

FDA Weekly Intelligence — Week 32, 2026 (English Edition)

Special Bonus: FDA Official Approval Letter Collection

Coverage period: 2026-07-30 to 2026-08-05. This compilation gathers the primary FDA-published source documents (official approval letters, or approval order statements for PMA devices) underlying the headline items in this week's report: new drug approvals, efficacy supplements, and major PMA Original / Panel-Track device approvals. Long letters are excerpted for length; the full text is always available at the linked FDA official page.

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OVEPOREXTON (ORZEYFUL)

Sponsor / Company: TAKEDA PHARMS USA

Date: 2026-08-05

Identifier: NDA220860 (ORIG-1)

FDA Official Page: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=220860>

Approval Letter (Source Document)

NDA 220860

NDA APPROVAL

Takeda Pharmaceuticals USA, Inc.

Attention: Mark Swarz

Senior Director, Global Regulatory Affairs

500 Kendall Street

Cambridge, MA 02142

Dear Mark Swarz:

Please refer to your new drug application (NDA) received December 10, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Orzeyful (oveporexton) tablets.

This NDA provides for the use of Orzeyful (oveporexton) tablets for the treatment of narcolepsy type 1 (narcolepsy with cataplexy) in adult patients.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTROLLED SUBSTANCE SCHEDULING

You were previously informed that FDA intends to recommend scheduling of Orzeyful under the Controlled Substances Act (CSA). The scheduling of this product in accordance with the CSA (21 U.S.C. 811) is not yet complete as of the date of this letter. Therefore, in accordance with the FDCA (21 U.S.C. 355(x)), the date of approval for Orzeyful shall be the date on which the Drug Enforcement Administration (DEA) publishes a notice in the Federal Register announcing the interim final scheduling of oveporexton.

We note that, when the drug is scheduled by the DEA, you will need to make appropriate revisions to the Prescribing Information and carton and container labeling by submitting a supplement to your NDA. This would include the statements in the labeling detailing the scheduling of oveporexton, as the scheduled substance in Orzeyful, as required under 21 CFR 201.57(a)(2) and (c)(10)(i). Therefore, Orzeyful may be marketed only after DEA has published the notice in the Federal Register

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your NDA to revise all applicable drug labeling to reflect the drug scheduling described in the notice. For changes to the Prescribing Information, and carton and container labeling to describe the scheduling of Orzeyful, you can submit a Changes Being Effected supplement described in 21 CFR 314.70(c)(6). Permission to use a Changes Being Effected supplement for this purpose reflects a waiver by the Agency, pursuant to 21 CFR 314.90, of the requirement to submit a Prior Approval Supplement for changes to reflect the scheduling to the Highlights of Prescribing Information for DRUG PRODUCT described in 21 CFR 314.70(b)(2)(v)(C).

We note that Orzeyful will be listed in the Orange Book upon the date of approval in accordance with 21 U.S.C. 355(x). With respect to the submission of patent information, as required under 21 CFR 314.53(c)(2)(ii), we note that you must submit Form FDA 3542 within 30 days after the date on which DEA has published the notice in the Federal Register announcing the interim final scheduling of ovelporexton .

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.

1 Content of labeling must be identical to the enclosed labeling (Prescribing Information) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in guidance for industry SPL Standard for Content of Labeling Technical Qs and As.

2

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to guidance for industry, SPL Standard for Content of Labeling Technical Qs & As. For administrative purposes, designate this submission "Final Printed Carton and Container Labeling for approved NDA 220860." Approval of this submission by FDA is not required before the labeling is used.

1 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

2 We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance

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DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Orzeyful (oveporexton) tablets shall be 24 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).

ADVISORY COMMITTEE

Your application for Orzeyful was not referred to an FDA advisory committee because the evaluation of the data (when used in the treatment of narcolepsy type 1) did not raise significant or unexpected safety or efficacy issues for a drug of this class or in the intended population. The application did not raise significant public health questions on the role of the drug in the diagnosis, cure, mitigation, treatment, or prevention of a disease. In addition, outside expertise was not necessary; overall, there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

(Excerpt only, truncated for length. See the FDA official page above for the full text.)

LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN (PLUVICTO)

Sponsor / Company: NOVARTIS

Date: 2026-07-31

Identifier: NDA215833 (SUPPL-37)

FDA Official Page: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215833>

Approval Letter (Source Document)

NDA 215833/S-037

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CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.

1 Content of labeling must be identical to the enclosed labeling (Prescribing Information) with the addition of any labeling changes in pending "Changes Being Effectuated" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in guidance for industry SPL Standard for Content of Labeling Technical Qs and As.

2

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which the FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable to conduct on the basis that prostate cancer is an adult-related condition that rarely occurs in the pediatric population.

1 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

2 We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

U.S. Food and Drug Administration

Silver Spring, MD 20993

www.fda.gov

Reference ID: 5845247

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POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS
UNDER SECTION 506B

We remind you of your postmarketing commitment:

5034-1 Complete the ongoing clinical trial, PSMAddition (NCT04720157), titled "An International Prospective Open-label, Randomized, Phase III Study comparing 177Lu-PSMA-617 in combination with Standard of Care, versus Standard of Care alone, in adult male patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC)," and provide the pre-planned final overall survival analysis, to further characterize the clinical benefit of 177Lu-PSMA-617 in combination with androgen receptor pathway inhibitor (ARPI) therapy for adults with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or-sensitive (mAPMN/S) prostate cancer.

The timetable you submitted on July 10, 2026, states that you will conduct this study according to the following schedule:

Trial Completion: 12/2027

Final Report Submission: 07/2028

Submit the final OS analysis and datasets with the final report submission.

