



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 25 2002

Food and Drug Administration
Rockville MD 20857

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VIA TELEFAX

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

Docket No. 01P-0585/CP1

Dear Mr. Minsk:

This letter is a followup to today's phone conversation with Christine Rogers of my office concerning your petition dated December 26, 2001, relating to Adderall. Your petition contained a certification stating: "The undersigned certifies, that to the best knowledge and belief of the undersigned, 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." Throughout the text of the petition, you cite several references. These references, which the petition relies upon, were not included with the petition as required by FDA regulations at 21 CFR § 10.30, and, therefore, the petition is not complete. Unless we receive the referenced materials within five business days from your receipt of this letter, the Agency will consider the petition to be withdrawn.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

David T. Read
Director, Division of Regulatory Policy I
Center for Drug Evaluation and Research

OIP-0585

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