



Food and Drug Administration
Rockville, MD 20857

February 11, 2004

Donna Chapman
RA/QA Manager
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618-2017

Dear Ms. Chapman:

Your petition requesting the Food and Drug Administration to issue a written opinion stating that Bio-Rad's longstanding practice, previously accepted by the agency, of developing unified, truthful labeling for domestic and international sales of its control products is lawful, was received by this office on February 6, 2004. It was assigned docket number 2004P-0055/CP 1 and it was filed on February 11, 2004. 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,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management