



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 6, 2001

Lorraine Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Dear Ms. Piestrak:

Your petition requesting the Food and Drug Administration to Reclassify Cyclosporine Diagnostic Test Devices from Class III to Class II, was received by this office on 03/06/01. It was assigned docket number 01P-0119/CCP 1 and it was filed on 02/22/01. 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,


Gloria Ortega
Dockets Management Branch

01P-0119

ACK 1