biological product that is shown to meet the standards described in section 351(k)(4), means that the biological product may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

This guidance gives an overview of important scientific considerations in demonstrating interchangeability with a reference product, including:

- The data and information recommended to support a demonstration of interchangeability
- Considerations for the design and analysis of a switching study or studies to support a demonstration of interchangeability
- Considerations regarding the comparator product in a switching study or studies
- Abbreviated considerations for developing presentations, container closure systems, and delivery device constituent parts for proposed interchangeable products

This guidance finalizes the draft guidance issued on January 18, 2017. Changes made to the guidance took into consideration the comments received. FDA provided changes to clarify its recommendations for demonstrating interchangeability with the reference product. FDA intends to provide more detailed recommendations on the data and information recommended to support the proposed interchangeable product's presentation and related issues in a separate guidance.

In the **Federal Register** of January 18, 2017 (82 FR 5579), FDA announced the availability of the draft guidance for industry ''Considerations in Demonstrating Interchangeability With a Reference Product.'' FDA requested comment on the following questions: (1) Are there considerations in addition to comparability assessments that FDA should consider in regulating post-approval manufacturing changes of interchangeable products and (2) how, if at all, should the Agency consider conditions of use that are licensed for the reference product after an interchangeable product has been licensed. The comments submitted in response to these questions are being considered; FDA will address these topics in future guidance, as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Considerations in Demonstrating Interchangeability With a Reference Product.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information under 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information under 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information under section 351(k) of the PHS Act have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: May 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10001 Filed 5–10–19; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records Notice

AGENCY: Office of the Secretary of Health and Human Services (OS), Department of Health and Human Services (HHS).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, HHS is revising a department-wide system of records, System No. 09–90–1601 titled Outside Experts Recruited for Non-FACA Activities, to add records about outside consultants used by HHS' Administration for Children and Families, Office of Trafficking in Persons (ACF/OTIP).

DATES: The modified system of records is effective June 13, 2019, with the exception of the new and revised routine uses. The new and revised routine uses will be effective 30 days after publication of this notice, unless comments are received that warrant a revision to this notice. Comments should be submitted within 30 days of publication, but may be made at any time.

ADDRESSES: The public should submit written comments by mail or email to Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Bldg., Ste. 729H, 200 Independence Ave. SW, Washington, DC 20201, or *beth.kramer@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: General questions about the modified system of records may be submitted by mail or email to Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Bldg., Ste. 729H, 200 Independence Ave. SW, Washington, DC 20201, or *beth.kramer@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Explanation of Modifications Made to System No. 09–90–1601

This department-wide system of records covers records about individuals outside the HHS workforce who serve or are considered for service on mission-related committees and other activities (such as peer review programs) which require specific expertise or experience but are not subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App., *et seq.* The system of records has been modified to add the following records maintained by the Administration for Children and Families' Office on Trafficking in Persons (ACF/OTIP):

- *Consultants on Office on Trafficking in Persons (OTIP) projects.* ACF/OTIP contractors arrange for outside consultants to be used in OTIP programs (in addition to peer review programs) when technical assistance is needed in conferences, meetings, and evaluation projects that involve a specialized area of research, review, or advice.

The ACF/OTIP consultant records are similar in type and function to the other records currently covered by System No. 09–90–1601; *i.e.,:*

- *Curricula Vitae of Consultants to the National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC/NCHS) (formerly covered under SORN 09–20–0168).* This program maintains records about individuals with special expertise, training, and professional experience who may be enlisted to assist CDC/NCHS as consultants. The records are used by CDC/NCHS to select individuals to participate in

assignments such as: Planning and conducting surveys, studies, statistical reporting programs, and statistical analyses of data; providing training and technical assistance; and planning and conducting conferences.

• *The Food and Drug Administration (FDA) Patient Representative Program.* This program enlists individuals with patient advocacy experience to serve as patient representatives on both FACA committees and non-FACA assignments. For example, patient representatives may provide input that is used in making decisions to approve devices or drugs, or may contribute to discussions at presentations and conferences. Records about patient representatives are retrieved by the representatives' names, and are covered under either SORN No. 09–90–0059 or SORN No. 09–90–1601, depending on whether the records pertain to service on a FACA committee or service on a non-FACA assignment.

