



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 23, 2003

FILE COPY

Mr. David G. Adams
Venable, Baetjer, Howard & Civiletti, LLP
1201 New York Avenue, N.W., Suite 1000
Washington, DC 20005-3917

Dear Mr. Adams:

Your petition, on behalf of Ranbaxy Laboratories Limited, requesting the Food and Drug Administration to confirm that the FDA has implemented the concept of shared exclusivity for multiple ANDAs submitted on the same day, and that Ranbaxy's ANDA No. 76-595 for modafinil 100 mg and 200 mg tablets will be entitled to shared 180-day exclusivity, was received by our office on 05/14/03. It was assigned docket number 2003P-0217/CP 1 and it was filed on 05/23/03. Please refer to this docket 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

2003P-0217

ACK1