

August 25, 2004

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

**CITIZEN PETITION**



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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Commissioner of the Food and Drug Administration to provide a determination whether the listed drug product has been withdrawn for safety or effectiveness reasons as outlined below: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 Penthrane (methoxyflurane, liquid, 99.9%) Inhalation (NDA 13-056), manufactured by Abbott Laboratories, has been voluntarily withdrawn from sale for safety or efficacy reasons.

**B. Statement of Grounds**

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), contains all FDA-approved drug products. Penthrane, Methoxyflurane, liquid, 99.9% for Inhalation appears in the discontinued section of the Orange Book.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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

2004A 0379

**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,

  
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Anthony C. Celeste  
President