

responsibility for recordkeeping in respect of assets or liabilities for that foreign branch resides at the U.S. branch or agency.) A separate FFIEC 002S must be completed for each managed or controlled non-U.S. branch and filed quarterly along with the U.S. branch or agency's FFIEC 002. The data from both reports are used for: (1) Monitoring deposit and credit transactions of U.S. residents; (2) monitoring the impact of policy changes; (3) analyzing structural issues concerning foreign bank activity in U.S. markets; (4) understanding flows of banking funds and indebtedness of developing countries in connection with data collected by the International Monetary Fund (IMF) and the Bank for International Settlements (BIS) that are used in economic analysis; and (5) assisting in the supervision of U.S. offices of foreign banks. The Federal Reserve System collects and processes these reports on behalf of all three agencies.

#### Current Actions

In a **Federal Register** notice published on January 15, 2008 (73 FR 2491), the Board, on behalf of the agencies, requested comment on a proposal to implement a number of revisions to the existing reporting requirements of the FFIEC 002. The proposed revisions would help to achieve consistency with the Reports of Condition and Income (Call Report) (FFIEC 031 and FFIEC 041) filed by insured commercial banks and state-chartered savings banks. The agencies also proposed to combine the FFIEC 002 and FFIEC 002S into one OMB control number, 7100-0032. In response to the January 15, 2008, notice, the agencies received four comment letters from a branch of a foreign bank, a federal agency, a bankers' organization, and a foreign banking organization. One commenter supported the proposed changes and described its use of the data to analyze the effect of quarterly developments on the U.S. International Transactions Accounts. Two commenters had no comments on the proposed revisions, but did offer comments on the use of International Financial Reporting Standards in regulatory reports such as the FFIEC 002 and the FFIEC 002S. The last commenter had no comments on the proposed revisions, but did suggest delaying the proposed implementation date for some of these revisions. After considering these comments, the FFIEC and the agencies have approved the revisions to the FFIEC 002 and the FFIEC 002S as originally proposed. However, the agencies will implement the changes as of the September 30, 2008, reporting date rather than the

proposed June 30, 2008, reporting date with one exception. The Schedule O changes will remain on the same interim transition period that had been proposed, which covers the June 30, 2008, through December 31, 2008, reporting dates.

#### Request for Comment

*Comments are invited on:*

- a. Whether the information collections are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;
- b. The accuracy of the agencies' estimates of the burden of the information collections, including the validity of the methodology and assumptions used;
- c. Ways to enhance the quality, utility, and clarity of the information to be collected;
- d. Ways to minimize the burden of the information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and
- e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this notice will be shared among the agencies. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or other forms of information technology as well as other relevant aspects of the information collection request.

Board of Governors of the Federal Reserve System, April 1, 2008.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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**BILLING CODE 6210-01-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### Privacy Act of 1974, New OIG Privacy Act System of Records: Administrative 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 "Administrative Files" (09-90-0076).

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 system of records contains certain administrative files for the purpose of maintaining, archiving, and filing records.

**DATES:** *Effective Date:* This system of records will become effective without further notice on June 3, 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 5, 2008.

**ADDRESSES:** In commenting, please reference file code OIG-794-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-794-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:** Joel Schaer, OIG Regulations Officer, Office of External Affairs, (202) 619-0089; or 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, 09-90-0076, "Administrative Files, HHS/OS/OIG/OCIG." The Inspector General Act of 1978 (5 U.S.C. app.) 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, the Office of Counsel to the Inspector General (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; (4) represents OIG in personnel actions; and (5) issues anti-kickback safe harbor regulations, renders advisory opinions on OIG sanctions, and issues special fraud alerts and other industry guidance.

In addition, in compliance with the "Incident Reporting and Handling Requirements" set forth in the Office of Management and Budget's Memoranda 07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*, OIG is incorporating the routine use language into this new system of records as part of our normal SORN review development process.

