DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA-2013-D-0168]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff." The purpose of this 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, product container, and/or packaging. 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 a complete absence of the allergens associated with hypersensitivity reactions to natural rubber latex in the medical product.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time. Comments received from the public, all of which were considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on labeling medical products to inform users that a product, product container, or product packaging 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 guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1768 to identify the guidance you are requesting.
IV. Paperwork Reduction Act of 1995

This 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 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” under OMB. 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 between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. Interested persons may submit either electronic comments to this docket at 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.

FOR FURTHER INFORMATION CONTACT:
Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: workshop.CTP@fda.hhs.gov.

I. Background

On September 17, 2014, FDA announced a public workshop to gather information about electronic cigarettes (e-cigarettes) as announced in Docket No. FDA–2014–N–0001–0079. Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding electronic cigarettes and the public health.

DATES: Submit written or electronic comments by April 15, 2015.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments 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.

II. Submission of Comments

Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding electronic cigarettes and the public health. Information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm.

Interested persons may submit either electronic comments to this docket at 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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at worksheet@hrsa.gov or call (301) 443–1984.