

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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21 CFR Part 801

Food and Drug Administration

[Docket No. 99P-1720]

**Approval of an Alternate Requirement of the User Labeling Requirements for Devices Containing Dry Natural Rubber that Contact Humans; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans.” FDA granted a petition submitted by the Health Industry Manufacturers Association (HIMA), on behalf of in vitro diagnostic device (IVD) manufacturers, that requested a variance from placing the warning statement about dry natural rubber on the immediate IVD package (vial) label. FDA is announcing the availability of its response to HIMA’s petition in order to inform affected manufacturers and the public.

**ADDRESSES:** Submit written requests for single copies on a 3.5’ diskette of the document entitled “Approval of an Alternate Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans” to the contact person named below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the alternative requirement document.

**FOR FURTHER INFORMATION CONTACT:** John J. Farnham, Center for Devices and Radiological Health (HFZ-321), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20852, 301-594-4616.

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**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA issued a final rule, codified in 21 CFR § 801.437(e), requiring labeling statements on medical devices containing dry natural rubber that are intended to contact or likely to contact humans. The rule became effective on September 30, 1998. On June 3, 1999, HIMA requested a variance for in vitro diagnostic products that have vial labels too small to accommodate the required statement. The petition said that manufacturers of the products could place the warning on the outer package, as well as on a package insert. On September 10, 1999, FDA issued a letter granting HIMA's petition.

**II. Electronic Access**

In order to receive the document entitled "Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans," via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from the touch-tone telephone. At the first voice prompt press 1 to access the Division of Small Manufacturers Assistance (DSMA) Facts, at second voice prompt press 2, and then enter the document number (1148) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the alternative requirement may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphic, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the "Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, labeling

matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The document entitled "Approval of an Alternative Requirement of the User Labeling for Devices that Contain Dry Natural Rubber that Contact Humans" will be available at <http://www.fda.gov/cdrh>.

Dated: 1/9/00  
January 9, 2000

Linda S. Kahan

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