#### **Description of the Proposed System of Records**

The "Administrative Files, HHS/OS/OIG/OCIG" system will specifically enable OCIG to access and maintain records for the purpose of archiving and filing records. The system will house various types of records and will permit OCIG to search and retrieve memoranda, opinions, correspondence, testimony, and other writings relevant to the functioning of OCIG.

#### **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. Accordingly, 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 OIG 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, State, local, 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 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.

6. The system of records may be disclosed 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.

7. 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**

OIG proposes to establish this system of records 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. OIG will make disclosures from the proposed system in accordance with the Privacy Act. OIG does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

This proposed new system of records will not otherwise increase access to these records.

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

**09-90-0076**

#### **SYSTEM NAME:**

Administrative Files, HHS/OS/OIG/OCIG.

**SYSTEM CLASSIFICATION:**

None.

**LOCATION:**

Office of Inspector General (OIG),  
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 system consists of information concerning persons mentioned in opinions, memoranda, correspondence, testimony, and other writings relevant to the Office of Counsel to the Inspector General (OCIG) within OIG. Individuals mentioned may include:

- Staff members and authors whose names are mentioned in memoranda, opinions, correspondence, testimony, and other writings;
- Individuals addressed in memoranda, opinions, correspondence, testimony, and other writings;
- Attendees at meetings and conferences described in memoranda, opinions, correspondence, testimony, and other writings; or
- Any individual identified in connection with questions presented to OCIG.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The system will consist of memoranda, opinions, correspondence, testimony, and other writings.

**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 memoranda, opinions, correspondence, testimony, and other writings of the office, (*e.g.*, Inspector General Act (5 U.S.C. App.)).

**PURPOSE(S):**

In accordance with the Inspector General Act of 1978, this system is maintained for the purposes of maintaining a searchable record of memoranda, opinions, correspondence, testimony, and other writings.

**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 OIG 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, State, local, 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 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.

f. The system of records may be disclosed 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.

g. 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, and maintained under secure conditions in limited access areas. Computer server containing files are locked in controlled-access rooms. Laptops that may contain files are protected with whole-disk encryption.

**RETRIEVABILITY:**

These records are retrievable by certain personal identifiers, such as by name, of the individuals covered by this system of record.

**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, are kept in rooms that are locked at the close of the business day, and are generally accessible only to OCIG staff. Paper files are stored in locked cabinets, in locked offices and are accessible to limited members of OCIG on a need-to-know basis.

**RETENTION AND DISPOSAL**

These records may be 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 PROCEDURE:**

Any individual who wants to know whether this system of records contains a record about him or her, who wants access to his or her record, or who wants to contest the contents of a record, should make a written request to the system manager.

**RECORD 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 in the System Manager(s) and Address section 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 SOURCES CATEGORIES:**

The information for this system is obtained through a number of sources including OCIG attorney, 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.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Non-Animal Methods and Approach for Evaluating Eye Irritation Potential for Antimicrobial Cleaning Products (AMCPs): Request for Nominations for an Independent Expert Panel and Submission of Relevant Data**

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Request nominations for an independent expert panel and submission of relevant data.

**SUMMARY:** At the request of the U.S. Environmental Protection Agency (EPA), the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is planning to assess the validation status of a proposed non-animal approach for evaluating the eye irritation potential of AMCPs that meets hazard classification and labeling requirements. On behalf of ICCVAM, NICEATM requests:

1. Nominations of expert scientists to serve as members of an independent peer review panel.
2. Submission of relevant data and information on AMCPs or related substances obtained from (1) human testing or experience including reports from accidental exposures, (2) rabbits using the standard eye test or the low volume eye test (LVET), and (3) *in vitro* test methods for assessing ocular

irritation, such as the Bovine Corneal Opacity and Permeability (BCOP) test, the Cytosensor Microphysiometer (CM) test, and the EpiOcular test, and data supporting the accuracy and reproducibility of these methods.

**DATES:** Submit nominations and data by May 19, 2008. Data submitted after this date will be considered in the evaluation, if feasible.

