

FDA每週情報 2026年第32週（繁體中文版）

特別資料 FDA官方核准函對照集

FDA Official Approval Letter Collection

涵蓋期間：2026-07-30 至 2026-08-05。本資料收錄本週FDA在全球範圍內具有重要監管及產業意義的新藥核准、適應症擴展及主要PMA原始核准/專家小組審查文件，並特別關注其對台灣醫藥及醫療器材企業的參考價值。每項案例均附有FDA官方核准函（或核准聲明）的繁體中文翻譯、英文原文，以及針對台灣相關賽道企業的啟示分析。原文較長時，依章節重要性摘錄（保留加速核准要求・上市後義務等實質內容，共通標準程序條文則僅列出章節名稱）。

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OVEPOREXTON (ORZEYFUL)

申請者/企業: TAKEDA PHARMS USA

日期: 2026-08-05

識別編號: NDA220860 (ORIG-1)

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

效期: 24個月 / 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)

諮詢委員會: 未付議: 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

小兒試驗要求(PREA): 免除: this drug product for this indication has an orphan drug designation

對台灣企業的啟示

本案未發現與台灣企業直接關聯之標的。收錄理由：作為FDA藥證審查實務之參考案例。

中文翻譯

NDA 220860

NDA 核准函

Takeda Pharmaceuticals USA, Inc.

收件人: Mark Swarz

全球法規事務資深總監

500 Kendall Street

Cambridge, MA 02142

敬愛的 Mark Swarz 先生:

茲通知，關於貴公司依據《聯邦食品、藥品和化妝品法案》（FD&C Act）第 505(b) 條，於 2025 年 12 月 10 日提交之新藥查驗登記（NDA）申請案及後續補件，申請 Orzeyful (oveporexton) 錠劑。

本 NDA 申請 Orzeyful (oveporexton) 錠劑用於治療成人第一型猝睡症（伴有猝倒症）。

核准與仿單

本署已完成此申請案（含補件）之審查。自本函發文日起，核准此案，其用途應依據隨函檢附之雙方協議仿單內容。

管制藥品分級

本署先前已通知貴公司，FDA 擬建議將 Orzeyful

依據《管制藥品法》（CSA）進行分級列管。截至本函發文日，此產品依據 CSA（21 U.S.C.

811）之分級程序尚未完成。因此，依據 FDCA（21 U.S.C. 355(x)），Orzeyful

之核准日期應為美國緝毒局（DEA）於《聯邦公報》上發布公告，宣布 oveporexton 臨時最終分級之日期。

請注意，當 DEA 將此藥品列管後，貴公司需對處方資訊及（未公開資訊）進行適當修訂。

保存期限

根據迄今提交之安定性數據，Orzeyful (oveporexton) 錠劑儲存於 20°C 至 25°C（68°F 至 77°F）時，其有效期限應為自製造日起 24 個月；容許之溫度偏移範圍為 15°C 至 30°C（59°F 至 86°F）（參見美國藥典管制室溫）。

諮詢委員會

貴公司對 Orzeyful 之申請案未提交 FDA 諮詢委員會審議，原因如下：此類藥物用於治療第一型猝睡症時，其數據評估未引發顯著或未預期之安全性或療效議題，於目標族群中亦然。此申請案未引發關於該藥物在疾病的診斷、治癒、緩解、治療或預防方面之重大公共衛生問題。此外，並無必要尋求外部專業意見；整體而言，無任何具爭議性之議題需透過諮詢委員會討論以獲取助益。

必要兒科評估

依據《兒科研究公平法案》（PREA；21 U.S.C. 355c），所有關於新活性成分（包含新鹽類及新複方）、新適應症、新劑型、新給藥方案或新投藥途徑之申請案，皆須包含該產品於兒科病患中用於申請適應症之安全性與有效性評估，除非此要求被免除、延後或不適用。

