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SUBMITTED ELECTRONICALLY

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION – ANDA SUITABILITY PETITION

Hyman, Phelps and McNamara, P.C., on behalf of a client, submits this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. §§ 314.93, 10.20 and 10.30, to request that the Food and Drug Administration ("FDA") determine that the drug product, Paclitaxel protein-bound particles for Injectable Suspension (albumin-bound) ("Paclitaxel for Injectable Suspension") in a 50 mg/vial and 300 mg/vial lyophilized powder, is suitable for submission in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that FDA determine that Paclitaxel for Injectable Suspension, in a 50 mg/vial and 300 mg/vial lyophilized powder, is suitable for submission in an ANDA.

As designated in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), the Reference Listed Drug ("RLD") upon which this petition is based is Abraxis Bioscience's Abraxane® (paclitaxel protein-bound particle) for Injectable Suspension, 100 mg, approved under NDA 021660. The petitioner seeks FDA permission, in accordance with 21 C.F.R. § 314.93(b), to submit an ANDA seeking FDA approval of additional strengths, 50 mg/vial and 300 mg/vial, in addition to the 100 mg/vial strength approved under NDA 021660. This change is specific to the total drug content rather than concentration. The active ingredient, route of administration, dosage form, and the dosage regimen for use are the same as that of the RLD.

B. Statement of Grounds

Section 505(j)(2)(A) of the FDC Act provides for the submission of an ANDA for a drug product that differs in strength from the listed drug provided FDA has first approved a petition permitting the submission of such an application.

The listed drug for the proposed drug product, Abraxane (paclitaxel) for Injectable Suspension (NDA 021660), is a lyophilized powder in vials containing 100 mg/vial. A copy of the relevant excerpt from the current electronic edition of the Orange Book 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 alternative strengths of 50 mg/vial and 300 mg/vial (total drug content) in addition to the 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 based on 1.6 m^2**	**Number of vials required per dose (mg)**			**Remarks**
			50 mg	**100 mg**	**300 mg**	
Metastatic Breast Cancer	260 mg/m2	416 mg	**1**	**1**	**1**	Lowest drug loss for reimbursement.
Non-Small Cell Lung Cancer	100 mg/m2	160 mg	-	**2**	-	Drug loss approx. 40mg with 2 vial. If BSA <1.5 m^2, then one 100 mg vial + one 50 mg vial to be used.
Adenocarcinoma of the Pancreas	125 mg/m2	200 mg	-	**2**	-	No drug loss & reduce to 2 vial

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

Because the average adult dosing requires multiple 100 mg vials, a larger vial size will provide greater convenience to healthcare professionals. And because adult dosages are not necessarily multiples of 100, offering a 50 mg vial size may also reduce drug product waste in the event that the calculated dose is slightly greater than 100 mg or 200 mg or 300 mg or 400 mg. Both the larger and the smaller vial sizes may also reduce the risk of medication errors.

There are no proposed changes in labeling with the exception of the 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 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**, and a side-by-side comparison of the proposed package insert with current RLD package insert as **Attachment-04**. The dilution volume required for reconstitution—10 mL for the 50 mg/vial and 60 mL for the 300 mg/vial presentation—does not present safety or efficacy concerns because the proposed product maintains the same concentration as the RLD for dosing purposes.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act by requiring certain applications for a drug submitted under FDC Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. See FDC Act § 505B(a)(I)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. See id. ANDAs submitted under an approved suitability petition for a change in strength are not subject to PREA requirements. See FDA, Draft Guidance for Industry, How to Comply with the Pediatric Research Equity Act, 4 (Sep. 2005). Petitioner asserts that PREA is not applicable to the proposed Paclitaxel for Injectable Suspension, 50 mg/vial and 300 mg/vial, drug products because the proposed changes concerns only new strengths. As such, PREA should not serve as an impediment to the Agency's granting of this petition.

Because the petitioner's request that the Commissioner permit the submission of an ANDA seeking approval of a 50 mg/vial and a 300 mg/vial (i.e., a change in total drug content) strength of Paclitaxel for Injectable Suspension raises no questions of safety or effectiveness, FDA should approve this 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.

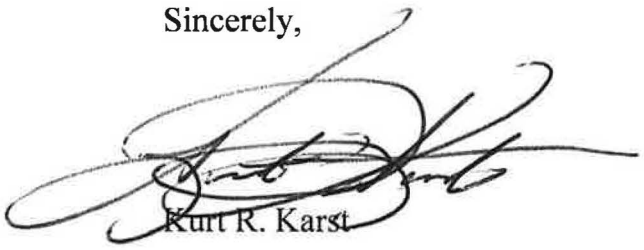
D. Economic Impact Statement

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,



Kurt R. Karst

KRK/eam
Attachments