Submit clinical protocols to your IND 133661 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical

studies/trials, number of patients/subjects entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "Postmarketing Commitment Protocol," "Postmarketing Commitment Final Report," or "Postmarketing Commitment Correspondence."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication

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[21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.³ Information and Instructions for completing the form can be found at FDA.gov.⁴

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the

(Excerpt only, truncated for length. See the FDA official page above for the full text.)

(Note: Automated text extraction failed for page 1 of the source PDF, so the excerpt above begins from page 2. Please refer to the FDA official page above for the complete original document, including page 1.)

SimpleScreen(TM) CRC

Sponsor / Company: Freenome, LLC

Date: 2026-07-24

Identifier: P250029

FDA Official Page: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P250029>

Supporting FDA Documents

- Approval Order: https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250029A.pdf
- Summary of Safety and Effectiveness Data (SSED): https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250029B.pdf
- Approved Labeling: https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250029D.pdf

Approval Order Statement

Device: SimpleScreen(TM) CRC

Generic Name: System, colorectal neoplasia, DNA methylation and hemoglobin detection

Applicant: Freenome, LLC Bldg. 1 3300 Marina Blvd. Brisbane, CA 94005

PMA Number: P250029

Date Received: 08/01/2025

Decision Date: 07/24/2026

Product Code: PHP

Docket Number: 26M-8165

Notice Date: 07/24/2026

Advisory Committee: Molecular Genetics

Clinical Trials: NCT04369053

Expedited Review Granted?: No

Combination Product: No

Predetermined Change Control Plan Authorized: No

Summary: Summary of Safety and Effectiveness

Labeling: Labeling Part 2

Post-Approval Study: Show Report Schedule and Study Progress

Approval Order Statement:

The SimpleScreen(TM) CRC test is a qualitative, in vitro diagnostic test intended to detect molecular signals associated with colorectal cancer. SimpleScreen CRC utilizes circulating cell-free DNA from plasma of peripheral whole blood collected in the SimpleScreen CRC blood collection kit. SimpleScreen CRC is indicated for colorectal cancer screening in adults aged 45 years and older who are at average risk for the disease. Patients with a positive result should be followed by colonoscopy. SimpleScreen CRC is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.

HiResolution(TM) Bionic Ear System

Sponsor / Company: Advanced Bionics

Date: 2026-07-22

Identifier: P960058S167

FDA Official Page: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960058>

Supporting FDA Documents

- Approval Order: https://www.accessdata.fda.gov/cdrh_docs/pdf/P960058S167A.pdf
- Summary of Safety and Effectiveness Data (SSED): https://www.accessdata.fda.gov/cdrh_docs/pdf/P960058S167B.pdf
- Approved Labeling: https://www.accessdata.fda.gov/cdrh_docs/pdf/P960058S167D.pdf

Approval Order Statement

Device: HiResolution(TM) Bionic Ear System

Generic Name: Implant, cochlear

Applicant: Advanced Bionics 28515 Westinghouse Pl. Valencia, CA 91355

PMA Number: P960058

Supplement Number: S167

Date Received: 01/29/2025

Decision Date: 07/22/2026

Product Code: MCM

Advisory Committee: Ear Nose & Throat

Supplement Type: Panel Track

Supplement Reason: Labeling Change - Indications/instructions/shelf life/tradename

Expedited Review Granted?: No

Combination Product: No

Predetermined Change Control Plan Authorized: No

Summary: Summary of Safety and Effectiveness

Labeling: Labeling Part 2

Approval Order Statement:

Unilateral Hearing Loss The HiResolution(TM) Bionic Ear System is indicated for individuals with unilateral hearing loss who meet the following criteria: Asymmetric Hearing Loss (AHL) Individuals with AHL are defined as those with a mild to moderately severe hearing loss in the better ear, i.e., a 4PTA of 31 to 65 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz, with a difference of at least 15 dB in the 4PTA between ears. It is recommended that individuals with AHL have at least two (2) weeks experience wearing an appropriately fitted Contralateral Routing of Signal (CROS) system or suitable hearing device prior to cochlear implantation. The ear to be implanted will be as follows: Adults (18 years of age or older): Severe to profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 80 dB HL) A score of = 20% on a Consonant-Nucleus-Consonant (CNC) word test Children (5 years through 17 years of age): Profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 90 dB HL) Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on a developmentally appropriate monosyllabic word list when tested in the ear to be implanted alone. Single-Sided Deafness (SSD) Individuals with SSD are defined as those with normal hearing or mild sensorineural hearing loss in the better ear (4PTA of = 30 dB HL at 500, 1000, 2000, and 4000 Hz). It is recommended that individuals with SSD have at least two (2) weeks experience wearing an appropriately fitted Contralateral Routing of Signal (CROS) system or suitable hearing device prior to cochlear implantation. The ear to be implanted will be as follows: Adults (18 years of age or older): Severe to profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 80 dB HL) A score of = 20% on a Consonant-Nucleus-Consonant (CNC) word test Children (5 years through 17 years of age): Profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 90 dB HL) Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on a developmentally appropriate monosyllabic word list when tested in the ear to be implanted alone.

(Note: Some numeric thresholds above are shown as "=" on the FDA's own official page, where clinically the intended symbol was likely "≥" (greater than or equal to) or "≤" (less than or equal to). This excerpt reproduces the FDA page verbatim; we have not guessed at or corrected the symbol. Please verify the exact clinical criteria against the official FDA approval letter (PDF).)