Guidance for Industry: Designation of Special Controls for Male Condoms Made of Natural Rubber Latex (21 CFR 884.5300); Small Entity Compliance Guide

Document issued on: January 5, 2009

OMB Control No. 0910-0633
Expiration Date: 12/31/2011

See additional PRA statement in Section V of this guidance

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation

Contains Nonbinding Recommendations

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1693) to identify the guidance you are requesting.

Guidance for Industry

Designation of Special Controls for Male Condoms Made of Natural Rubber Latex (21 CFR 884.5300); Small Entity Compliance Guide

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

On November 10, 2008, the Food and Drug Administration (FDA) published a final rule in the **Federal Register**, entitled "Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex" (73 FR 66522). This final rule amended the classification regulation for condoms under 21 CFR 884.5300 and designated a special controls guidance document for male condoms made of natural rubber latex without spermicidal lubricant. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121). This guide is intended to provide guidance to small businesses on the requirements of Title 21, Code of Federal Regulations, amended Section 884.5300.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving

the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center Least Burdensome web page.

III. Summary of the Regulation

The final rule changes the classification regulation for condoms under 21 CFR 884.5300 by:

- updating terminology in the identification section
- creating new classifications sections to distinguish condoms made of natural rubber latex from condoms made of other materials
- changing the classification of condoms from class II (performance standards) to class II (special controls)
- designating a guidance document containing labeling recommendations as the special control for the subset of male condoms made of natural rubber latex.

IV. Questions and Answers on the Rule

1. What wording in the identification section of 21 CFR 884.5300(a) did the final rule change?

- FDA updated the term "venereal disease" to "sexually transmitted infection" which is a more accurate term used clinically.

  The identification section reads as follows:

  A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive and for prophylactic purposes (preventing transmission of sexually transmitted infections). The device may also be used to collect semen to aid in the diagnosis of infertility.

2. How did the final rule change the classification of condoms under 21 CFR 884.5300(b)?

- The final rule changed the classification of condoms from class II (performance standards) to class II (special controls).
- The final rule created two new classification sections to distinguish between
  - condoms made of materials other than natural rubber latex, including natural membrane (skin) or synthetic (21 CFR 884.5300(b)(1)), and
  - condoms made of natural rubber latex (21 CFR 884.5300(b)(2)).
- The final rule also designated a *guidance document* as the special control for condoms classified under 21 CFR 884.5300(b)(2).

3. What types of condoms are subject to the designated special controls guidance document?

- The special controls guidance document entitled "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300," is limited to male condoms made from natural rubber latex as described in 21 CFR 884.5300(b)(2).

4. What types of condoms are *not* within the scope of the special controls guidance document?

- This guidance document was *not* established as a special control for
    - male condoms with spermicidal lubricant (21 CFR 884.5310)
    - male condoms made of natural membrane (skin) (21 CFR 884.5300(b)(1))
    - male condoms made of synthetic materials (21 CFR 884.5300(b)(1)).

  Because male condoms with spermicidal lubricant, natural membrane condoms, and synthetic condoms differ in some respects from latex condoms without spermicidal lubricant, the special control guidance does not address these products.

5. Where can I find the special controls guidance document for male condoms made of natural rubber latex?

- The guidance document is available on the Internet (21 CFR 884.1(e))
- You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (1688) to identify the guidance you are requesting.

6. Do the labeling recommendations in the special controls guidance replace other labeling requirements for male condoms made of natural rubber latex?

- No. Male condoms made of natural rubber latex still must comply with the requirements for:
    - User labeling for latex condoms (21 CFR 801.435) addressing expiration dating
    - User labeling for devices containing natural rubber (21 CFR 801.437) addressing latex sensitivity
    - General labeling requirements applicable to all devices, including a statement of principal intended action(s) and adequate directions for use as described in 21 CFR part 801.

7. When does the final rule go into effect?

- The final rule is effective January 9, 2009.

8. When does FDA expect a firm to comply with the requirement of special controls under 21 CFR 884.5300(b)(2)?

- FDA expects a firm to show that its latex condom device meets the recommendations of the special control guidance or in some other way provides equivalent assurances of safety and effectiveness according to the following schedule:

- Premarket notification submissions (510(k)s) filed on or after January 9, 2009, are expected to comply with the requirement of special controls *at the time that the 510(k) is submitted*.
- Latex condoms cleared for marketing on or after January 9, 2009, but submitted in 510(k)s filed before January 9, 2009, are expected to comply with the requirement of special controls *on or before March 10, 2009*.
- Latex condoms legally marketed before January 9, 2009, are expected to comply with the requirement of special controls *by December 10, 2009.*

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 time required to complete this information collection is estimated to average 12 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0633 (expires 12/31/2011).