(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

https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market).

On February 13, 2020, Eisai requested that FDA withdraw approval of NDA 022529 for BELVIQ and NDA 208524 for BELVIQ XR under § 314.150(d) (21 CFR 314.150(d)), and waived its opportunity for a hearing.

For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 022529 BELVIQ (lorcaserin HCl) tablets and 208524 BELVIQ XR (lorcaserin HCl) extended-release tablets, and all amendments and supplements thereto, are withdrawn under § 314.150(d). Distribution of BELVIQ into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: September 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20458 Filed 9–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–2002–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—April Through June 2020

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from April through June 2020. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Jon Dorman, by telephone at (571) 457–7220, or by email at *jon.dorman@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary within the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage organizations (MAOs), Medicaid State agencies, and applicable plans, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors (PDPSs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization determination, coverage determination, and at-risk determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an Independent Review Entity (IRE) for Part C organization determination appeals, or by PDPSs and an IRE for Part D coverage determination and at-risk determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges and attorney adjudicators. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council (Council). In addition, OMHA and the DAB administer the second and third levels of appeal, respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. To help ensure nationwide consistency in that effort, OMHA established a manual, the OCPM. Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations and at-risk determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that the Secretary publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every three months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the three-month period of April through June 2020. A hyperlink to the available chapters on the OMHA website is provided below. The OMHA website contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA website provides more timely access to the current OCPM chapters for those involved in the Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals processes. We also believe the website offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive notification of certain updates to the OMHA website, including when new or revised OCPM chapters are posted. If accessing the OMHA website proves to be difficult, the contact person listed above can provide the information.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. The OCPM can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*