• *Peer Review Programs at the Administration for Children and Families (ACF), Health Resources and Services Administration (HRSA), and Substance Abuse and Mental Health Services Administration (SAMHSA) that recruit and use outside individuals to serve on peer review committees formed to review applications for grants and cooperative agreements.* These programs exist in several HHS components, but only ACF, HRSA, and SAMHSA sometimes use a personal identifier (*i.e.,* name) to retrieve administrative records about the outside individuals they recruit and use. Other components (including the Office of the Assistant Secretary for Health (OASH), Centers for Medicare & Medicaid Services (CMS), and National Institutes of Health (NIH)) use only non-personal identifiers (*e.g.,* expertise type, or funding opportunity announcement number) for retrieval.

• *Consultants on Other SAMHSA Projects.* SAMHSA contractors arrange for outside consultants to be used in other SAMHSA programs (besides peer review programs) when technical assistance is needed in conferences, meetings, and evaluation projects that involve a specialized area of research, review, or advice.

The System of Records Notice (SORN) for System No. 09–90–1601 has been reformatted to comply with OMB Circular A–108, issued December 23, 2016, and has been revised as follows to cover ACF/OTIP consultant records:

• The System Manager(s) section and Records Location section have been updated to identify the component responsible for ACF/OTIP consultant records.

• The Authority section now includes the legal authorities applicable to ACF/OTIP consultant records.

• The Categories of Individuals section has been revised to add ''human trafficking'' to the list of examples of outside experts' areas of expertise or experience.

• In the Categories of Records section, ''[d]ates and descriptions of current assignments'' has been added to the list of data elements that may be contained in the records.

• Routine use 7 has been revised to remove the following unnecessary wording: ''and that, therefore, the use of such records by the DOJ, court or other tribunal is deemed by HHS to be compatible with the purpose for which the agency collected the records.'' The wording is unnecessary because a routine use is defined in subsection (a)(7) of the Privacy Act as a disclosure of a record for a use that is compatible with the purpose for which the record was collected.

Because some of these revisions are significant, a report on the modified system of records was sent to Congress and OMB in accordance with 5 U.S.C. 552a(r).

Dated: May 8, 2019.

Michael S. Marquis,

Director, FOIA/Privacy Act Division, Assistant Secretary for Public Affairs.

Dated: May 8, 2019.

Anita E. Alford,

Chief Information Security Officer and OpDiv Senior Officer for Privacy, Office of the Chief Information Officer, Administration for Children and Families.

SYSTEM NAME AND NUMBER

Outside Experts Recruited for Non-FACA Activities, 09–90–1601.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of each agency component responsible for the system of records is provided in the System Manager(s) section. Records locations include:

▪ CDC program offices that recruit consultants to assist in statistical projects and reporting programs conducted or sponsored by NCHS, in Atlanta, GA and Hyattsville, MD;

▪ FDA's committee management office in Silver Spring, MD;

▪ Program offices at ACF in Washington, DC, at HRSA in Rockville, MD, and at SAMHSA in Rockville, MD, that recruit individuals to serve as peer reviewers; and

▪ Locations of SAMHSA contractors that arrange use of consultants on SAMHSA projects, and locations of ACF/OTIP contractors that arrange use of consultants on OTIP projects.

SYSTEM MANAGER(S):

For CDC/NCHS Consultant Records: Centers for Disease Control and Prevention (CDC), Director, National Center for Health Statistics, OPHSS, Prince George's Metro IV Bldg., Rm. 7209, MS P08, 3311 Toledo Rd., Hyattsville, MD 20782, (301) 458–4000.

For FDA Patient Representative Records: Food and Drug Administration (FDA), Advisory Committee Oversight & Management Staff, 10903 New Hampshire Ave., Bldg. WO32, Rm. 5129, Silver Spring, MD 20993–002, (301) 443–0572.

For ACF Peer Reviewer Records: Administration for Children and Families (ACF), Privacy Act Contact, Office of the Chief Information Officer, 330 C St. SW, Washington, DC 20201, *OCIO.Privacy@acf.hhs.gov,* (202) 401–4628.

For HRSA Peer Reviewer Records: Health Resources and Services Administration (HRSA), Chief, Policy, Analysis & Training Branch, Division of Independent Review, Office of Federal Assistance Management, 5600 Fishers Ln., Rockville, MD 20857, (301) 443–4767.

For SAMHSA Peer Reviewer Records: Substance Abuse and Mental Health Services Administration (SAMHSA), Director, Division of Grant Review, 5600 Fishers Ln., Rockville, MD 20852, (240) 276–1199.

For Other Consultant Records, Maintained by SAMHSA Contractors: Substance Abuse and Mental Health Services Administration (SAMHSA), Director, Division of Contracts Management, Office of Program Services, 5600 Fishers Ln., Rockville, MD 20852, (240) 276–1500.

