



FILE COPY

December 27, 2001

Alan Minsk
Arnall Golden Gregory, LLP
1201 West Peachtree Street, Suite 2800
Atlanta, GA 30309-3450

Dear Mr. Minsk:

Your petition requesting the Food and Drug Administration to require the applicant of an abbreviated new drug application for mixed salts of single entity amphetamine bioequivalence to conduct necessary testing to assure strict equivalence with key pharmacokinetic parameters of the reference listed drug, ADDERALL, was received by this office on 12/26/01. It was assigned docket number 01P-0585/CP 1 and it was filed on 12/27/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

OIP-0585

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