d. A reasonably specific description of the record content being sought.

Individuals requesting access to records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 2606).

CONTESTING RECORD PROCEDURES:

Because the information in these records is updated on a periodic basis, most record corrections can be handled through established administrative procedures for updating records. However, individuals can obtain information on the procedures for contesting the records under the provisions of the Privacy Act by contacting the DAEO or designee at the agency where the reports were filed.

NOTIFICATION PROCEDURES:

Individuals wishing to inquire whether this system of records contains information about them should contact the DAEO at the department or agency concerned. For records maintained at OGE, contact the OGE Senior Agency Official for Privacy, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917.

Individuals wishing to make such an inquiry must furnish the following information for their records to be located and identified:

a. Full name.

b. Department or agency and component where employed or where proposed to be employed.

c. Dates of employment.

Individuals seeking to determine if an OGE system of records contains information about them must also follow OGE's Privacy Act regulations regarding verification of identity (5 CFR part 2606).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This system of records was originally published in full at 55 FR 6327 (Feb. 22, 1990) and subsequently amended by 68 FR 3097 (Jan. 22, 2003) and 68 FR 24744 (May 8, 2003).

Approved: September 4, 2019.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2019–19373 Filed 9–6–19; 8:45 am]

BILLING CODE 6345–03–P

OFFICE OF GOVERNMENT ETHICS

Privacy Act of 1974; Systems of Records

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of a modified system of records.

SUMMARY: OGE proposes to revise an existing Governmentwide system of records under the Privacy Act, covering Executive Branch Personnel Public Financial Disclosure Reports and Other Name-Retrieved Ethics Program Records.

DATES: This action will be effective without further notice on November 8, 2019 unless comments received before this date would result in a contrary determination.

ADDRESSES: Comments may be submitted to OGE by any of the following methods:

Email: usoge@oge.gov (Include reference to ''OGE/GOVT–1'' in the subject line of the message.)

Mail, Hand Delivery/Courier: Office of Government Ethics, 1201 New York Avenue NW, Suite 500, Attention: Jennifer Matis, Associate Counsel, Washington, DC 20005–3917.

Instructions: Comments may be posted on OGE's website, *www.oge.gov.* Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information before posting.

FOR FURTHER INFORMATION CONTACT: Jennifer Matis at the U.S. Office of Government Ethics; telephone: 202–482–9216; TTY: 800–877–8339; FAX: 202–482–9237; Email: *jmatis@oge.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, this document provides public notice that OGE is proposing to revise and update the OGE/GOVT–1 Governmentwide system of records in several respects. A Governmentwide system of records is a system of records where one agency (in this case, OGE) has regulatory authority over records in the custody of multiple agencies and the agency with regulatory authority publishes a system of records notice that applies to all of the records regardless of their custodial location.

OGE proposes to add or modify several routine uses to allow for greater transparency into executive branch ethics records. Specifically, the new routine use (l.) permits OGE to make public without restriction a certificate of divestiture issued by OGE. The new routine use (m.) permits OGE to make public without restriction waivers of the requirements contained in Executive Order 13770 ''Ethics Commitments by Executive Branch Appointees'' (January 28, 2017) or any superseding Executive order. OGE also proposes to modify routine use (k.) (formely routine use (l.)) to clarify that certifications of ethics agreement compliance may be disclosed in the same manner as the ethics agreements themselves. Notwithstanding any of these changes, however, OGE will continue to release documents only to the extent consistent with 5 CFR 2634.603(b).

These changes further the purposes of the Freedom of Information Act, as amended, 5 U.S.C. 552, and the Office of Management and Budget's (OMB) Open Government Directive, M–10–06, (December 8, 2009). OGE's prevention mission involves engaging the public to inform them about the systems in place to detect and resolve conflicts of interests of their Government leaders. This, in turn, allows the public to engage in overseeing the integrity of its Government and increases public confidence in Government decisionmaking. Accordingly, promoting transparency into the executive branch ethics program is also a key element of OGE's 2018–2022 Strategic Plan, which sets forth strategic objectives to *Inform the Public about OGE and the Executive Branch Ethics Program* (Strategic Objective 4.1) and *Make Ethics Information Publicly Available* (Strategic Objective 4.2). Moreover, OGE's stakeholders, including non-governmental organizations, Congress, and the general public, have expressed interest in increased transparency into the ethics commitments made by executive branch officials.

