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March 8, 2006

OVERNIGHT COURIER 03/08/06

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

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(C) and 21 C.F.R. §§ 10.20, 10.30 and 314.93 on behalf of a client requesting the Commissioner of the Food and Drug Administration to make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Temazepam Orally Disintegrating Tablets, 7.5 mg, 15 mg, 22.5 mg, and 30 mg.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Temazepam Orally Disintegrating Tablets, 7.5 mg, 15 mg, 22.5 mg, and 30 mg is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is Restoril® (temazepam capsules, USP) 7.5 mg, 15 mg, 22.5 mg and 30 mg. The reference-listed drug product, NDA 18-163, which is currently held by Tyco Healthcare, appears in the electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations 25th Edition,* accessed March 8, 2006 (Attachment 1). Therefore, the petitioner seeks a change in the dosage form from an immediate-release capsule to an orally disintegrating tablet.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a new drug that differs in dosage form from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application.

The proposed change in dosage form, from a capsule to an orally disintegrating tablet, is designed to provide a more convenient dosage form for those adult patients that find it difficult to swallow capsules or other solid oral dosage forms. The proposed product will be found to be bioequivalent to the RLD and will also provide a dosage form that can be taken with or without water as the tablets will dissolve on the tongue. According to the labeling of the reference-listed drug product, the average dosage of Restoril® (temazepam capsules USP) is "15 mg before retiring", although "...7.5 mg may be sufficient for some patients, and others may need 30 mg".

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The package insert for Restoril® (temazepam capsules, USP) is provided in Attachment 2 of this petition. The dosage for the proposed tablet product is identical. This dosage is the same as that stated in the approved labeling of the reference-listed drug product.

In summary, the proposed change in dosage form from that of the reference-listed drug (i.e., a change from a capsule to an orally disintegrating tablet), will not affect the product's safety or efficacy. The indication remains unchanged and the proposed dosing is the same as the dosing recommendations in the approved labeling for the reference-listed drug. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed labeling for Temazepam Orally Disintegrating Tablets is included in Attachment 3. Labeling for the proposed product will be consistent with the approved labeling for Restoril® (temazepam capsules, USP) with the exception of the additional directions for use of the orally disintegrating tablet.

Pediatric Waiver Request

In December 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food, Drug and Cosmetic Act to provide the Agency authority to require drug firms to study certain drugs in pediatric patients, if the Agency felt that such study would provide beneficial health data for that patient population. The Act also provided a provision for a waiver from such requirement if:

(iii) the drug or biological product –

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and
(II) is not likely to be used in a substantial number of pediatric patients.

The petition hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit a subsequent ANDA filing. The drug product, Temazepam, does not appear on the historical list of drugs for which additional information may produce benefits in the pediatric population.

Based on the use and nature of the RLD, the proposed change in dosage form to an orally disintegrating tablet from a capsule will not make the product any more likely to be used in pediatric patients. In addition, NDC Health (Per-Se Technologies) prescription data shows prescriptions written for pediatric patients to be 9666 prescriptions for all patients less than 19 years of age last year, significantly less than the 50,000-prescription threshold cited in previous FDA documents as a barometer to determine if the product would likely be used in a significant number of pediatric patients.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Temazepam Orally Disintegrating Tablets, 7.5 mg, 15 mg, 22.5 mg and 30 mg.

C. Environmental Impact

According to 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

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,

Robert Pollock

Robert W. Pollock
Senior Vice President

RWP/pk

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Orange Book listing Accessed March 8, 2006
2. Approved labeling for reference-listed drug product (RLD), Restoril® (temazepam capsules, USP) (Tyco Healthcare), Rev. 092804
3. Draft Insert Labeling Proposed for Temazepam Orally Disintegrating Tablets, 7.5 mg, 15 mg, 22.5 mg and 30 mg

cc: Arianne Camphire (OGD)

M03P6067

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