**ADDRESSES:** Submit nominations and data to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC-17, Research Triangle Park, NC, 27709, (fax) 919-541-0947 (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC, 27709. Responses can also be submitted electronically via the ICCVAM-NICEATM Web site ([http://iccvam.niehs.nih.gov/contact/FR\\_pubcomment.htm](http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm)).

**FOR FURTHER INFORMATION CONTACT:**

Other correspondence should be directed to Dr. William S. Stokes (919-541-2384 or [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov)).

**SUPPLEMENTARY INFORMATION:**

**Background**

In June 2004, the EPA Office of Pesticide Programs informed NICEATM that they were developing, via a subgroup of the Pesticide Program Dialogue Committee, a non-animal assessment approach for evaluating eye irritation potential and labeling requirements for AMCPs. Subsequently, the EPA in collaboration with the Alternative Testing Working Group (ATWG) developed a non-animal approach for this limited group of products. The ATWG is comprised of seven consumer product companies (Clorox, Colgate Palmolive, Dial, EcoLabs, Johnson Diversey, Procter & Gamble, and SC Johnson). The Institute for *In Vitro* Sciences, Inc. (IIVS), which coordinated the EPA-ATWG collaboration, performed additional testing to complete parallel sets of *in vivo* and *in vitro* data, and prepared a background review document (BRD) describing the final approach. More information concerning this submission is available at: <http://iccvam.niehs.nih.gov/methods/ocutox/AMCP.htm>.

In January 2008, IIVS submitted the BRD, *An In Vitro Approach for EPA Toxicity Labeling of Anti-Microbial Cleaning Products*, to NICEATM. The EPA and the ATWG requested that NICEATM and ICCVAM use information within the BRD to conduct a technical review of the proposed approach to determine whether ICCVAM could assure the EPA, with a

reasonable degree of certainty, that the approach would be useful for making labeling decisions for AMCPs that appropriately inform the user.

NICEATM and ICCVAM are now conducting a preliminary evaluation of the submission to determine its completeness and adherence to ICCVAM guidelines, which are available at [http://iccvam.niehs.nih.gov/SuppDocs/SubGuidelines/SD\\_subg034508.pdf](http://iccvam.niehs.nih.gov/SuppDocs/SubGuidelines/SD_subg034508.pdf). If they decide to move forward with an evaluation, NICEATM and ICCVAM will convene an independent peer review panel to review the validation status of the proposed approach.

**Request for Nominations of Scientific Experts**

NICEATM requests nominations of scientists with relevant knowledge and experience to serve on the peer review panel should it be convened. Areas of relevant expertise include, but are not limited to:

- Biostatistics
- Human and veterinary

ophthalmology, with an emphasis on evaluation and treatment of chemical injuries

- *In vivo* ocular toxicity testing
- *In vitro* ocular toxicology
- Test method validation

Each nomination should include the nominee's name, affiliation, contact information (i.e., mailing address, e-mail address, telephone and fax numbers), curriculum vitae, and a brief summary of relevant experience and qualifications. Nominations previously submitted to NICEATM in response to an earlier request for scientific experts for a possible peer panel review of *in vitro* ocular test methods used to evaluate AMCPs (**Federal Register** Vol. 70, No. 53, pp. 13512-13513, available at <http://iccvam.niehs.nih.gov>) do not need to be resubmitted.

**Request for Data**

NICEATM invites the submission of relevant data and information on AMCPs or related substances obtained from (1) human testing or experience including reports from accidental exposures, (2) rabbits using the standard eye test or the low volume eye test (LVET), and (3) *in vitro* test methods for assessing ocular irritation, such as the Bovine Corneal Opacity and Permeability (BCOP) test, the Cytosensor Microphysiometer (CM) test, and the EpiOcular test, including data supporting the accuracy and reproducibility of these methods.

Although data can be accepted at any time, data received by May 19, 2008 will be considered during the ICCVAM