DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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SEP 11 2002

Ms. Yvette Lloyd
Senior Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvin, CA 92618-2017

Dear Mr. Lloyd,

This is an additional interim response to the citizen petition you submitted to the Food and Drug Administration (FDA) on behalf of Bio-Rad Laboratories. In the petition you requested that FDA permit the use of symbols "to replace certain text required by 21 C.F.R. 809.10(a) & 809.10(b)," the in-vitro diagnostic (IVD) labeling regulation. You ask us to permit the use of symbols as a substitute for required labeling text either through our response to your citizen petition, by issuing guidance that lets symbols replace required text, or by amending the IVD labeling regulation.

Because of the complexity and extent of the analysis necessary to thoroughly evaluate your request, we are unable to give you a final response to your petition at this time. We hope to complete our review of your petition early in 2003 and determine our course of action regarding your request. We will send you a final response as soon as possible after we complete that review.

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

Sincerely yours,

Linda S Kahan

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

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9200 Corporate Boulevard
Rockville MD 20850

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Ms. Yvette Lloyd
Senior Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvin, California 92618-2017

Dear Ms. Lloyd,

This letter responds to your citizen petition on behalf of Bio-Rad Laboratories requesting that the Food and Drug Administration permit the use of symbols "to replace certain text required by 21 C.F.R. 809.10(a) & 809.10(b)," the in-vitro diagnostic (IVD) labeling regulation. You ask us to permit the use of symbols as a substitute for required labeling text either through our response to your citizen petition, by issuing guidance that lets symbols replace required text, or by amending the IVD labeling regulation. You do not specify any particular symbols or indicate which regulatory requirements you propose to fulfill with symbols.

FDA commends efforts to provide clear, understandable, and user-friendly labeling. We also appreciate industry concern with meeting the demands of a global market. To this end, FDA is continuing to review your request and other similar proposals to determine whether and under what conditions specific symbols without text may be employed to provide information required in the labeling of IVDs. We will send you a final response to your petition after we complete our review of this issue.

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

Sincerely yours,

Linda S Kahan

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