4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0168]

# Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex." The purpose of this draft guidance is to make recommendations on the appropriate language to include in the labeling of a medical product to convey that natural rubber latex was not used as a material in the manufacture of the product or product container. FDA is concerned that statements submitted for inclusion in medical product labeling such as "latex-free," "does not contain natural rubber latex," or "does not contain latex" are not accurate because it is not possible to reliably assure that there is an absence of the allergens associated with hypersensitivity reactions to natural rubber latex in the medical product. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit written or electronic comments on the draft guidance by [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments to http://www.regulations.gov. Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

## I. Background

Contact with devices containing natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. FDA medical device regulations include provisions that require certain labeling statements on medical devices if the device or device packaging is composed of or contains natural rubber that contacts humans. (See 21 CFR 801.437.) The biological products regulations require that the package label or package insert declare the presence of known sensitizing substances, but do not specifically mention natural rubber latex (21 CFR 610.61(l)). Specific regulations for labeling of natural rubber latex content in medical products or their containers do not exist for drugs or veterinary products.

At this time, there are no regulations requiring the labeling of a medical product to state that natural rubber latex was not used as a material in the manufacture of a medical product or medical product container. However, some manufacturers have included the promotional statements “latex-free” or “does not contain latex” in medical product labeling to inform users that natural rubber latex, dry natural rubber, or synthetic derivatives of natural rubber latex were not used. These labeling statements are not sufficiently specific, not necessarily scientifically accurate and may be misunderstood or applied too widely, and therefore, it is inappropriate to include such statements in medical product labeling. Use of these terms may give users allergic to natural rubber latex a false sense of security when using a medical product. The draft guidance provides recommendations for scientifically accurate labeling that can be used by manufacturers who wish to convey that natural rubber latex was not used as a material in the manufacture of a medical product or medical product container.

## II. Significance of Guidance

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on labeling medical products to inform users that a product or product container was not made with natural rubber latex. It does not create or confer any 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 and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents also are available at http://www.regulations.gov. To receive "Draft Guidance for Industry and FDA Staff: Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex," you may either send an email request to dsmica@fda.hhs.gov for an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1768 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The collections of information in 21 CFR part 801 are approved under OMB control

number 0910-0485 and the collections of information in 21 CFR part 610 subpart G are approved under OMB control number 0910-0338.

The labeling provisions recommended in this draft guidance are not subject to review by OMB because they do not constitute a "collection of information" under the PRA. Rather, the recommended labeling is a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

## V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

## VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.

1. Ahmed, S.M., T.C. Aw, and A. Adisesh, "Toxicological and Immunological Aspects of Occupational Latex Allergy," Toxicological Reviews, vol. 23, pp. 123-134, 2004.

Dated: March 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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