

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 18 1993

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Dear Official Correspondent:

The Food and Drug Administration (FDA) will soon publish in the Federal Register (FR), regulations requiring the labels of certain medical devices to declare latex content.

The regulation will require all medical devices which contain natural rubber latex, which comes directly or indirectly in contact with the body, to state on the principal display panel: "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX." Manufacturers may expand on this statement should they believe additional information on allergic reactions is desired. For example, the Agency would have no objection to the following wording: "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS IN SOME INDIVIDUALS."

In addition FDA will no longer permit the use of terms such as "hypoallergenic" on latex containing medical devices, such as gloves.

The International Latex Conference: Sensitivity to Latex in Medical Devices, held in Baltimore, Maryland on November 5 - 7, 1992, highlighted the need for FDA's actions. Since October 1988, FDA has received over 800 adverse reaction reports related to latex containing products. Sensitivity to latex has been reported in a wide array of latex containing medical devices.

FDA believes that latex in devices poses a significant health risk to some users and that these users and their health care providers should be informed of its presence. The new labeling will assist physicians when there is a need to create a latex free environment.

The term "hypoallergenic" is inconsistent and misleading with respect to latex containing products, because the basis of the claim, the modified Draize test, is not an appropriate measure of latex sensitivity. Such a labeling claim may put the latex sensitive user at risk for a serious adverse reaction.

In this regard FDA will be indicating, in the FR notice, the need for biocompatibility testing for all latex examination gloves. This criterion currently exists for surgeon's gloves and other latex containing products.

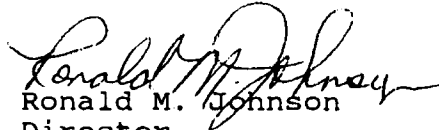
Modification of the labeling as indicated, for a marketed product, will not require a new 510(k) if there is no significant change that may affect the product's safety and efficacy. Once the regulation is published, there will be a six month effective date.

Page 2

Pending publication and the effective date of the regulation, FDA is encouraging the industry to voluntarily label latex containing devices in accord with this letter.

Questions regarding this issue and any labeling changes should be directed to: Byron Tart, Chief, Device Labeling Compliance Branch, (HFZ-326), 1390 Piccard Drive, Rockville, MD 20850, TEL. (301) 427-1342.

Sincerely yours,


Ronald M. Johnson
Director
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health