

**LACHMAN CONSULTANT SERVICES, INC.**  
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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March 17, 2006

**OVERNIGHT COURIER 3/17/06**

Division of Dockets Management  
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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness for the reasons as outlined below.

**A. Action Requested**

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Dexedrine® (dextroamphetamine sulfate) Oral Solution 5 mg / 5 mL has been voluntarily withdrawn from sale for safety or efficacy reasons.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 that are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the Orange Book, contains all FDA-approved drug products. Dexedrine® (dextroamphetamine sulfate) Oral Solution 5 mg / 5 mL, ANDA 83-902 was approved by the FDA prior to 1982 and is considered to be a "listed drug product". The current listing of the product in the electronic Orange Book, accessed March 17, 2006, does not list Dexedrine® (dextroamphetamine sulfate) Oral Solution 5 mg / 5 mL in the active section of the Orange Book. Rather, the product appears in the "Discontinued" section of the Orange Book. It is believed that the innovator has discontinued marketing the product for economic reasons.

Under FDA regulations drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or discontinued from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

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As stated above at the time of submission of this petition, there is no evidence that the innovator is currently marketing its Dexedrine® (dextroamphetamine sulfate) Oral Solution 5 mg / 5 mL product. Therefore, because the product has been discontinued from marketing, it is requested that the FDA determine whether the applicant holder's decision to discontinue marketing of Dexedrine® (dextroamphetamine sulfate) Oral Solution 5 mg / 5 mL was for reasons of safety or effectiveness. Such a determination will permit the FDA to approve ANDAs for the drug product.

Should the ANDA holder reintroduce Dexedrine® (dextroamphetamine sulfate) Oral Solution 5 mg / 5 mL to the market after the submission of this petition and prior to FDA response, and there is evidence that the product is available in the marketplace, LCS will consider the petition moot. We will at that time take appropriate action to request withdrawal of the 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 the undersigned's 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, which are unfavorable to the petition.

Respectfully submitted,



Robert W. Pollock  
Senior Vice President

RWP/pk

cc: Martin Shimer (Office of Generic Drugs)

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