

Food and Drug Administration Rockville MD 20857

## FILE COPY

June 18, 2001

Yvette Lloyd Bio-Rad Laboratories Diagnostics Group 9500 Jeronimo Road Irvine, CA 92618-2017

Dear Ms. Lloyd:

Your petition requesting the Food and Drug Administration to Permit mfrs. to remove intended use statement from box label, was received by this office on 06/15/01. It was assigned docket number 01P-0272/CP1 and it was filed on 06/15/01. 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,

<sup>\*</sup>Helen K. Harris

Dockets Management Branch

K. Harri

011-0272

ACKI