For Other Consultant Records, Maintained by ACF/OTIP Contractors: Office on Trafficking in Persons (OTIP), Deputy Director, Mary E. Switzer Building, 330 C St. SW, Washington, DC 20201, (202) 401–9372.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

For CDC/NCHS Consultant Records: 42 U.S.C. 242b(b)(3).

For FDA Patient Representative Records: 21 U.S.C. 360bbb–8c, 371 *et seq.,* 379d–1(b)(1)(A).

For ACF Peer Reviewer Records: 42 U.S.C. 799(f), 806(e).

For HRSA Peer Reviewer Records: 42 U.S.C. 799(f), 806(e).

For SAMHSA Peer Reviewer and Other Consultant Records: 42 U.S.C. 241, 249(c), 290aa *et seq.,* 290aa–5, 290bb *et seq.,* 290bb–21 *et seq.,* 290bb–

31 *et seq.,* 5121 *et seq.,* 10801 *et seq.;* 8 U.S.C. 1522 note; Executive Order 12341.

For OTIP Consultant Records: 22 U.S.C. 7104(b), 7105(b)(1)(G), (c)(4), and (f); 42 U.S.C. 1314b.

See also: 5 U.S.C. 3109.

PURPOSE(S):

The records are used within the agency on a need-to-know basis for the purpose of staffing committees and other assignments and managing administrative matters pertaining to individuals serving on committees and other assignments, including to:

- Prepare reports and lists of past, present, and recommended members, vacancies, acceptances, and separations;
- Send recruitment notices to individual prospective candidates, and send informational notices to selectees;
- Identify qualified candidates and document the selections; and
- Manage and coordinate the selected individuals' participation in assignment activities (including sharing information within the agency to coordinate aspects such as badging, parking, travel, training, and payment of any stipend or honorarium).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records in this system pertain to individuals outside the HHS workforce who serve or are considered for service on HHS mission-related committees or other assignments that require specific outside expertise or experience (for example, medical, scientific, manufacturing, or human trafficking expertise, or patient advocacy experience), but that are not subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App., *et seq.*

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of recruitment and other administrative records, including:

- An application and resume or curricula vitae, describing the individual's qualifications;
- Nomination/recommendation records, or other records used in evaluating an individual's qualifications and any potential conflicts of interest and selecting an individual for a specific assignment; and
- Records used to plan and arrange the individual's participation in the assigned activities, including scheduling records and records used to coordinate parking, badging, and payment of any stipend or honorarium.

The records may contain these data elements:

- The individual's name and other identifying information (*e.g.,* sex, place and date of birth);
- Contact information (*e.g.,* home and business addresses, telephone numbers, email addresses);
- Occupation, job titles, employers, employment status and history, and whether currently employed by the federal government;
- Work and organizational affiliations, memberships, credentials, and licenses;
- Degrees held, and general educational and/or experience background;
- Racial classification or ethnic background;
- Areas of specialization, expertise, or experience, and special qualifications (*e.g.,* language or technical skills, ability to drive to an assignment);
- Dates and descriptions of past assignments or past experience;
- Dates and descriptions of current assignments;
- Sources and references, and any information provided by sources/references; and
- Information about availability and any special needs.

Any special needs, medical condition, or similar information contained in an individual's records is maintained and used in accordance with relevant provisions of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 791 *et seq.,* and implementing regulations at 29 CFR parts 1614 and 1630, and the Genetic Information Nondiscrimination Act of 2008 at 42 U.S.C. 2000ff *et seq.*

RECORD SOURCE CATEGORIES:

Most information is obtained directly from the individual record subject. Information pertaining to references and recommendations is obtained from other private individuals, educational institutions, current and former employers, HHS program personnel, biographical reference books, private organizations, members of Congress, and other government sources.

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

HHS may make the following disclosures of information about an individual record subject from this system of records to parties outside the agency without the individual's prior, written consent:

1. Disclosures may be made to federal agencies and Department contractors that have been engaged by HHS to assist in accomplishment of an HHS function relating to the purposes of this system of records and that have a need to have access to the records in order to assist HHS in performing the activity. Any contractor will be required to comply with the requirements of the Privacy Act.

2. Records may be disclosed to parties such as educational institutions, current and former employers, and qualified experts, when necessary to check or obtain an opinion about a candidate's qualifications.

3. Records about consultants and patient advocates may be disclosed to parties organizing or hosting assignment activities, such as grantee institutions and federal, foreign, state, tribal, local, and other government agencies and public authorities (*e.g.,* U.S. Embassies and Ministries of Health), when necessary to apprise them of an individual's qualifications for the assignment or coordinate the individual's participation in the activities.

