DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 8 2004

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

Re: Docket No. 2004P-0055

Dear Ms. Chapman:

This is an interim response to your petition, filed by the Food and Drug Administration (FDA) on February 11, 2004. In your petition, you request that FDA 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. In your petition, you state that FDA (1) has historically permitted Bio-Rad to refer to unapproved test kits in its labeling, (2) must align its position on unapproved uses with First Amendment law; and (3) labeling for Bio-Rad's controls does not raise the usual concerns associated with labeling for unapproved uses.

Because of the complex legal issues presented by your petition, we are unable to issue a final response to you at this time. We expect to issue a final response in the near future

If you have any questions about this interim response, please contact Joseph M. Sheehan of our Regulations Staff at (301) 827- 2974.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health

2004P-0055

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