

<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tablets and 208524 BELVIQ XR (lorcaserin HCl) extended-release tablets, and all amendments and supplements thereto, are withdrawn under § 314.150(d).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]

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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 (PDPs), 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 PDPs 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>.

IV. OCPM Releases for April Through June 2020

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of OCPM provisions that were issued or revised in the three-month period of April through June 2020. This information is available on our website at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>.

OCPM Chapter 2: Information Disclosure

On June 17, 2020, OMHA issued OCPM Chapter 2, which describes the process used by OMHA staff when addressing communications with parties and non-parties, responding to inquiries from the public and governmental entities, safeguarding information in accordance with applicable law, and, when necessary, reporting unauthorized disclosures of protected information. The chapter explains how OMHA is responsible for protecting personal, tax, and health information in accordance with the Social Security Act, the Privacy Act, the Freedom of Information Act (FOIA), the Internal Revenue Code, and other applicable Federal statutes and regulations, while also ensuring information is provided upon request to appropriate individuals or entities.

Karen W. Ames,

Executive Director, Office of Medicare Hearings and Appeals.

[FR Doc. 2020-20550 Filed 9-16-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: October 21, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bo-Shiun Chen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 496-9223, bo-shiun.chen@nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders B NSD-B.

Date: October 22-23, 2020.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joel A Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH NSC, 6001 Executive Blvd., Room 3205, MSC 9529, Bethesda, MD 20892, (301)-496-9223, joel.saydoff@nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel BRAIN Initiative Exploratory Team Brain Circuit Programs U01 Review.

Date: October 23, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Li Jia, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH, 6001 Executive Boulevard, Room 3208D, Rockville, MD 20852, 301 451-2854, li.jia@nih.gov.

Name of Committee: Neurological Sciences Training Initial Review Group NST-2 Subcommittee NINDS Post-doc Fellowships.

Date: November 9-11, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: DeAnna Lynn Adkins, Ph.D., Scientific Review Officer, Scientific Review Branch, NSC Building Bethesda, MD 20892, 301-496-9223, deanna.adkins@nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel NINDS Institutional Research Training Program T32.

Date: November 16-17, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Delany Torres, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS, Neuroscience Center Building (NSC), 6001 Executive Blvd., Suite 3208 Bethesda, MD 20892, delany.torressalazar@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: September 11, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-20494 Filed 9-16-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; RFA-AI-20-001: Combating Antibiotic-Resistant Bacteria (CARB) Interdisciplinary Research Units (U19 Clinical Trial Not Allowed).

Date: October 14-16, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21,