

Bio-Rad Laboratories

Diagnostics Group 9500 Jeronimo Road Irvine, California 92618-2017 Telephone: (949) 598-1200

July 3, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Mail Stop: HFA-305
Rockville, MD. 20852

To Whom It May Concern:

I am resubmitting a Citizen's Petition in consideration for review by your department to permit the use of symbols on In-Vitro Diagnostic labeling.

The original document was mailed to the agency on June 13, 2001, but appears to not have been received.

Should you require additional information, please contact me directly at (949) 598-1465, via facsimile at (949) 598-1555, or via the Internet at yvette_lloyd@bio-rad.com.

Thank you.

With best regards,

Yvette Lloyd

Senior Regulatory Affairs Specialist

Bio-Rad Laboratories



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Diagnostics Group 9500 Jeronimo Road Irvine, California 92618-2017 Tolephone: (949) 598-1200

June 8, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Mail Stop: HFA-305
Rockville, MD. 20852

To Whom It May Concern:

The undersigned submits this petition under 21 CFR §10.30 to request the Commissioner of Food and Drugs to amend 21 CFR §809.10 to permit the use of symbols on the labeling required for products used for In-Vitro Diagnostic purposes or issue new regulations which would permit the use of symbols on medical device labeling.

This Citizen's Petition has been created in accordance with the format required by 21 CFR §10.30. The sections required in said regulation have been provided in appendices 1 - 4.

Should you have questions related to this petition, please contact me directly at (949) 598-1465, via facsimile at (949) 598-1555, or via the Internet at yvette lloyd@bio-rad.com.

Thank you.

With best regards,

Yvette Lloyd

Senior Regulatory Affairs Specialist

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