In addition to these changes promoting transparency, OGE proposes to modify routine use (h.) (formerly routine use (i.)) to explicitly indicate that statements notifying an employee's supervising ethics office of the commencement of negotiations for future employment or compensation, or of an agreement for future employment or compensation, may be disclosed to reviewing officials in a new office, department, or agency when an employee transfers or is detailed from one covered position to another. These statements, mandated by the Representative Louise McIntosh Slaughter Stop Trading on Congressional Knowledge Act (STOCK Act), Public Law 112–105 (2012), are commonly called ''STOCK Act notifications.'' It is OGE's position that such disclosures are currently permitted

pursuant to routine use (d.) (formerly routine use (e.)). However, this change would provide greater clarity for agency ethics officials and executive branch employees who may not realize that such a disclosure is permitted under the current language.

OGE proposes to add two additional new routine uses as required by OMB Memorandum ''Preparing for and Responding to a Breach of Personally Identifiable Information,'' M–17–12, (January 3, 2017). These new routine uses allow agencies to disclose information when necessary to respond to a suspected or confirmed breach or to prevent, minimize, or remedy harm resulting from such a breach.

OGE proposes to modify routine uses (g.) (formerly routine use (h.)) and (i.) (formerly routine use (j.)) and remove the old routine use (d.) in accordance with OMB and Department of Justice guidance and applicable case law. The remaining routine uses have been re-designated accordingly.

OGE proposes to change the description of the categories of individuals covered by the system of records to make it more clear and easy to understand. By eliminating much of the technical description, the new language is more concise and consistent with plain language goals. No substantive change in the categories of individuals covered by the system of records is proposed.

Finally, the changes will update the system manager and notification procedure in accordance with OGE's current organizational structure, update the authority for maintenance of the system, update the administrative, technical, and physical safeguards, clarify the language in the ''Purpose'' section, and make minor editorial changes.

Accordingly, the Office of Government Ethics is publishing the following notice of a revised Governmentwide system of records covering Executive Branch Personnel Public Financial Disclosure Reports and Other Name-Retrieved Ethics Program Records:

SYSTEM NAME AND NUMBER:

OGE/GOVT–1, Executive Branch Personnel Public Financial Disclosure Reports and Other Name-Retrieved Ethics Program Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917, and designated agency ethics offices.

SYSTEM MANAGER(S):

a. For records filed directly with the Office of Government Ethics by non-OGE employees: General Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917.

b. For records filed with a Designated Agency Ethics Official (DAEO) or the head of a department or agency: The DAEO at the department or agency concerned.

c. For records filed with the Federal Election Commission (FEC) by candidates for President or Vice President: The General Counsel, Office of General Counsel, Federal Election Commission, 999 E Street NW, Washington, DC 20463.

d. For general questions about this system of records, contact the OGE Senior Agency Official for Privacy, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); 31 U.S.C. 1353; E.O. 12674 (as modified by E.O. 12731); E.O. 13770 or any superseding Executive order; Representative Louise McIntosh Slaughter Stop Trading on Congressional Knowledge Act (STOCK Act), Public Law 112–105 (2012); 5 CFR part 2634.

PURPOSE(S) OF THE SYSTEM:

