

and 316.21. These requirements include, but are not limited to, documentation of the following:

- The disease or condition for which the drug is intended affects fewer than 200,000 people in the United States (e.g., tuberculosis, malaria, trypanosomiasis).
- If the drug is a vaccine, diagnostic drug, or preventative drug, the persons to whom the drug will be administered in the United States are fewer than 200,000 per year.
- For a drug intended for diseases or conditions affecting 200,000 or more people, or for a vaccine, diagnostic drug, or preventative drug to be administered to 200,000 or more persons per year in the United States, there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States.

Antimicrobial drugs that have qualified for orphan drug designation in the past include some indicated for the treatment of tuberculosis, malaria, and trypanosomiasis.

## II. Purpose and Scope of the Hearing

This hearing is intended to provide the infectious disease community, sponsors, and other interested parties an opportunity to discuss their experience with and concerns about the emerging threat of antimicrobial resistance, possible strategies fostering prudent use to prevent the development of antimicrobial resistance, and the potential for the provisions of the Orphan Drug Act or other incentives to facilitate antimicrobial drug development, including what, if any, conditions might be required to accompany such incentives.

## III. Issues for Discussion

FDA invites comments from interested parties on the following questions:

1. Please discuss strategies that should be considered to limit the development of antimicrobial resistance, and studies that could be done to assess the utility, safety and effectiveness of those strategies. Possible examples include limiting the approved conditions of use, limiting the duration of therapy, restricting distribution to encourage appropriate use, using shorter courses of therapy with higher doses of antimicrobials, and using directly observed therapy.
2. Please discuss the possible utility and effectiveness of economic incentives in promoting drug development for antimicrobial resistant organisms.

a. What is the potential role of the Orphan Drug Act in providing incentives to facilitate antimicrobial drug development? Please describe the serious and life-threatening infectious diseases for which the Orphan Drug Act provides viable research and development incentives. Please comment on the potential complexities associated with identifying appropriate orphan populations in the infectious disease context.

b. Are there specific incentives (other than those provided by the Orphan Drug Act) that could facilitate the development of new antimicrobial therapies for serious and life-threatening diseases? Describe those serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antimicrobial-resistant bacteria, which could be considered under an alternative incentive program.

## IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and FDA's Office of Orphan Drugs.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in 21 CFR 15.30(h).

## V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit

written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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

## VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: April 9, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 08-1129 Filed 4-10-08; 12:23 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Privacy Act of 1974, New OIG Privacy Act System of Records: Litigation Files

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

**ACTION:** Notice of proposed new Privacy Act systems of records.

**SUMMARY:** The Office of Inspector General (OIG) is proposing a new system of records, entitled Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG (09-90-0077). This proposed notice is in accordance with the Privacy Act

requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition. This new system will replicate the existing system of records, entitled Litigation Files, Administrative Complaints, and Adverse Personnel Actions, HHS/OS/OGC (09–90–0064), to reflect that responsibility for providing legal services to the Inspector General has transferred to OIG's Office of Counsel to the Inspector General (OCIG). The existing Litigation Files system of records (09–90–0064) remains with the Department's Office of General Counsel and will be unchanged. This notice specifically covers that portion of the records that transferred to, or have been since created and maintained by, OCIG. The Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG system of records will be maintained for the purposes of representing OIG and its components in court cases and administrative proceedings, in accordance with the Inspector General Act of 1978 (5 U.S.C. App.).

**DATES:** *Effective Date:* This system of records will become effective without further notice on June 16, 2008, unless comments received on or before that date result in a contrary determination.

*Comment Date:* Comments on this new system of records will be considered if we receive them at the addresses provided below no later than 5 p.m. Eastern Standard Time on May 15, 2008.

**ADDRESSES:** In commenting, please reference file code OIG–796–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission. However, you may submit comments using one of the following three ways (no duplicates, please):

1. *Electronically.* You may submit electronically 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 mail your printed or written submissions to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–796–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.* You may deliver, by hand or courier, before the

close of the comment period, your printed or written comments to the 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. *Inspection of Public Comments:* All comments received before the end of the comment period will be posted on <http://www.regulations.gov> for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619–0089.