由於此藥品用於此適應症已取得孤兒藥資格認定，貴公司豁免此項要求。

依據第 505(o) 條之上市後要求

FD&C Act 第 505(o)(3) 條授權 FDA，若 FDA 做出該法規所要求之特定裁決，可要求已核准之藥品與生物製品申請案持有者，為特定目的執行上市後研究與臨床試驗。

本署已判定，僅分析依據 FD&C Act 第 505(k)(1)

款通報之上市後自發性不良事件，不足以識別與懷孕及哺乳期間暴露於 ovelorexton 相關之未預期嚴重風險。

此外，依據 FD&C Act 第 505(k)(3) 條可取得之主動性上市後風險識別與分析系統，亦不足以評估此等嚴重風險。

因此，基於適當之科學數據，FDA 已判定貴公司必須執行以下研究：

5020-1 執行一項回溯性懷孕世代研究，使用理賠資料或電子健康紀錄數據，並進行病歷驗證，此研究需具有足夠統計檢定力，以評估懷孕期間暴露於 ovelorexton

的婦女，相較於適當對照族群，其發生重大先天性畸形、自然流產、死產、早產及小於胎齡兒出生的情形。

貴公司於 2026 年 7 月 21 日提交之時程表載明，貴公司將依下列時程執行此研究：

研究計畫書草案提交：2027 年 2 月

研究計畫書最終版提交：2028 年 2 月

期中報告提交／其他：2029 年 4 月

2030 年 4 月

2031 年 4 月

2032 年 4 月

2033 年 4 月

2034 年 4 月

2035 年 4 月

2036 年 4 月

2037 年 4 月

研究完成：2038 年 4 月

最終報告提交：2039 年 4 月

5020-2 透過一項前瞻性懷孕暴露登錄研究（宜為以疾病為基礎的多產品懷孕登錄研究）收集數據，使用世代分析，及時比較懷孕期間（不論適應症為何）暴露於（藥品名稱）的婦女與未暴露對照族群之孕產婦、胎兒及嬰兒結果。研究計畫書應與美國境外之計畫書保持一致，以達目標樣本數。此登錄研究應識別並記錄懷孕併發症、重大及輕微先天性畸形、自然流產、死產、人工流產、早產、小於胎齡兒出生，以及任何其他不良結果，包含出生後生長與發育。計畫書中所述之結果將於整個孕期進行評估。嬰兒結果，包含對出生後生長與發育之影響，將評估至出生後至少滿一歲。

貴公司於 2026 年 7 月 21 日提交之時程表載明，貴公司將依下列時程執行此研究：

研究計畫書最終版提交：2027 年 8 月

研究完成：2037 年 8 月

期中報告提交／其他：2028 年 8 月

2029 年 8 月

2030 年 8 月

2031 年 8 月

2032 年 8 月

2033 年 8 月

2034 年 8 月

2035 年 8 月

2036 年 8 月

最終報告提交：2038 年 2 月

5020-3 執行一項哺乳期研究，使用經驗證的分析方法，測量 ovesporexton 及其主要代謝物在母乳中之濃度。建議採用母嬰對研究。若研究族群可取得相關資料，應評估對哺乳嬰兒之影響。

