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ELECTRONIC SUBMISSION VIA REGULATIONS.GOV
CITIZEN PETITION
ANDA SUITABILITY PETITION

March 19, 2019

Dear Sir or Madam:

The undersigned submits this suitability petition, on behalf of a client, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30, to request that the Food and Drug Administration ("FDA") determine that the drug product, Paclitaxel for Injectable Suspension, in a 200 mg/vial lyophilized powder is suitable for submission in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that the FDA declare that the drug product, Paclitaxel for Injection Suspension, in a 200 mg/vial lyophilized powder is suitable for submission in an ANDA. The listed drug upon which this petition is based is Abraxis Bioscience's Abraxane® (paclitaxel protein-bound particle) for Injectable Suspension. The listed drug is approved under NDA 021660. This petition seeks an addition of alternative strength (i.e. 200 mg/vial) along with listed drug product (i.e. 100 mg/vial). Note, this is only an alteration in total drug content and not concentration.

B. Statement of Grounds

The FD&C Act § 505 (j)(2)(A) permits the submission of an ANDA for a drug product that differs in strength from the listed drug provided the FDA has approved a petition that proposed filing such an application. The listed drug for the proposed drug product, Abraxane (paclitaxel) for Injectable Suspension by Abraxis Bioscience is a lyophilized powder in vials containing 100 mg/vial. A copy of the relevant excerpt from the current electronic edition of the Approved Drug Products with Therapeutic Equivalence Evaluations is provided as **Attachment-01**. A copy of the current labeling for Abraxane (paclitaxel) for Injectable Suspension by Abraxis Bioscience is provided as **Attachment-02.** This petition is seeking an alternative strength 200 mg/vial (total drug content) in addition with 100 mg/vial

Like Abraxane, the proposed drug product would be a lyophilized powder for reconstitution (single-use). The proposed strength (total drug content) is contemplated by the approved labeling

for the listed drug. Specifically, the Dosage and Administration Section of the Abraxane prescribing information provides the following information on dosing:

Dosing

Indication	Recommended Dose	Total Dose/Number of Vials*
Metastatic Breast Cancer	260 mg/m^2	416 mg/4+ vials
Non-Small Cell Lung Cancer	100 mg/m^2	160 mg/2 vials
Adenocarcinoma of the Pancreas	125 mg/m^2	200 mg/2 vials

*Calculated based on an average body surface are of 1.6 m^2 (See Attachment 2, Abraxane PI, Dosage and Administration.)

Since average adult dosing requires multiple 100 mg vials, a larger vial size will provide greater convenience to healthcare professionals. Offering a larger fill volume may also reduce the risk for medication errors.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition and the dilution volume required for reconstitution. The active ingredient, dosage form, and route of administration are the same as those of the current listed drug, as are the uses, indication, warnings, and directions for use. The draft package insert incorporating the proposed strength is provided as **Attachment-03**. The dilution volume required for reconstitution is 40 mL for 200 mg/vial presentation should not present a safety or efficacy concern because the same concentration of drug is being maintained for dosing.

Inapplicability of the Pediatric Research Equity Act ("PREA"). PREA, which is codified at FD&C Act§ 505B, does not apply to a new strength, such as the one proposed in this petition. As such, PREA should not serve as an impediment to the Agency's granting of this petition.

Therefore, the petitioner's request for the Commissioner to find that a addition in alternative strength of 200 mg/vial (i.e., a change in total drug content) should raise no questions of safety or effectiveness, and the FDA should approve the petition.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 C.F.R. § 25.3l(a) from the requirement to submit an environmental assessment.

D. Economic Impact Statement

The petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

Sharif Ahmed Digitally signed by Sharif Ahmed
Date: 2019.03.19 14:28:52 -04'00'

Sharif Ahmed, MS, RAC
Principal Consultant

Attachments:

1. Orange Book Listing for Abraxane® (paclitaxel) for Injectable Suspension accessed 11/22/16
2. Reference Listed Drug Prescribing Information for Abraxane (paclitaxel) for Injectable Suspension
3. Proposed Prescribing Information for Paclitaxel for Injectable Suspension, 100 mg/vial and 200 mg/vial