**FOR FURTHER INFORMATION CONTACT:**

Melissa McCurdy, Office of Counsel to the Inspector General, (202) 619–0335.

**SUPPLEMENTARY INFORMATION:** The Office of Inspector General (OIG) proposes to establish a new Privacy Act system of records, 09–90–0077, Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG. The new system will duplicate an existing Privacy Act system of Records—Litigation Files, Administrative Complaints, and Adverse Personnel Actions HHS/OS/OGC (09–90–0064)—which was last revised and updated in the **Federal Register** on November 9, 1994 (59 FR 55845), by adding a new routine use to permit the disclosure of information from this system to certain individuals working in various offices within the Office of the Secretary, but who do not have the status of agency employees and, in many instances, do not receive pay for their work.

The new system of records—Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG (09–90–0077)—will replicate the 09–90–0064 system of records, but will modify the “System Name,” “System Location,” “Categories of Individuals Covered by the System,” “Authority for Maintenance of the System,” “Routine Uses,” “Purposes,” “System Safeguards,” and “System Manager(s) and Address” sections. Records in the system have been located and maintained in OIG's headquarters. The modification of the “System Name,” “System Location,” “Authority

for Maintenance of the System,” “Routine Uses,” “Purposes,” “Storage,” “System Safeguards,” and “System Manager(s) and Address” sections are to reflect that responsibility for providing legal services to the Inspector General transferred to the Office of Counsel to the Inspector General (OCIG).

The Inspector General Act of 1978 established OIG “to conduct and supervise audits and investigations relating to the programs and operations” of the Department of Health and Human Services (HHS). Within OIG, OCIG (1) provides general legal services to OIG including, among other things, advice and representation on HHS programs and operations, administrative law issues, and criminal procedure; (2) imposes program exclusions and civil money penalties on health care providers and litigates those actions within the Department; (3) represents OIG in the global settlement of cases arising under the False Claims Act; and (4) represents OIG in personnel actions.

**Description of the Proposed System of Records**

The Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG system will enable OCIG to access and maintain records for the purpose of representing OIG and its components in court cases and administrative proceedings. The system will house records pertaining to litigation, administrative complaints, and personnel actions in which OIG is, or was, involved.

**Agency Policies, Procedures, and Restrictions on the Routine Use**

The Privacy Act permits OIG to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. Any such disclosure of data is known as a routine use. We are proposing to establish the following routine use disclosures of records maintained in the system:

1. Disclosure 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 that individual.

2. In the event of litigation, information from the 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, any 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.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation, or order issued pursuant thereto.

4. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

5. A record from this system of records may be disclosed as a "routine use" 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 security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

6. A record from 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.

7. 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 concerning the hiring or retention of an employee, the issuance of a license, grant, or other benefit.

8. To student volunteers and other individuals performing functions for the Department, but technically not having the status of agency employees, if they

need access to the records in order to perform their assigned agency functions.

9. 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.

#### **Safeguards**

OIG has safeguards in place for authorized users and monitors users to ensure against unauthorized use. The system will conform to all applicable Federal laws and regulations and Federal, HHS, and OIG policies and standards as they relate to information security and data privacy.

#### **Effects of the Proposed System of Records on Individual Rights**

This system is established in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records notice.

OIG will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of applicants whose data are maintained in the system. OCIG will make disclosures from the proposed system in accordance with the Privacy Act. OCIG does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

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

Dated: April 10, 2008.

**Daniel R. Levinson,**  
*Inspector General.*

**09-90-0077**

#### **SYSTEM NAME:**

Litigation Files, Administrative Complaints, and Personnel Actions, HS/OS/OIG/OCIG.

#### **SECURITY CLASSIFICATION:**

None.

