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June 8, 2001

Dockets Management Branch Food and Drug Administration Department of Health and Human Services Room 1-23 12420 Parklawn Drive Rockville, MD 20857

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(a) to allow the intended use statement to be removed from the box 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 <u>yvette_lloyd@bio-rad.com</u>.

Thank you.

With best regards,

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Yvette Lloyd Senior Regulatory Affairs Specialist Bio-Rad Laboratories

011-0272

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