DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

July 30, 2001

Kathleen M. Sanzo, Esq.
Morgan, Lewis & Bockius, LLP
1800 M Street, N.W.
Washington, DC 20036

Dear Ms. Sanzo:

Your petition on behalf of Pfizer Inc. & Pharmacia Corp. requesting the Food and Drug Administration to amend its October 1999 505(b)(2) draft guidance document & its regulations at 21 C.F.R./314.54 to reflect that the FDA cannot rely on or otherwise use any non-public proprietary info. in an innovator's NDA or other non-public filings to approve applications submitted pursuant to section 505(b)(2) of the FFDCA or the Act (2) not rely on or otherwise use non-public proprietary info. in an innovator's NDA or otherwise use non-public filings to approve section 505(b)(2) applications; & (3) not assign "A" therapeutic equivalence evaluation codes to drug products approved pursuant to section 505(b)(2) of the Act, & modify FDA's equivalency rating practices accordingly, was received by this office on 07/30/01. It was assigned docket number 01P-0323/CP1 and it was filed on 07/30/01. 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,

Helen K. Harris

Helen K. Harris
Dockets Management Branch

01P-0323

ACK1