Monday, October 23rd, 2006
Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane; Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDC Act) and 21 C.F.R. § 314.93, § 10.20, and § 10.30 to request permission from the Commissioner of Food and Drugs to submit an abbreviated new drug application (ANDA) for a proposed drug product that differs from the reference listed drug in strength.

A. Action Requested

We request that the Food and Drug Administration (FDA) permit an ANDA to be filed for Paclitaxel, USP.

B. Statement of Grounds

The reference listed drug for this petition is Paclitaxel, USP. This petition requests permission to submit an ANDA for a generic version of that product at a strength of 0.1 pM.

The proposed drug product is a different strength of the reference listed drug. Under section 505(j)(2)(C of the FDC Act and 21 C.F.R. § 314.93(b), an ANDA suitability petition may be submitted for a change in strength.

Taxol® is approved for non-small cell carcinoma of the lung cancer and has been used at doses ranging from 135 mg/m^2 and 250 mg/m^2.

The current FDA-approved labeling for Taxol® is for injection, (obtained from www.fda.gov/cder/ (20-262/S-032)). A list of the proposed labeling changes for the proposed drug product, based on the labeling of the reference listed drug Taxol®, is for aerosol administration.

The active ingredient of the proposed drug product is of the same pharmacological or therapeutic class as that of the reference listed drug, in that it is the same active ingredient. See 21 C.F.R. § 314.93(d)(1) .

The proposed drug product is expected to have the same therapeutic effect as the reference listed drug when administered to patients for each conditions of use in the reference listed drug's labeling for which an ANDA will be submitted, in that the proposed drug product will contain the same active ingredient at the same concentration, administered under the same conditions of use as the reference listed drug. See 21 C.F .R. § 314.93(d)(2). The proposed product will be shown to be bioequivalent to the reference product in accordance with FDA's usual criteria. If appropriate, the sponsor of the proposed product will seek a waiver of a demonstration of in vivo bioequivalence under 21 C.F.R. § 320.22(b)(3).

Investigations should not be necessary to show the safety and effectiveness of the proposed product, as the product only differs in strength from currently approved products that are, respectively, at lower and greater strengths. See 21 C.F .R. § 314.93(e)(1)(i).

In petitioner's view, this ANDA suitability petition does not present any new or novel issues.

C. Environmental Impact

This petition is eligible for a categorical exclusion under 21 C.F .R. § 25 .31(a) because approval of this petition will not increase the use of the active moiety. The proposed drug product will not be administered at higher dosage levels, for longer duration, or for different indications than the reference listed drug .

D. Economic Impact

Information on economic impact will be submitted upon request.

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.

Respectfully submitted,

Richard Rotondo
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