sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Below we provide AHRQ's projected average annual estimates for the next three years:

Current Actions: New collection of information.

Type of Review: New Collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of activities: 10.

Respondents: 10,900.

Annual responses: 10,900.

Frequency of Response: Once per request.

The total number of respondents across all 10 activities in a given year is 10,900.

Average minutes per response: 19.

Burden hours: 3,383.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 11, 2020.

Marquita Cullom-Stott,

Associate Director.

[FR Doc. 2020–20467 Filed 9–16–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program

AGENCY: Centers for Medicare and Medicaid Services, Department of Health and Human Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) is providing notice of a new agreement re-establishing the ''Do Not Pay Initiative'' matching program between CMS and the Department of Treasury, Bureau of Fiscal Service (Fiscal Service).

DATES: The deadline for comments on this notice is October 19, 2020. The matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. Pursuant to 31 U.S.C. 3354(d)(1)(C), the matching program will be conducted for an initial term of 36 months (approximately October 13, 2020 to October 12, 2023) and within three months of expiration may be renewed for three additional years if the parties make no change to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit written comments on this notice to the CMS Privacy Act Officer by mail at: Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850, or email *walter.stone@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact John Sofokles, Government Technical Lead, Center for Program Integrity, Centers for Medicare & Medicaid Services, at 410–786–6373, by email at *john.sofokles@cms.hhs.gov,* or by mail at 7500 Security Blvd., Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a), provides certain protections for individuals applying for and receiving payments under federal benefit programs. The law governs the use of computer matching by federal agencies when records in a system of records (meaning, federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other federal or non-federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o)(2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopulos.

Privacy Advisor, Division of Security, Privacy Policy and Governance, Office of Information Technology, Centers for Medicare & Medicaid Services.

PARTICIPATING AGENCIES:

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Department of the Treasury (Treasury), Bureau of Fiscal Service (Fiscal Service) is the source agency.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

The statutory authorities for the matching program are Executive Order 13520 ''Reducing Improper Payments''

(Nov. 20, 2009); Presidential Memorandum on Enhancing Payment Accuracy through a ''Do Not Pay List'' (June 18, 2010); 31 U.S.C. 3351 *et seq.;* OMB Memorandum M–18–20 Transmittal of Appendix C to OMB Circular A–123, Requirements for Payment Integrity Improvement (June 16, 2018), and 5 U.S.C. 552a.

PURPOSE(S):

The purpose of the matching program is to provide CMS with information from Treasury's Working System which CMS will use to identify Medicare providers and suppliers who are ineligible for Medicare enrollment; to promptly suspend or revoke the Medicare billing privileges of the identified disqualified providers and suppliers; to enable recoupment of past payments made to those providers and suppliers; to assist CMS in detecting and preventing fraud, waste, abuse and in avoiding making future improper payments to disqualified providers and suppliers; and to enhance patient safety for beneficiaries in CMS programs.

CATEGORIES OF INDIVIDUALS:

The categories of individuals involved in the matching program are individual providers and suppliers who bill Medicare for payment.

CATEGORIES OF RECORDS:

The categories of records used in the matching program are identifying data, and payment eligibility status data. To request information from Treasury's Working System, CMS will provide Fiscal Service with the following information about a Medicare provider or supplier: Tax Identification Number (TIN), Business Name, Person First Name, Person Middle Name, Person Last Name, Address, City Name, State Code, Person Date of Birth, Person Sex, Vendor/Payee Phone Number, Vendor/Payee Email Address.

When Fiscal Service is able to match the TIN and other identifying data provided by CMS, Fiscal Service will disclose to CMS the following information about that provider or supplier:

Record Code.
Payee Identifier.
Agency Location Code.
Tax Identification Type.
Tax Identification Number.
Business or Individual or Government.
DUNS Number.
Payee Business Name.
Payee Business DBA Name.
Person Full Name.
Person First Name.
Person Middle Name.
Person Last Name.
Address.
Person Date of Birth.
Person Sex.
Vendor/Payee Status.
Phone Type.
Vendor/Payee Phone Number.
Vendor/Payee Fax Number.
Vendor/Payee Email Address.
Vendor/Payee Active Date.
Vendor/Payee Expiration Date.
Agency Record Grouping.
Other Agency Data.
Match Type.
Match Source.
Match Level.
Match Date/Time.
Matched Party Type.
Matched Tax ID Number.
Matched Tax ID Type Code (alternate).
Matched Tax ID Number (alternate).
Match DUNS Number.
Matched Full Name.
Matched First Name.
Matched Middle Name.
Matched Last Name.
Matched Business Name.
Matched DBA Business Name.
Matched Birth Date.
Matched Death Date.
Matched List Status Code.
Matched List Status Code Description.
Matched List Effective Date.
Matched Address.
Matched City.
Matched State Code.
Matched Zip Code.
Matched Country Code.

SYSTEM(S) OF RECORDS:

The records used in this matching program will be disclosed from the following systems of records, as authorized by relevant routine uses published in the System of Records Notices (SORNs) cited below:

A. SYSTEM OF RECORDS MAINTAINED BY CMS:

• The Provider Enrollment, Chain, and Ownership System (PECOS), System No. 09–70–0532, 71 FR 60536 (Oct. 13, 2006), 78 FR 32257 (May 29, 2013) and 83 FR 6591 (Feb. 14, 2018).

B. SYSTEM OF RECORDS MAINTAINED BY FISCAL SERVICE:

• The Department of the Treasury, Bureau of the Fiscal Service .017—Do Not Pay Payment Verification Records, 85 FR 11776 at 11803 (Feb. 27, 2020).

[FR Doc. 2020–19956 Filed 9–16–20; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2020–N–1735]

Eisai, Inc.; Withdrawal of Approval of Two New Drug Application for BELVIQ (lorcaserin hydrochloride) and BELVIQ XR (lorcaserin hydrocholoride)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of two new drug applications for BELVIQ (lorcaserin hydrochloride (HCl)) tablets and BELVIQ XR (lorcaserin HCl) extended-release tablets held by Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07677 (Eisai). Eisai requested withdrawal of these applications and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 17, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: FDA approved NDA 022529 for BELVIQ (lorcaserin HCl) 10 milligrams (mg) tablets and NDA 208524 for BELVIQ XR (lorcaserin HCl) 20 mg extended-release tablets on June 27, 2012 and July 15, 2016, respectively, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

• 30 kg/m^2 or greater (obese) or
• 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (*e.g.,* hypertension, dyslipidemia, type 2 diabetes).

On January 14, 2019, FDA issued a Drug Safety Communication alerting the public that results from a clinical trial assessing the risk of heart-related problems show a possible increased risk of cancer with BELVIQ and BELVIQ XR (see *https://www.fda.gov/drugs/drug-safety-and-availability/safety-clinical-trial-shows-possible-increased-risk-cancer-weight-loss-medicine-belviq-belviq-xr*). On February 13, 2020, FDA announced it had asked Eisai to voluntarily withdraw BELVIQ and BELVIQ XR from the U.S. market because a safety clinical trial showed an increased occurrence of cancer (see