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 BURDEN**

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

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

**TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN**

<table>
<thead>
<tr>
<th>21 CFR Part</th>
<th>No. of Recordkeepers</th>
<th>Annual Frequency of Recordkeeping</th>
<th>Total Annual Records</th>
<th>Hours per Recordkeeper</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>113 and 114</td>
<td>8,950</td>
<td>1</td>
<td>8,950</td>
<td>250</td>
<td>2,237,500</td>
</tr>
</tbody>
</table>

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.


Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. E8–4067 Filed 3–3–08; 8:45 am]

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/OIG.

SECURITY CLASSIFICATION:
None.

SYSTEM LOCATION:
Region 1, Office of Investigations (OI), OIG, JFK Federal Building, Room 2475, Boston, Massachusetts 02203.
Region 4, OI, OIG, Atlanta Federal Office, 61 Forsyth Street, SW., Suite 5T18, Atlanta, Georgia 30303.
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:
d. 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
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 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,
vestiges, 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).

[FR Doc. E8–4105 Filed 3–3–08; 8:45 am]
BILLING CODE 4152–01–P