American Latex Allergy Association

FDA Consumer Update: There?s No Guarantee of ?Latex Free?

March 8, 2013

.

FDA Consumer Update: There?s No Guarantee of ?Latex Free?

To avoid giving a false sense of security to people who are allergic to natural rubber latex, the Food and Drug Administration (FDA) is recommending that manufacturers of FDA-regulated medical products stop using statements on labels such as ?latex-free? or ?does not contain latex.?

The problem with that language is that FDA is aware of no tests that can show a medical product is completely without the natural rubber latex proteins that can cause allergic reactions. Without a way to verify that a product is free of these proteins, claims that a product is ?latex free? may be misleading. FDA wants to promote scientifically accurate labeling.

As a result, FDA is recommending in a **draft guidance document** [1][6] announced in the Federal Register on March 8, 2013 that manufacturers who want to indicate that natural rubber latex was not used as a material instead use the more scientifically accurate labeling statement ?not made with natural rubber latex.? Public comments are welcome. Details on how to submit comments are provided in the draft guidance document and Federal Register notice.

Natural rubber latex made from plant sources such as the sap of the Brazilian rubber tree or its synthetic derivatives is used in numerous medical products, including adhesive bandages, condoms, medical gloves, catheters, sanitary napkins, crutches and blood-pressure monitoring cuffs. Repeated exposure can result in sensitivity to natural rubber latex proteins, with symptoms ranging from skin redness, rash, hives or itching to difficulty breathing and wheezing. Rarely, shock and even death can occur.

To view entire article: FDA Consumer Update: **There?s No Guarantee of ?Latex Free?** [2]

.

Reprinted from

American Latex Allergy Association
P.O. Box 198
Slinger, WI 53086
Phone: 262-677-9707 1-888-97-ALERT
Website: www.latexallergyresources.org

Source URL: http://www.latexallergyresources.org/news/fda-consumer-update-there-s-no-guarantee-latex-free

Links:
[1] https://www.latexallergyresources.org/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm340972.htm
[2] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm342641.htm