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OVERNIGHT DOCUMENT 01/03/03

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client in quadruplicate pursuant to 21 CFR 10.30, and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn (discontinued from marketing) for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Levo-Dromoran (Levorphanol Tartrate) Tablets, 2 mg (NDA 08-720), manufactured by ICN Pharmaceuticals, has been voluntarily withdrawn (discontinued from marketing or withheld from sale) for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). The *Approved Drug Products with Therapeutic Equivalence Evaluations* (List), commonly referred to as the Orange Book, contains all FDA-approved drug products. Levo-Dromoran Tablets, 2 mg, was approved by the FDA and appears in the active section of the Orange Book. The product is, therefore, considered a "listed drug product" in the Orange Book. In addition, Levo-Dromoran is designated as the Reference Listed Drug product for Levorphanol Tartrate Tablets. While the approval and designation of Levo-Dromoran is documented in the Orange Book, for some reason unknown to the petitioner, the NDA holder has either permanently or temporarily discontinued the marketing of the 2 mg Levo-Dromoran drug product.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn, discontinued from marketing or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

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Based on the fact that the FDA-designated Reference Listed Drug product, Levo-Dromoran, 2 mg Tablets, is not currently being marketed, it is not possible for an ANDA applicant to obtain supplies of the Reference Listed Drug product upon which to perform the required bioequivalence studies to support approval of an ANDA. Therefore, because the NDA holder has apparently discontinued marketing its Levo-Dromoran drug product, it is requested that the FDA determine whether ICN's decision to discontinue marketing of its 2 mg Levorphanol Tartrate drug product was for reasons of safety or effectiveness.

Should the FDA determine that the ICN product was not discontinued from marketing for safety or efficacy reasons, it is also requested that the FDA take the appropriate steps to assure that an ANDA may be submitted for a generic equivalent of Levorphanol Tartrate by designating a second Reference Listed Drug product (a marketed generic product) for Levorphanol Tartrate Tablets.

During the course of the review of this petition, should the petitioner learn that ICN begins marketing its 2 mg Levo-Dromoran product, we will withdrawal this petition.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

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

Respectfully submitted,

Robert W. Pollock

Robert W. Pollock
Vice President

RWP/kt/m

cc: G. Davis (Office Of Generic Drugs)
C. Parise (Office of Generic Drugs)
D. Hare (Office of Generic Drugs)

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