All records are collected and maintained in accordance with the requirements of the Ethics in Government Act of 1978 and the Ethics Reform Act of 1989, as amended, and Executive Order 12674, as modified, and OGE and agency regulations thereunder. These records include the filing of financial disclosure reports and ethics agreements, waivers issued to an officer or employee pursuant to section 208 of title 18 or Executive order, and certificates of divestiture issued pursuant to section 502 of the Ethics Reform Act. Such reports and related records are required to assure compliance with ethics laws and regulations, and to determine if an actual or apparent conflict of interest exists between the employment of individuals by the Federal Government and their outside employment and financial interests.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records contains records about individuals whose positions have been designated as public financial disclosure filing positions in accordance with 5 U.S.C. app. 101 and 5 CFR 2634.202. This system of records includes both former and current employees in these categories who have filed financial disclosure statements under the requirements of the Ethics in Government Act of 1978, as amended, or who otherwise come under the requirements of the Ethics in Government Act. This system of records also contains information that is necessary for administering all provisions of the Ethics in Government Act of 1978 and the Ethics Reform Act of 1989 (Pub. L. 101–194), as amended, and E.O. 12674, as modified, on any current or former officer or employee of the executive branch.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records contains: Financial information such as salary, dividends, retirement benefits, interests in property, deposits in a bank and other financial institutions; information on gifts received; information on certain liabilities; information about positions as an officer, director, trustee, general partner, proprietor, representative, employee, or consultant of any corporation, company, firm, partnership, or other business, non-profit organization, labor organization, or educational institution; information about non-Government employment agreements, such as leaves of absence to accept Federal service, continuation of payments by a non-Federal employer; and information about assets placed in trust pending disposal. This system of records also includes other documents developed or information and material received by the Director of the Office of Government Ethics, or agency ethics officials in administering the Ethics in Government Act of 1978 or the Ethics Reform Act of 1989, as amended, which are retrieved by name or other personal identifier. Such other documents or information may include, but will not be limited to: ethics agreements, documentation of waivers issued to an officer or employee by an agency pursuant to section 208(b)(1) or section 208(b)(3) of title 18, U.S.C., or pursuant to Executive orders; certificates of divestiture issued by the President or by the Director of OGE pursuant to section 502 of the Ethics Reform Act of 1989; information necessary for the rendering of ethics counseling, advice or formal advisory opinions, or the resolution of complaints; the actual opinions issued; and records of referrals and consultations regarding current and former employees who are or have been the subject of conflicts of interest or standards of conduct inquiries or

determinations, or employees who are alleged to have violated department, agency or Federal ethics statutes, rules, regulations or Executive orders. Such information may include correspondence, documents or material concerning an individual's conduct, reports of investigations with related exhibits, statements, affidavits or other records obtained during an inquiry. The information does not include information from confidential financial disclosure reports, which is maintained in OGE/GOVT–2, Executive Branch Confidential Financial Disclosure Reports.

These records may include information related to personal and family financial and other business interests, positions held outside the Government and acceptance of gifts. The records may also contain reports of action taken by the agency and decisions and reports on legal or disciplinary action resulting from any referred administrative action or prosecution.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by:

a. The subject individual or by a designated person, such as a trustee, attorney, accountant, banker, or relative.

b. Federal officials who review the statements to make conflict of interest determinations.

c. Persons alleging conflict of interests or violations of other ethics laws and persons contacted during any investigation of the allegations.

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

These records and information in these records may be used:

a. To disclose information furnished in accordance with sections 105 and 402(b)(1) of the Ethics in Government Act of 1978, 5 U.S.C. app., as amended, and subject to the limitations contained therein, to any requesting person.

b. To disclose to any requesting person, in accordance with section 105 of the Ethics in Government Act, as amended, and subject to the limitations contained in section 208(d)(1) of title 18, U.S.C., any determination granting an exemption pursuant to 208(b)(1) or 208(b)(3) of title 18, U.S.C. These determinations are commonly called ''conflict of interest waivers.''

c. To disclose pertinent information to the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

d. To disclose information to any source when necessary to obtain information relevant to a conflict-of-interest investigation or determination.

e. To disclose information to the National Archives and Records Administration or the General Services Administration in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

f. To disclose information to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A–19.

g. To disclose information when the disclosing agency determines that that the records are arguably relevant to a proceeding before a court, grand jury, or administrative or adjudicative body; or in a proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

h. To disclose the public financial disclosure report and any accompanying documents, including statements notifying an employee's supervising ethics office of the commencement of negotiations for future employment or compensation or of an agreement for future employment or compensation pursuant to section 17 of the STOCK Act (Pub. L. 112–105), to reviewing officials in a new office, department or agency when an employee transfers or is detailed from a covered position in one office, department or agency to a covered position in another office, department or agency.

i. To disclose information to a Member of Congress or a congressional office in response to an inquiry made on behalf of, and at the request of, an individual who is the subject of the record.

j. To disclose information to contractors, grantees, experts, consultants, detailees, and other non-Government employees performing or working on a contract, service, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records.

k. To disclose on the OGE website and to otherwise disclose to any person, including other departments and agencies, any written ethics agreements, including certifications of ethics agreement compliance, filed with the Office of Government Ethics, pursuant to 5 CFR 2634.803, by an individual nominated by the President to a position requiring Senate confirmation when the position also requires the individual to file a public financial disclosure report.

