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September 30, 2002

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VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Citizen Petition

Dear Sirs:

The undersigned submits this petition pursuant to 21 C.F.R. § 10.30 and in accordance with the regulations at 21 C.F.R. § 314.161(b) for a determination whether the listed drug, DELCOBESE® tablets and capsules (amphetamine sulfate), ANDA Nos. 83-563 – 83-564 has been voluntarily withdrawn for safety and effectiveness reasons, as outlined below.

A. Action Requested

This petition seeks a determination whether the listed drug, DELCOBESE® tablets and capsules, was withdrawn by Lemmon Co. for safety and effectiveness reasons.

B. Statement of Grounds

The reference product, DELCOBESE® tablets and capsules, has been discontinued by Lemmon Co. and is currently listed in the Approved Drug Products with Equivalence Evaluations (the "Orange Book") under "DISCONTINUED DRUG PRODUCT LIST." Provided in Tab 1 is a copy of the *Federal Register* notice announcing FDA's withdrawal of approval of the ANDA's for DELCOBESE® tablets and capsules (83-563 and 83-564) because the ANDA holder stated that the drug was no longer marketed. Tab 2 is a copy of the entry from the Orange Book.

C. Environmental Impact

Pursuant to 21 C.F.R. § 25.31(a), action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement.

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D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic information is submitted only when requested by the Commissioner. This information will be provided if so requested.

E. Certification

The undersigned certifies, that to the best of his knowledge and belief, 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,



Peter S. Reichertz

Attachments