貴公司於 2026 年 7 月 21 日提交之時程表載明，貴公司將依下列時程執行此研究：

研究計畫書草案提交：2027 年 2 月

研究計畫書最終版提交：2027 年 8 月

研究完成：2029 年 8 月

期中報告提交／其他：不適用

最終報告提交：2030 年 2 月

最後，本署已判定，僅有臨床試驗（而非非臨床或觀察性研究）足以評估嚴重肝功能不全病患藥物暴露量較低或較高之嚴重風險信號。

因此，基於適當之科學數據，FDA 已判定貴公司必須執行以下試驗：

5020-4 評估嚴重肝功能不全對 ovesporexton 安全性與藥物動力學之影響。

貴公司於 2026 年 7 月 21 日提交之時程表載明，貴公司將依下列時程執行此試驗：

研究計畫書草案提交：2026 年 12 月

研究計畫書最終版提交：2027 年 6 月

研究完成：2028 年 10 月

最終報告提交：2028 年 12 月

FDA 認定「最終版」一詞係指申請者已提交研究計畫書，FDA

審查團隊已將意見寄送給申請者，且計畫書已依需要修訂以達成該研究或臨床試驗之目標。³

請將所要求之臨床研究計畫書提交至您的 IND 154232 案，並附上交互參照至本 NDA

之函件。請將非臨床及化學、製造與管制之研究計畫書及所有最終報告提交至您的

NDA。提交文件時，請於首頁頂端以粗體大寫字母標明以下適當字樣：REQUIRED POSTMARKETING PROTOCOL UNDER 505(o)（依據 505(o) 條要求之上市後研究計畫書）、REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o)（依據 505(o) 條要求之上市後最終報告）、REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o)（依據 505(o) 條要求之上市後函件）。

將必要上市後觀察性研究之研究計畫書提交至您的 IND 案僅為行政追蹤之目的。此等研究不構成 21 CFR 312.3(b) 所述之臨床研究，因此不受 21 CFR part 312 之 IND 規定所規範。

FD&C Act 第 505(o)(3)(E)(ii) 條要求您定期報告依本條要求執行之任何研究或臨床試驗的進度。本條亦要求您定期向 FDA 報告為調查安全性議題而進行之任何其他研究或臨床試驗的進度。FD&C Act 第 506B(a)(1) 條及 21 CFR 314.81(b)(2)(vii) 要求您每年報告任何上市後承諾事項或必要研究或臨床試驗的進度。

FDA 將視貴公司依據第 506B(a)(1) 條及 21 CFR 314.81(b)(2)(vii) 提交之年度報告，為滿足第 505(o)(3)(E)(ii) 條之定期報告要求，前提是您的報告須包含第 505(o) 條及 21 CFR 314.81(b)(2)(vii) 所列之要素。謹提醒您，為符合第 505(o) 條之規定，您的年度報告亦須包含為調查安全性議題而進行之任何其他研究或臨床試驗的進度報告。若未於規定日期提交依據第 505(o) 條要求之研究或臨床試驗的年度報告，將被視為違反 FD&C Act 第 505(o)(3)(E)(ii) 條，並可能導致執法行動。

³ 參見產業指引《上市後研究與臨床試驗--聯邦食品、藥品和化妝品法案第 505(o)(3) 條之執行》（2019 年 10 月）。
<https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>。

英文原文

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

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

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.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING REQUIREMENTS

UNDER 505(o)

Section 505(o)(3) of the FD&C Act authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FD&C Act will not be sufficient to identify an unexpected serious risk associated with exposure to oveporexton during pregnancy and lactation.

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Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FD&C Act will also not be sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

5020-1 Conduct a retrospective pregnancy cohort study using claims or electronic health record data with medical chart validation that is adequately powered to assess major congenital malformations, spontaneous abortions, stillbirths, preterm births, and small-for-gestational-age births in women exposed to ovelorexton during pregnancy compared to appropriate comparator population(s).

The timetable you submitted on July 21, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission: 02/2027

Final Protocol Submission: 02/2028

Interim Report Submission/Other: 04/2029

04/2030

04/2031

04/2032

04/2033

04/2034

04/2035

04/2036

04/2037

Study Completion: 04/2038

Final Report Submission: 04/2039

5020-2 Collect data from a prospective pregnancy exposure registry, preferably a disease-based multiproduct pregnancy registry, using a cohort analysis that compares the maternal, fetal, and infant outcomes of women exposed to drug name regardless of indication during pregnancy with unexposed comparator population(s) in a timely manner. Align the study protocol with protocol(s) outside the United States to reach the target sample size. The registry should identify and record pregnancy complications, major and minor congenital malformations, pregnancy complications, spontaneous abortion, stillbirths, elective pregnancy terminations, preterm births, small-for-gestational-age births, and any other adverse outcomes, including postnatal growth and development. Outcomes described in the protocol will be assessed throughout pregnancy. Infant outcomes, including effects

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on postnatal growth and development, will be assessed through at least the first year of life.

