



NDA 218762

COMPLETE RESPONSE

Accord Healthcare Inc.
Attention: Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
1009 Slater Road, Suite 210-B
Durham, NC 27703

Dear Sabita Nair:

Please refer to your new drug application (NDA) (b) (4)
(b) (4)
or paclitaxel protein-bound particles for injectable suspension
(albumin-bound).

We have completed our review of this application and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

(b) (4)

PRESCRIBING INFORMATION

- (2) We reserve comment on the proposed labeling until the application is otherwise adequate. We encourage you to review the labeling review resources on the Prescription Drug Labeling Resources¹ and Pregnancy and Lactation Labeling Final Rule² websites, including regulations and related guidance documents and

¹ <https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources>

² <https://www.fda.gov/drugs/labeling-information-drug-products/pregnancy-and-lactation-labeling-drugs-final-rule>

the Selected Requirements for Prescribing Information (SRPI) – a checklist of important format items from labeling regulations and guidances.

CARTON AND CONTAINER LABELING

- (3) We reserve comment on the proposed labeling until the application is otherwise adequate.

FACILITY INSPECTIONS

- (4) Following surveillance inspection of the (b) (4) [REDACTED] drug product manufacturing facility listed in this application, we conveyed deficiencies to the representative of the facility. Satisfactory resolution of the observations is required before this NDA may be approved.

- (5) Following surveillance inspection of the (b) (4) [REDACTED] drug substance manufacturing facility listed in this application, we conveyed deficiencies to the representative of the facility. Satisfactory resolution of the observations is required before this NDA may be approved.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

- (1) Describe in detail any significant changes or findings in the safety profile.
- (2) When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:
 - Present new safety data from the studies/clinical trials for the proposed indication using the same format as in the original submission.
 - Present tabulations of the new safety data combined with the original application data.
 - Include tables that compare frequencies of adverse events in the original application with the retabulated frequencies described in the bullet above.

- ### ADDITIONAL COMMENTS

• (b) (4)

We recommend that you respond to the OPQR requests in a timely manner.

OTHER

A resubmission must fully address all the deficiencies listed in this letter and should be clearly marked with **"RESUBMISSION"** in large font, bolded type at the beginning of the cover letter of the submission. The cover letter should clearly state that you consider this resubmission a complete response to the deficiencies outlined in this letter. A partial

Reference ID: 5366277

response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*.

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

If you have any questions, contact

(b) (4)

Sincerely,

{See appended electronic signature page}

(b) (4)

Center for Drug Evaluation and Research

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/

(b) (4)

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Signing on Behalf of

(b) (4)