#### **SYSTEM LOCATION:**

Office of Counsel to the Inspector General (OCIG), Department of Health and Human Services, Room 5527,

Wilbur J. Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

#### **CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

The individuals on whom records are maintained in this system are individuals who are involved in civil, criminal, or administrative litigation with the Department or the United States (regarding matters within the jurisdiction of the Department) either as plaintiffs or as defendants, and individuals who either file administrative complaints with the Department or are the subjects of administrative complaints initiated by the Department.

#### **CATEGORIES OF RECORDS IN THE SYSTEM:**

These records contain information pertaining to the subject matter of the litigation, administrative complaint, or personnel action. Such records would include complaints, litigation reports, administrative transcripts, various litigation documents, investigative materials, correspondence, briefs, court orders, and judgments.

#### **AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The authority for maintaining this system is found in the various statutes, regulations, rules, or orders pertaining to the subject matter of the litigation, administrative complaint, or adverse personnel action, (e.g., Inspector General Act and the Social Security Act).

#### **PURPOSE(S):**

To advise and represent the Office of Inspector General and its components in court cases and administrative proceedings.

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

a. Disclosure 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 that individual.

b. In the event of litigation, information from the 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, any 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.

c. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

d. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

e. A record from this system of records may be disclosed as a "routine use" 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 security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

f. A record from this system of records may be disclosed to a Federal agency, 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.

g. 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 concerning the hiring or retention of an employee, the issuance of a license, grant, or other benefit.

h. To student volunteers and other individuals performing functions for the Department, but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions.

i. 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, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in electronic form and paper files are stored in locked file cabinets.

**RETRIEVABILITY:**

These records are retrievable by name of the plaintiff or the first plaintiff if there is more than one, or by the name of the first defendant if the plaintiff is the United States. In the case of personnel actions, records are retrievable by name of the individual involved.

**SAFEGUARDS:**

Office buildings in which these records are maintained are secured by a variety of security systems. The computer terminals used to access the records are secured with passwords, encryptions, and other security devices, comply with all relevant computer security procedures, and are kept in rooms that are locked at the close of the business day, and are generally accessible only to OCIG staff.

**RETENTION AND DISPOSAL:**

These records are maintained for an indefinite duration.

**SYSTEM MANAGER(S) AND ADDRESS:**

The agency official responsible for the system policies and practices outlined above is: The Chief Counsel, Office of Counsel to the Inspector General, Department of Health and Human Services, Wilbur J. Cohen Building, Room 5527, 330 Independence Avenue, SW., Washington, DC 20201.

**NOTIFICATION PROCEDURES:**

Any inquiries regarding these systems of records should be addressed to the System Manager. An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. (These notification and access procedures are in accordance with Department regulations (45 CFR 5b.6).)

**RECORDS ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. (These access procedures are in accordance with Department regulations (45 CFR 5b.5 (a)(2).)

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address System Manager(s) and Address above, and reasonably identify the record and specify the information to be contested and corrective action sought with supporting justification. (These procedures are in accordance with Department regulations (45 CFR 5b.7).)

**RECORD SOURCE CATEGORIES:**

The information for this system is obtained through a number of sources including the exchange of legal pleadings, documents, formal and informal discovery, program offices and component agencies, private attorneys, State and local governments, their agencies and instrumentalities, and officers of other Federal agencies and the individuals involved.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. E8-7987 Filed 4-14-08; 8:45 am]

BILLING CODE 4152-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Amended Notice of Call for Nominations for the National Cancer Institute Director's Consumer Liaison Group**

Notice is hereby given of a change in the Call for Nominations for the National Cancer Institute Director's Consumer Liaison Group which was published in the **Federal Register** on March 18, 2008, 73 FR 14476-14477.

This call for nominations is being amended to revise the due date for candidates interested in being considered for appointment to the Director's Consumer Liaison Group to postmark their nomination package by April 30, 2008 instead of April 15, 2008.

Dated: April 8, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-7929 Filed 4-14-08; 8:45 am]

BILLING CODE 4140-01-M