4. Records may be disclosed to supervisors and administrative assistants at the individual's place of employment, for administrative purposes such as coordinating the individual's participation in the activities.

5. Records may be disclosed to external parties that audit committee or assignment activities.

6. Relevant information will be included in any required reports to the President, the Office of Management and Budget (OMB), and the General Services Administration (GSA) about committees and other assignments that are mission-related.

7. Information may be disclosed to the U.S. Department of Justice (DOJ) or to a court or other tribunal, when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation and, by careful review, HHS determines that the records are both relevant and necessary to the litigation.

8. 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.

9. Disclosures may be made to the National Archives and Records Administration (NARA) and/or the General Services Administration (GSA) for the purpose of records management

inspections conducted under 44 U.S.C. 2904 and 2906.

10. Information may be disclosed to a Member of Congress or a Congressional staff member in response to a written inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained. The Congressional office does not have any greater authority to obtain records than the individual would have if requesting the records directly.

11. Records may be disclosed to the U.S. Department of Homeland Security (DHS) if captured in an intrusion detection system used by HHS and DHS pursuant to a DHS cybersecurity program that monitors internet traffic to and from federal government computer networks to prevent a variety of types of cybersecurity incidents.

12. Records may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records, (2) HHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HHS (including its information systems, programs, and operations), the federal government, or national security, and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

13. Records may be disclosed to another federal agency or federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

The disclosures authorized by publication of the above routine uses pursuant to 5 U.S.C. 552a(b)(3) are in addition to other disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b)(4)–(11).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in hard-copy files and electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the individual's name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records pertaining to recruitment and use of outside peer reviewers are destroyed three years after final action; they are retained longer if required for business use (see General Records Schedule (GRS) 1.2, Item 010, Grant and Cooperative Agreement Program Management Records). Records pertaining to recruitment and use of other outside individuals (*e.g.,* experts, patient advocates, and members of mission-related non-FACA committees) are currently unscheduled. Unscheduled records must be retained indefinitely pending the agency's submission, and NARA's approval, of a disposition schedule. HHS anticipates proposing to NARA, as an appropriate retention period for these records, ''three years after final action, or longer if required for business use'' (similar to the period provided in GRS 1.2, Item 010) or ''when no longer needed for administrative purposes'' (similar to the periods applicable to similar records not retrieved by personal identifier which are not covered under this SORN; *i.e.:* N1–442–93–1, Item 37 for the Agency for Toxic Substances and Disease Registry's Curriculum Vitae Files, and NC1–235–82–1, Item 100–3 for the Office of the Secretary's Advisory Committee Candidate Resume Files).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Safeguards conform to the HHS Information Security and Privacy Program, *https://www.hhs.gov/ocio/securityprivacy/index.html.* Information is safeguarded in accordance with applicable laws, rules and policies, including the HHS Information Technology Security Program Handbook, all pertinent National Institutes of Standards and Technology (NIST) publications, and OMB Circular A–130, Managing Information As a Strategic Resource. Records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras, securing hard-copy records in locked file cabinets, file rooms or offices during off-duty hours, limiting access to electronic databases to authorized users based on roles and two-factor authentication (user ID and password), using a secured operating system protected by encryption, firewalls, and intrusion detection systems, requiring encryption for records stored on removable media, and training personnel in Privacy Act and information security requirements. Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800–88.

RECORD ACCESS PROCEDURES:

An individual seeking access to records about him or her in this system should submit a written request to the relevant System Manager indicated in the ''System Manager(s)'' section above. The requester must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act, subject to a five thousand dollar fine.

CONTESTING RECORD PROCEDURES:

An individual seeking to amend a record about him or her in this system should contact the relevant System Manager indicated in the ''Section Manager(s)'' section, verify his or her identity in the manner indicated in the ''Record Access Procedures'' section, and reasonably identify the record, specify the information contested, state the corrective action sought, and provide the reasons for the amendment, with any supporting documentation.

NOTIFICATION PROCEDURES:

An individual who wishes to know if this system contains records about him or her should contact the relevant System Manager indicated in the ''Section Manager(s)'' section and verify his or her identity in the manner indicated in the ''Record Access Procedures'' section.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HISTORY:

81 FR 83246 (Nov. 21, 2016), 83 FR 6591 (Feb. 14, 2018).

[FR Doc. 2019–09926 Filed 5–13–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Meeting of the National Clinical Care Commission

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Clinical Care Commission (the Commission) will