DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

NOV 18 2003

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

Docket No.: 01P-0298

Dear Ms. Lloyd.

This letter further responds to your citizen petition on behalf of Bio-Rad Laboratories requesting that the Food and Drug Administration (FDA) permit the use of symbols "to replace certain text required by 21 CFR 809.10(a) & 809.10(b)," the in-vitro diagnostic (IVD) labeling regulation. We previously sent you interim responses dated January 11, 2002 and September 11, 2002. 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. You urge FDA to permit symbols to replace IVD labeling text because you believe symbols provide three benefits:

1) Symbols make the product more user-friendly by replacing small, difficult-to-read text on vial and box labeling;
2) Symbols may eliminate the need for small-label exemptions by permitting the placeme1nt of more information on small labels than does text; and
3) Symbols permit manufacturers to create labeling that would accord with international labeling requirements.

FDA is granting your petition to the extent outlined below. FDA's recommendations regarding the use of symbols in the labeling of IVDs intended for professional use, and the reasons for those recommendations, are further described in the guidance document and the notice of availability referenced below.

In the **Federal Register** of Octpober 28, 2003, FDA announced the availability of a draft guidance document entitled "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use" (enclosed). This document provides guidance on the use of selected symbols in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use by 21 CFR 809.10, FDA's labeling requirements for in vitro diagnostic devices, and 21 CFR parts 610 and 660, FDA's labeling requirements for biologics (including IVDs) that are licensed under the Public Health Service (PHS) Act. These recommendations apply to the use of symbols on the labels and in labeling only of IVDs intended for professional use, and not for over-the-counter or prescription home-use IVDs. This guidance does not address the use of "unique and generally recognized" symbols to identify the manufacturer of a device, as described in Section 502(u) of the Federal Food, Drug, and Cosmetic Act.

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In accordance with the consensus standards recognition process established by section 514(c) of the Act, in the **Federal Register** of April 28, 2003 (68 FR 22391) (enclosed), FDA published a notice recognizing certain international consensus standards, including the two standards listed below concerning the use of symbols in labeling. In the **Federal Register** of October 28, 2003 (68 FR 61449) (enclosed), FDA published a notice correcting the April 28th notice with respect to the extent of the recognition of the two standards.

Currently therefore, FDA recognizes 25 symbols for IVD devices for professional use from the following two international consensus standards:

- ISO 15223, Medical Devices -Symbols to be used with medical device labels, labeling and information to be supplied
- EN 980, Graphical symbols for use in the labeling of medical devices.

Through the process for recognizing international consensus standards, under section 514(c) of the Act, FDA received acceptable evidence in the form a user comprehension study conducted in the United States that indicates that professional users of IVDs can understand labels and labeling that use the identified symbols in place of equivalent text. Consequently, after reviewing the comments on the draft guidance, FDA intends to finalize the guidance, if appropriate. FDA recognizes that use of these symbols on labels and labeling of IVDs for professional can satisfy the requirements of section 502 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352, and of the applicable IVD labeling regulations.

After reviewing comments on the draft guidance, FDA may also propose to amend its regulations to address more specifically the use of symbols in labeling of IVDs. We invite you to submit any comments you may have on the draft guidance and on any rule that we may propose. If you have any questions about this response, please contact Paula Silberberg of our Office of Health and Industry Programs at 301-594-1217.

Sincerely yours,

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