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May 22, 2006

Division of Dockets Management
Food and Drug Administration
Dep. Of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Citizen Petition**

Dear Sirs:

The undersigned submits this petition under 21 CFR 10.25(a) and 21 CFR 10.30 to request the Commissioner of the Food and Drug Administration to determine whether a listed drug that has been voluntarily shortened from distribution and sale was shortened for safety or effectiveness reasons and if the listed drug was shortened for reasons other than for safety or effectiveness, to permit the filing of an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Triamcinolone Diacetate Suspension, 40 mg/mL (NDA 012802) manufactured by Sandoz has been voluntarily shortened from distribution and 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 ANDA's. The List, referred to as the Orange Book, contains all FDA-approved drug products. Triamcinolone Diacetate Suspension, 40 mg/mL was approved by the FDA prior to January 1982.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness. (21 CFR 314.162) The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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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The Petitioner has no evidence concerning the reason why Sandoz shortened from distribution and sale Triamcinolone Diacetate Suspension, 40 mg/mL, but nevertheless contends that the reasons were unrelated to safety or effectiveness.

The Petitioner requests that the FDA determine that Sandoz's decision to shorten from distribution and sale Triamcinolone Diacetate Suspension, 40 mg/mL, was for reasons other than safety or effectiveness.

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 her 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,

Elizabeth A. Marro
Senior Director, Regulatory Affairs and Quality Assurance