5 U.S.C. 5101, *et seq.*; Pub. L. 97-255; Office of Management and Budget Circular A-127.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The primary use of records in the system is to provide a repository for data from FPPS (Federal Personnel Payroll System) and FFS (Federal Financial System) that allows agencies to query the data in order to produce required reports in support of fiscal operations and personnel payroll processing.

Disclosure outside the Department of the Interior may be made:

(1) To other Federal agencies to produce required reports, in support of their fiscal and personnel/payroll processing.

(2) (a) To any of the following entities or individuals, when the circumstances set forth in paragraph (b) are met:

(i) The U.S. Department of Justice (DOJ);

(ii) A court or an adjudicative or other administrative body;

(iii) A party in litigation before a court or an adjudicative or other administrative body; or

(iv) Any DOI employee or DOI emergency worker acting in his or her

individual capacity if DOI or DOJ or the DOI emergency worker's agency has agreed to represent that individual or pay for private representation of the individual;

(b) When:

(i) One of the following is a party to the proceeding or has an interest in the proceeding:

(A) DOI or any component of DOI;

(B) Any DOI emergency worker's agency;

(C) Any other Federal agency appearing before the Office of Hearings and Appeals;

(D) Any DOI employee or DOI emergency worker acting in his or her official capacity;

(E) Any DOI employee or DOI emergency worker acting in his or her individual capacity if DOI or DOJ or the DOI emergency worker's agency has agreed to represent that individual or pay for private representation of the individual;

(F) The United States, when DOJ determines that DOI or any DOI emergency worker's agency is likely to be affected by the proceeding; and

(ii) DOI or any DOI emergency worker's agency deems the disclosure to be:

(A) Relevant and necessary to the proceeding; and

(B) Compatible with the purpose for which the records were compiled.

(3) To appropriate agencies, entities, and persons when:

(a) It is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; and

(b) The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to an economic or property interest, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and

(c) The disclosure is made to such agencies, entities and persons who are reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize or remedy such harm.

(4) To a congressional office in response to a written inquiry that an individual covered by the system, or the heir of such individual if the covered individual is deceased, has made to the office.

(5) To any criminal, civil or regulatory law enforcement authority (whether federal, state, territorial, local, tribal or foreign) when a record, either alone or

in conjunction with other information, indicates a violation or potential violation of law—criminal, civil or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

(6) To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

(7) To Federal, state, territorial, local, tribal or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

(8) To representatives of the National Archives and Records Administration to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

(9) To state and local governments and tribal organizations to provide information needed in response to court order and/or for discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

(10) To an expert, consultant or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records maintained in the Datamart are electronic and contain information from source systems. They are stored in magnetic media at the central computer processing center. All NIST guidelines, as well as Departmental and OMB guidance are followed concerning the storage of the records.

RETRIEVABILITY:

Records may be retrieved by entries reflecting the various categories of records in the system including name of individual, name of emergency contact, Social Security Number, Tax Identification Number, vendor code or number, date of birth, organizational code, etc.

SAFEGUARDS:

Electronic records are maintained with safeguards meeting all appropriate statutory and regulatory guidelines, as

well as Departmental guidance addressing the security requirements of Departmental Privacy Act Regulations (43 CFR 2.51) for automated records, and with Office of Management and Budget, and NIST. Further, agency officials only have access to records pertaining to their agencies.

(1) Physical security: Computer systems are maintained in locked rooms housed within secure Department of the Interior buildings.

(2) Technical Security: Electronic records are maintained in conformity with Office of Management and Budget and Departmental guidelines reflecting the implementation of the Federal Information Security Management Act. The electronic data are protected through user identification, passwords, database permissions, encryption and software controls. Such security measures establish different degrees of access for different types of users. An audit trail is maintained and reviewed periodically to identify unauthorized access. A Privacy Impact Assessment was completed to ensure that Privacy Act requirements and personally identifiable information safeguard requirements are met.

(3) Administrative Security: All DOI and contractor employees with access to Datamart are required to complete Privacy Act, Federal Records Act and IT Security Awareness training prior to being given access to the system, and on an annual basis thereafter. In addition, Federal employees supervise and monitor the use of Datamart.

RETENTION AND DISPOSAL:

Records contained in this system are documented as items 1400 and 7554 of the Department of the Interior, Office of the Secretary's pending records schedule.

SYSTEM MANAGER AND ADDRESS:

Chief, Applications Management and Technical Services Branch, National Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, Denver, CO 80235-2230.

NOTIFICATION PROCEDURES:

Inquiries regarding the existence of records should be addressed to the System Manager. The request must be in writing, signed by the requester, and meet the requirements of 43 CFR 2.60, which requires writing PRIVACY ACT INQUIRY prominently on your envelope and correspondence.

RECORDS ACCESS PROCEDURES:

A request for access should be submitted to the System Manager at the above address. It must be submitted in

writing, signed by the requester, and meet the requirements of 43 CFR 2.63, which requires writing PRIVACY ACT REQUEST FOR ACCESS prominently on the envelope and the front of the request.

CONTESTING RECORDS PROCEDURES:

A petition for amendment should be addressed to the System Manager. The request must be in writing, signed by the requester, and meet the content requirements of 43 CFR 2.71, which include stating the reasons why the petitioner believes the record is in error, and the changes sought.

RECORD SOURCE CATEGORIES:

The source data for the system comes from FPPS and FFS.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.
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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-MB-2008-NO156; 91200-1231-9BPP]

Take of Migrant Peregrine Falcons in the United States for Use in Falconry

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: This notice is to announce the availability of a *Final Environmental Assessment and Management Plan (FEA)* for take of migrant peregrine falcons (*Falco peregrinus*) in the United States for use in falconry.

ADDRESSES: The FEA is available from the Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 634, Arlington, VA 22203-1610. You can request a copy of the FEA by calling 703-358-1825. The FEA also is available on the Division of Migratory Bird Management Web site at <http://www.fws.gov/migratorybirds/>.

FOR FURTHER INFORMATION CONTACT: Dr. George Allen, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, at 703-358-1825.

SUPPLEMENTARY INFORMATION: We published a notice of the availability of a Draft Environmental Assessment on November 13, 2007 (72 FR 63921). We stated in the DEA that our management goal is to allow a reasonable harvest of migrant Northern peregrines while not increasing cumulative harvest of the U.S. portion of the Western or the