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November 9, 2004

OVERNIGHT COURIER 11/9/04

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

CITIZEN PETITION

The undersigned, on behalf of a client, submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("the FDC Act") and 21 C.F.R. 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Meperidine Hydrochloride Tablets, USP in two strengths of 75 mg and 150 mg.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that Meperidine Hydrochloride Tablet drug products, in two strengths, 75 mg and 150 mg, are suitable for submission in an ANDA. The reference-listed drug products upon which this petition is based are DEMEROL® (Meperidine Hydrochloride Tablets, USP, 50 mg and 100 mg) manufactured by Sanofi-Synthelabo, Inc. NDA 5-010. Therefore, this petition requests a change in the strength of the active ingredient (meperidine hydrochloride) from 50 mg and 100 mg tablets to include a 75 mg tablet and a 150 mg tablet. Because this request involves a change in strength, there should be no need to evaluate this petition in regard to the Pediatric Research Equity Act of 2003.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition requests a change in the strength of the active ingredient, meperidine hydrochloride, from the approved 50 mg and 100 mg tablets to include a 75 mg tablet and a 150 mg tablet. The listing of reference drug products upon which this petition is based, DEMEROL® (Meperidine Hydrochloride Tablets, USP) 50 mg and 100 mg, appears on page 3-234 of the 23rd Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluation* (commonly referred to as "The Orange Book"). See **Attachment A**.

According to the labeling of the reference-listed drug products, the usual dosage of DEMEROL® is "50 mg to 150 mg orally, every 3 to 4 hours as necessary". The approved package insert for DEMEROL® Tablets (Meperidine Hydrochloride Tablets, USP 50 mg and 100 mg) is included in **Attachment B**. The dosage for the proposed product is "50 mg to 150 mg orally, every 3 to 4 hours as necessary". This dosage is consistent with that stated in the approved labeling of the reference listed drug product. The proposed products will permit dosing over the approved dosage range (i.e., 50-150 mg) without the need to take multiple tablets or the need to break tablets in half to obtain the appropriate dose as prescribed by the health care practitioner and consistent with the individual patient's needs or requirements.

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In summary, the proposed change in strength of the proposed products from that of the reference-listed drug is consistent with the approved labeling of the RLDs. This change in strength, therefore, should not affect the safety or efficacy of the proposed product. The indication remains unchanged, and the proposed dosing is consistent with dosing recommendations in the labeling of the approved reference-listed drug product's labeling and dosing for the narcotic component for other FDA approved products. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed labeling for Meperidine Hydrochloride Tablets, USP 75 mg and 150 mg is included as **Attachment C**. Labeling for the proposed product will be consistent with the approved labeling for DEMEROL® (Meperidine Hydrochloride Tablets, USP) 50 mg and 100 mg.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Meperidine Hydrochloride Tablets, USP 75 mg and 150 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 Statement

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

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 pk

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RWP/pk

Attachment A: Page 3-234 of the 23rd Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluation*
Attachment B: Approved package insert for DEMEROL® Tablets (Meperidine Hydrochloride Tablets, USP 50 mg and 100 mg)
Attachment C: Proposed labeling for Meperidine Hydrochloride Tablets, USP 75 mg and 150 mg

cc: Emily Thakur (Office of Generic Drugs)

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