

where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public

health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be

marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Form No. | 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---------------------------------|-------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| Form FDA 2541 (Registration) | 108.25 and 108.35 | 515 | 1 | 515 | .17 | 88 |
| Form FDA 2541a (Process Filing) | 108.25 and 108.35 | 1,489 | 8.62 | 12,835 | .333 | 4,274 |
| Form FDA 2541c (Process Filing) | 108.35 | 84 | 7.77 | 653 | .75 | 490 |
| Total | | | | | | 4,852 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 21 CFR Part | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|-------------|----------------------|-----------------------------------|----------------------|------------------------|-------------|
| 113 and 114 | 8,950 | 1 | 8,950 | 250 | 2,237,500 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based its estimate on registrations and process filings received over the past 3 years. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 26, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Privacy Act of 1974; Revisions to OIG's Privacy Act System of Records: Criminal Investigative Files

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of proposed revisions to existing Privacy Act systems of records.

SUMMARY: The Office of Inspector General (OIG) proposes to revise and update the existing system of records, entitled "Criminal Investigative Files" (09-90-0003). This proposed notice is in accordance with the Privacy Act requirement that agencies publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition. This system of records, maintained by OIG, was last revised and updated on December 8, 2006.

DATES: Effective Date: These revisions will become effective without further notice on April 18, 2008 unless comments received on or before that date result in a contrary determination.

Comment Date: Comments on these revisions will be considered if we receive them at the addresses provided below no later than 5 p.m. on April 3, 2008. Interested parties may submit written comments on this proposed revision to the addresses indicated below.

ADDRESSES: In commenting, please refer to file code OIG-793-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-793-PN, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close period to Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 358-3141.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Regulations Officer, Office of External Affairs, (202) 619-0089.

SUPPLEMENTARY INFORMATION: In accordance with the Inspector General Act of 1978, 5 U.S.C. App. 3, the Criminal Investigative Files system of records is maintained for the purpose of (1) conducting, documenting, and tracking investigations conducted by OIG or other investigative agencies regarding HHS programs and operations; (2) documenting the outcome of OIG reviews of allegations and complaints received concerning HHS programs and operations; (3) aiding in prosecutions brought against the subjects of OIG investigations; (4) maintaining a record of the activities that were the subject of investigations; (5) reporting the results of OIG investigations to other departmental components for their use in operating and evaluating their programs and the imposition of civil or administrative sanctions; and (6) acting as a repository and source for information necessary to fulfill the reporting requirements of 5 U.S.C. App. 3.

In accordance with the Privacy Act requirement, agencies are to publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition. This system of records was last revised and updated on December 8, 2006 (71 FR 71180), by updating the "Systems Location" section of that document.

OIG has reviewed and is now proposing to revise the criminal investigative file system of records by (1) amending the "Routine Uses of Records Maintained in the System" section by adding a new paragraph o. to address the requirement for a routine use for the disclosure of information in the investigation of data breaches of Personally Identifiable Information, in accordance with Office of Management and Budget Memorandum M-07-16; and (2) amending the "Policies and Practices for Storing, Retrieving, Reviewing, Retaining, and Disposing of Records in the Storage System" portion of the system of records to update the discussion on access methods for the mainframe and the storage location of data so that it is consistent with current technology. OIG will accept and consider comments and feedback in response to only the specific revisions to the current system of records addressed in this notice.

This proposed change will not otherwise increase access to these records.

Dated: February 27, 2008.

Daniel R. Levinson,
Inspector General.

SYSTEM NAME:

Criminal Investigative Files of the Inspector General HHS/OS/OIG.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Inspector General, HHS, Room 5409, Wilbur J. Cohen Bldg., 330 Independence Avenue, SW., Washington, DC 20201.

Region 1, Office of Investigations (OI), OIG, JFK Federal Building, Room 2475, Boston, Massachusetts 02203.

Region 2, OI, OIG, 26 Federal Plaza, Room 13-124, New York, New York 10278.

Region 3, OI, OIG, Public Ledger Bldg., 150 South Independence Mall West, Suite 326, Philadelphia, Pennsylvania 19106.

Region 4, OI, OIG, Atlanta Federal Office, 61 Forsyth Street, SW., Suite 5T18, Atlanta, Georgia 30303.

Region 5, OI, OIG, 233 North Michigan Avenue, Suite 1330, Chicago, Illinois 60601.

Region 6, OI, OIG, 1100 Commerce Street, Room 629, Dallas, Texas 75242.

Region 7, OI, OIG, 1201 Walnut, Suite 920, Kansas City, Missouri 64106.

Region 9, OI, OIG, 50 United Nations Plaza, Room 174, San Francisco, California 94102.

Los Angeles Region, OI, OIG, 600 West Santa Ana Blvd., Suite 1100, Santa Ana, California 92701.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals relevant to a criminal investigation, including but not limited to the subjects of an investigation, complainants, and key witnesses where necessary for future retrieval.

CATEGORIES OF RECORDS IN THE SYSTEM:

Criminal investigative files and extracts from that file consisting of computerized case management and tracking files.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Inspector General Act of 1978, 5 U.S.C. App. 3, authorizes Inspectors General to conduct, supervise, and coordinate investigations relating to the programs and operations of their respective agencies.

