DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 31 2003

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

Re: Docket No. 03P-0217/CP1

Dear Mr. Adams,

This letter responds to your citizen petition dated May 13, 2003, requesting the Food and Drug Administration (FDA) to confirm (1) that the concept of shared exclusivity for multiple ANDAs submitted on the same day is required by law and is being implemented by FDA and (2) that Ranbaxy's ANDA No. 76-595 for modafinil 100-mg and 200-mg tablets will be entitled to shared 180-day exclusivity upon the triggering of such exclusivity under 21 U.S.C. 355(j)(5)(B)(iv).

FDA has carefully considered the issues raised in your petition and is issuing a guidance document that essentially grants your request as to issue (1) identified above. Enclosed is a copy of the guidance document, *180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day.* As to issue (2), Ranbaxy's eligibility for 180-day exclusivity for modafinil 100-mg and 200-mg tablets under the approach described in the guidance will be determined when one or more ANDAs for that drug are ready for approval.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Enclosure

2003P-0217 LET1