

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

216338Orig1s000

OTHER ACTION LETTERS



NDA 216338

TENTATIVE APPROVAL

Teva Pharmaceuticals, Inc.
Attention: Beth Regina, MA, RAC
Director, Regulatory Affairs, Gx Steriles
400 Interpace Parkway, Building A
Parsippany, NJ 07054

Dear Ms. Regina:

Please refer to your new drug application (NDA) dated and received on September 30, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound), 100 mg/vial.

We acknowledge receipt of your amendment dated December 8, 2022, which constituted a complete response to our July 15, 2022, action letter.

This NDA provides for the use of Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound), for:

- The treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- The first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- The first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, it is not approved and will not be approved until FDA issues an approval after any necessary additional review of the NDA. Enclosed are the tentatively approved labeling (text for the Prescribing Information and Patient Package Insert). This tentative approval determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. Final approval of your application is subject to expiration of a period of patent protection and/or

exclusivity. Therefore, final approval of your application under section 505(c)(3) of the FD&C Act [21 U.S.C. 355(c)(3)] may not be granted before the period has expired.

Your application contains certifications to patents under section 505(b)(2)(A)(iv) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications"). Section 505(c)(3)(C) of the FD&C Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the FD&C Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the Paragraph IV certifications. This action must be taken prior to the expiration of 45 days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the FD&C Act. However, because the 45-day period described in section 505(c)(3)(C) of the FD&C Act has not yet expired, final approval cannot be granted at this time.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved.

This drug product not approved and cannot be legally marketed until you have been notified in writing that this NDA is approved. The use of the enclosed tentatively approved labeling is not permitted for marketing this drug product.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* (April 2016)¹, guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* (December 2020), and

¹ 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>.

PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022.)²

If you have any questions, call Jeannette Dinin, Regulatory Project Manager, at 240-402-4978 or email: Jeannette.Dinin@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

² <https://www.fda.gov/media/151712/download>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LALEH AMIRI KORDESTANI
02/06/2023 12:24:44 PM



NDA 216338

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This NDA provides for the use of Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound), for the treatment of metastatic breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the Prescribing Information, Patient Package Insert, and carton and container labeling). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be granted before the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the patent(s) or (2) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved,

i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

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If you have any questions, call Jeannette Dinin, Regulatory Project Manager, at 240-402-4978 or email: Jeannette.Dinin@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
- Carton and Container Labeling

¹ 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>.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LALEH AMIRI KORDESTANI
07/15/2022 09:18:47 AM