The timetable you submitted on July 21, 2026, states that you will conduct this study according to the following schedule:

Final Protocol Submission: 08/2027

Study Completion: 08/2037

Interim Report Submission/Other: 08/2028

08/2029

08/2030

08/2031

08/2032

08/2033

08/2034

08/2035

08/2036

Final Report Submission: 02/2038

5020-3 Conduct a lactation study to measure concentrations of oreporexton and its major metabolites in breast milk using a validated assay. A mother-infant pair study is recommended. Assess the effects on the breastfed infant, if available, based on study population.

The timetable you submitted on July 21, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission: 02/2027

Final Protocol Submission: 08/2027

Study Completion: 08/2029

Interim Report Submission/Other: N/A

Final Report Submission: 02/2030

Finally, we have determined that only a clinical trial (rather than a nonclinical or observational study) will be sufficient to assess a signal of serious risk of lower or higher drug exposure in patients with severe hepatic impairment.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following trials:

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5020-4 Evaluate the effect of severe hepatic impairment on safety and pharmacokinetics of opeporexton.

The timetable you submitted on July 21, 2026 states that you will conduct this trial according to the following schedule:

Draft Protocol Submission: 12/2026

Final Protocol Submission: 06/2027

Study Completion: 10/2028

Final Report Submission: 12/2028

FDA considers the term final to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.

3

Submit the requested clinical protocol(s) to your IND 154232 with a cross-reference letter to this NDA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **REQUIRED POSTMARKETING PROTOCOL UNDER 505(o)**, **REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o)**, **REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o)**.

Submission of the protocol(s) for required postmarketing observational studies to your IND is for purposes of administrative tracking only. These studies do not constitute clinical investigations pursuant to 21 CFR 312.3(b) and therefore are not subject to the IND requirements under 21 CFR part 312.

Section 505(o)(3)(E)(ii) of the FD&C Act requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FD&C Act, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any

POSTMARKETING COMMITMENTS

or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies

3 See the guidance for Industry, Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).

<https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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or clinical trials required under 505(o) on the date required will be considered a violation of FD&C Act section 505(o)(3)(E)(ii) and could result in enforcement action.

【本函其餘章節】 CARTON AND CONTAINER LABELING/CONTENT OF LABELING/PROMOTIONAL MATERIALS/REPORTING REQUIREMENTS/COMPENDIAL STANDARDS (以上為各核准函共通之標準程序條文，本刊物略過。全文請見官方頁面)

LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN (PLUVICTO)

申請者/企業: NOVARTIS

日期: 2026-07-31

識別編號: NDA215833 (SUPPL-37)

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

上市後承諾 (PMR/PMC) :

5034-1 (NCT04720157)

試驗完成: 12/2027

最終報告提交: 07/2028

對台灣企業的啟示

本案未發現與台灣企業直接關聯之標的。收錄理由：作為適應症擴展路徑之參考。

中文翻譯

NDA 215833/S-037

第2頁

必要兒科評估

根據《兒科研究平等法案》(PREA) (美國法典第21篇第355c節)，所有關於新活性成分（包含新鹽類與新固定劑量複方）、新適應症、新劑型、新給藥方案或新投藥途徑之申請案，皆必須包含該產品於兒科病患中用於申請適應症之安全性與有效性評估，除非此項要求被免除、延後或不適用。

我們免除本申請案之兒科研究要求，理由是攝護腺癌為一種成人相關疾病，罕見於兒科族群，故必要之研究為不可能或執行上極度困難。

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

² 我們會定期更新指引。欲查詢最新版指引，請至FDA指引文件資料庫

<https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>。

美國食品藥物管理局

Silver Spring, MD 20993

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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>.

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POSTMARKETING COMMITMENTS

SUBJECT TO

【本函其餘章節】CONTENT OF LABELING/REPORTING REQUIREMENTS/PROMOTIONAL MATERIALS (以上為各核准函共通之標準程序條文，本刊物略過。全文請見官方頁面)