9/10/1999

Ms. Carolyn D. Jones, J. D.
Associate Vice President
Technology and Regulatory Affairs
HIMA
1200 G Street, NW, Suite 400
Washington, D.C. 20005

Re: Docket #99P-1720/CP 1

Dear Ms. Jones:

This is in response to your petition dated June 3, 1999, requesting a variance from the requirements of the labeling regulation for natural rubber-containing medical devices, incorporated in 21 CFR 801.437.

Specifically, your petition requested that manufacturers of in vitro diagnostic devices (IVD's) be allowed to omit the statement "This Product Contains Dry Natural Rubber," from the label on the vials of these products. The variance is being sought for those products that have vial labels that are too small to accommodate the required statement and that provide the required information on an outer package as well as in a package insert.

The request is based on the insufficiency of space on the labels for IVD vials and on the precedent that FDA established by granting a similar variance to an individual manufacturer of these devices, Bio-Rad Laboratories. The current petition seeks to expand the variance granted to Bio-Rad into a general variance that includes other IVD manufacturers that are in a similar situation. The petition argues that both FDA and industry resources would be conserved by issuing such a variance.

The agency agrees with HIMA, and is hereby granting a general variance to manufacturers of in vitro diagnostic devices from the requirements of 21 CFR 801.437(e) with respect to the location of the warning statement on the immediate device package (vial) label. This variance is based on an insufficiency of label space on the vial label, and the availability of adequate warning statements on the outer package and package insert in accordance with 21 CFR 809.10 and 21 CFR 801.437.

Any manufacturer of an in vitro diagnostic device who wishes to apply this generic variance to their specific products must employ the following criteria:

1. The insufficiency of label space on the vial label must not be caused by:
   a. The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;
   b. The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502(c) of the act;
   c. The use of label space for any representation in a foreign language;

2. The product must have an outer package, container, or wrapper, and

3. The labeling of the product must otherwise comply with the requirements of 21 CFR 801.437(e) which stipulate that the required warning appear on "the outside package, container or wrapper" and "all other labeling" including the package insert.

4. The product must otherwise comply with the requirements of 21 CFR 809.10, "Labeling for in vitro diagnostic products."

The agency intends to announce the availability of this variance in the Federal Register in the near future. Thank you for your continued interest in this matter. We trust this response has been helpful.

Sincerely yours,

David Feigal, M.D.
Director
Center for Devices and
Radiological Health