PURPOSE(S):

Pursuant to the Inspector General Act of 1978, 5 U.S.C. App. 3, this system is maintained for the purpose of conducting, documenting, and tracking

investigations conducted by OIG or other investigative agencies regarding HHS programs and operations, documenting the outcome of OIG reviews of allegations and complaints received concerning HHS programs and operations, aiding in prosecutions brought against the subjects of OIG investigations, maintaining a record of the activities that were the subject of investigations, reporting the results of OIG investigations to other departmental components for their use in operating and evaluating their programs and the imposition of civil or administrative sanctions, and acting as a repository and source for information necessary to fulfill the reporting requirements of 5 U.S.C. App. 3.

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

a. Information from this system of records may be disclosed to any other Federal agency or any foreign, State, or local government agency responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation where that information is relevant to an enforcement proceeding, investigation, or prosecution within the agency's jurisdiction.

b. Information from this system of records may be disclosed to (1) The Department of Justice in connection with requests for legal advice and in connection with actual or potential criminal prosecutions or civil litigation pertaining to the Office of Inspector General, and (2) a Federal or State grand jury, a Federal or State court, administrative tribunal, opposing counsel, or witnesses in the course of civil or criminal proceedings pertaining to the Office of Inspector General.

c. Information in this system of records may be disclosed to a Federal, State, or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a license, grant or other benefit.

d. Information in this system of records may be disclosed to a Federal agency in response to its request in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

e. Relevant information may be disclosed from this system of records to the news media and general public where there exists a legitimate public interest, e.g., to provide information on events in the criminal process, such as indictments, and where necessary, for protection from imminent threat to life or property.

f. Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service, or issue a subpoena to the department for records in this system or records, the department will make such records available.

g. When the department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system, relevant records will be disclosed to such contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

h. Disclosures may be made to organizations deemed qualified by the Secretary to carry out quality assessments.

i. Information from this system of records may be disclosed in the course of employee discipline of competence determination proceedings.

j. Disclosures may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

k. Information from this system of records may be disclosed to the Department of Justice, to a judicial or administrative tribunal, opposing counsel, and witnesses, in the course of proceedings involving HHS, an HHS employee (where the matter pertains to the employee's official duties), or the United States, or any agency thereof where the litigation is likely to affect HHS, or HHS is a party or has an interest in the litigation and the use of the information is relevant and necessary to the litigation.

l. Information of this system of records may be disclosed to a Federal, State or local agency maintaining pertinent records, if necessary, to obtain a record relevant to a department decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

m. Information from this system of records may be disclosed to third party contacts, including public and private organizations, in order to obtain information relevant and necessary to the investigation of potential violations in HHS programs and operations, or

where disclosure would enable the OIG to identify violations in HHS programs or operations or otherwise assist the OIG in pursuing on-going investigations.

n. A record may be disclosed to any official charged with the responsibility to conduct qualitative assessment reviews of internal safeguards and management procedures employed in investigative operations. This disclosure category includes members of the President's Council on Integrity and Efficiency and officials and administrative staff within their investigative chain of command, as well as authorized officials of the Department of Justice and the Federal Bureau of Investigation.

o. A record may be disclosed to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

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

The records, which take the form of index cards, investigative reports, microcomputer disks, drives and/or CDs, files and printed listings are maintained under secure conditions in limited access areas. Written documents and computer disks are maintained in secure rooms, in security type safes or in lock bar file cabinets with manipulation proof combination locks. Computer servers containing files are locked in controlled-access rooms. Laptops that may contain files are protected with whole-disk encryption.

RETRIEVABILITY:

Records are retrievable by manual or computer search of indices containing the name or Social Security number of the individual to whom the record applies. Records may be cross-referenced by case or complaint number.

SAFEGUARDS:

Records are maintained in a restricted area and accessed only by Department personnel. Access within OIG is strictly limited to authorized staff members. All employees are given instructions on the sensitivity of such files and the restrictions on disclosure. Access within HHS is strictly limited to the Secretary, Under-Secretary, and other officials and employees on a need-to-know basis. All files and printed materials are

safeguarded in accordance with the provisions of the National Institute of Standards and Technology, OMB Memoranda, and HHS Information Security policies and guidelines.

RETENTION AND DISPOSAL:

Investigative files are retained for 10 years after completion of the investigation and/or action based thereon. Paper and computer indices are retained permanently. The records control schedule and disposal standards may be obtained by writing to the Systems Manager at the address below.

SYSTEM MANAGER(S) AND ADDRESS:

Inspector General, Room 5250, Wilbur J. Cohen Building, Department of Health and Human Services, 330 Independence Avenue, SW., Washington, DC 20201.

NOTIFICATION PROCEDURES:

Exempt. However, consideration will be given requests addressed to the system manager. For general inquiries, it would be helpful if the request included date of birth and Social Security number, as well as the name of the individual.

RECORDS ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought.

CONTESTING RECORD PROCEDURES:

Contact the system manager at the address specified above, and reasonably identify the record, specify the information to be contested, and the corrective action sought with supporting justification.

RECORD SOURCE CATEGORIES:

OIG collects information from a wide variety of sources, including information from the Department and other Federal, State, and local agencies, witnesses, complaints and other nongovernmental sources.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

In accordance with subsection (j)(2) of the Privacy Act, 5 U.S.C. 552a(j)(2), the Secretary has exempted this system from the access, amendment, correction, and notification provisions of the Act, 5 U.S.C. 552a(c)(3), (d)(1)-(4), (e)(3), and (e)(4)(G) and (H).

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