l. To disclose on the OGE website and to otherwise disclose to any person, including other departments and agencies, any certificate of divestiture issued by the Office of Government Ethics, pursuant to 26 U.S.C. 1043.

m. To disclose on the OGE website and to otherwise disclose to any person, including other departments and agencies, any waiver issued by the President or the President's designee of the restrictions contained in Executive Order 13770 ''Ethics Commitments by Executive Branch Appointees'' (January 28, 2017) or any superseding Executive order.

n. To disclose information to appropriate agencies, entities, and persons when: (1) The agency maintaining the records suspects or has confirmed that there has been a breach of the system of records; (2) the agency maintaining the records has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the agency (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 the agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

o. To disclose information to another Federal agency or Federal entity, when the agency maintaining the record 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.

Note: When an agency is requested to furnish records in this system of records to the Director or other authorized officials of the Office of Government Ethics (OGE), such a disclosure is to be considered as made to those officers and employees of the agency which co-maintains the records who have a need for the records in the performance of their official duties in accordance with the Ethics in Government Act of 1978, 5 U.S.C. app., and other ethics-related laws, Executive orders and regulations conferring pertinent authority on OGE, pursuant to the provisions of the Privacy Act at 5 U.S.C. 552a(b)(1).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records are maintained in paper and/or electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are retrieved by the name or other programmatic identifier assigned to the individual about whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with the National Archives and Records Administration General Records Schedule 2.8 Employee Ethics Records, these records are generally retained for a period of six years after filing, or for such other period of time as is provided for in that schedule for certain specified types of ethics records. In cases where records are filed by, or with respect to, a nominee for an appointment requiring confirmation by the Senate when the nominee is not appointed and Presidential and Vice-Presidential candidates who are not elected, the records are generally destroyed one year after the date the individual ceased being under Senate consideration for appointment or is no longer a candidate for office. However, if any records are needed in an ongoing investigation, they will be retained until no longer needed in the investigation. Destruction is by shredding or electronic deletion.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

These records are maintained in file cabinets which may be locked or in specified areas to which only authorized personnel have access. Access to the data in the executive branch-wide *Integrity* public financial disclosure information system and OGE electronic systems is protected by electronic controls, such as multifactor authentication and password protection. Access to the systems is controlled based on user roles and responsibilities. Executive branch agencies control their users' access to information in *Integrity* and are responsible for properly safeguarding the records maintained in their systems.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should contact the appropriate office as shown in the Notification Procedure section. Individuals must furnish the following information for their records to be located and identified:

a. Full name.

b. Department or agency and component with which employed or proposed to be employed.

c. Dates of employment.

d. A reasonably specific description of the record content being sought.

Individuals requesting access to records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 2606).

CONTESTING RECORD PROCEDURES:

Because the information in these records is updated on a periodic basis, most record corrections can be handled through established administrative procedures for updating the records. However, individuals can obtain information on the procedures for contesting the records under the provisions of the Privacy Act by contacting the appropriate office shown in the Notification Procedure section.

NOTIFICATION PROCEDURES:

Individuals wishing to inquire whether this system of records contains information about them should contact, as appropriate:

a. For records filed directly with OGE by non-OGE employees, contact the General Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917;

b. For records filed with a Designated Agency Ethics Official (DAEO) or the head of a department or agency, contact the DAEO at the department or agency concerned; and

c. For records filed with the FEC by candidates for President or Vice President, contact the FEC General Counsel, Federal Election Commission, 999 E Street NW, Washington, DC 20463.

Individuals wishing to make such an inquiry must furnish the following information for their records to be located and identified:

a. Full name.

b. Department or agency and component with which employed or proposed to be employed.

c. Dates of employment.

Individuals seeking to determine if an OGE system of records contains information about them must also follow OGE's Privacy Act regulations regarding verification of identity (5 CFR part 2606).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This system of records was originally published in full at 55 FR 6327 (Feb. 22, 1990) and subsequently amended by the following notices: 68 FR 3097 (Jan. 22, 2003); 68 FR 24744 (May 8, 2003); 76 FR 24489 (May 2, 2011); 77 FR 45353 (July 31, 2012); 78 FR 73863 (Dec. 9, 2013).

Approved: September 4, 2019.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2019–19372 Filed 9–6–19; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0549]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Use of Symbols in Labeling—Glossary To Support the Use of Symbols in Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by October 9, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0740. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.