Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Ob/Gyn, Gastroenterology and Urology Devices Branch
Division of Enforcement A
Office of Compliance

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. Alternatively, electronic comments may be submitted to **Regulations.gov (http://www.regulations.gov)**. When submitting comments, please refer to Docket No. FDA-2004-D-0375. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Table of Contents

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300

I. Introduction

The Food and Drug Administration (FDA) has developed this guidance as a special controls guidance for male condoms made from natural rubber latex without spermicidal lubricant (latex condoms).[1] This guidance is issued in conjunction with a Federal Register notice announcing the amendment of 21 CFR 884.5300, an existing classification for condoms, from class II (performance standards) to class II (special controls). The amended classification designates this guidance document as the special control for latex condoms.

Latex condoms that are the subject of premarket notification submissions (510(k)s) filed on or after January 9, 2009, the effective date of the final rule designating this as a special control, are expected to comply with the requirement of special controls immediately upon the rule taking effect. Therefore, a firm submitting a 510(k) for a latex condom on or after the effective date of the rule must address the issues of safety and effectiveness identified in this special controls guidance, either by following the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

Latex condoms that are the subject of a 510(k) that is pending on the effective date of the final rule but are subsequently cleared are expected to comply with the requirement of special controls and address the issues of safety and effectiveness identified in this special controls guidance, either by following the recommendations in this guidance or by some other means that provides equivalent assurances of safety and effectiveness, on or before March 10, 2009.

Latex condoms that were legally marketed prior to the effective date of the final rule are expected to comply with the requirement of special controls and address the issues of safety and effectiveness identified in this special controls guidance, either by following the recommendations in this guidance or by some other means that provides equivalent assurances of safety and effectiveness, on or before December 10, 2009.

If you want to discuss an alternative means of satisfying the requirement of special controls for latex condoms, you may 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.

The Least Burdensome Approach

In developing this 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 comply with 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 (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

II. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide a reasonable assurance of the safety and effectiveness of latex condoms. Thus, a manufacturer who intends to market a device of this type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR Part 807, Subpart E, and the Quality Systems Regulation (21 CFR Part 820); and (2) address the specific issues requiring special controls associated with these devices as identified in this guidance, either in the user labeling as recommended here or in some other way that provides equivalent assurances of safety and effectiveness.

This special controls guidance document provides the classification and product code for latex condoms (refer to Section IV). In addition, other sections of this guidance document list the issues requiring special controls identified by FDA and describe labeling measures that, if followed by

manufacturers, will generally address the issues requiring special controls associated with this device.

The labeling recommendations in this guidance document reflect an extensive review on the part of the Agency, in consultation with the National Institutes for Health (NIH) and the Centers for Disease Control and Prevention (CDC), of the available medical literature on the safety and effectiveness of latex condoms intended to prevent pregnancy and sexually transmitted infections (STIs). In addition, the Agency considered other relevant information related to the barrier properties of latex condoms and the various routes of transmission of STIs, as well as public comments on the draft of this guidance, issued November 14, 2005 (70 FR 69156).

III. Other Labeling Requirements

While this guidance document provides examples of labeling recommended to meet the requirement of special controls for latex condoms under 21 CFR 884.5300(b)(2), there are also other specific labeling requirements for latex condoms contained in the following two regulations:

- user labeling for latex condoms (21 CFR 801.435), and
- user labeling for devices that contain natural rubber (21 CFR 801.437).

Additionally, condom manufacturers must ensure that their devices meet the general labeling requirements for medical devices described in 21 CFR Part 801.

Labeling requirements for latex condoms include the following:

A. Expiration date (21 CFR 801.435)

The retail and primary condom package (individual foil packet) must include an expiration date that is no later than five years from the date of product packaging. This expiration date must be supported by shelf life data developed by the condom manufacturer. For details, please see 21 CFR 801.435, "*User labeling for latex condoms*." This regulation addresses the risk of condom deterioration due to product aging.

B. Caution regarding natural rubber latex and allergic reactions (21 CFR 801.437)

Latex condoms, and all other devices composed of, or containing, natural rubber latex that contacts humans, are required to bear the following statement in bold print:

Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

This statement must appear on all device labels, and other labeling, and must also appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. For details, please see 21 CFR 801.437,

"User labeling for devices that contain natural rubber." This labeling requirement is necessary because devices composed of, or containing, natural rubber latex, pose a significant health risk to some individuals.

C. General labeling requirements

All devices, including latex condoms, are subject to the general labeling provisions described in 21 CFR Part 801, Subpart A. Additionally, latex condoms are over-the-counter (OTC) devices, and are therefore subject to the requirements for OTC devices described in 21 CFR Part 801, Subpart C. You should familiarize yourself with these labeling requirements. This special controls guidance is consistent with these requirements and, in fact, some of the labeling terminology used in this guidance is described by these regulations.

Latex condoms must also include adequate directions for use to avoid being misbranded (section 502(f) of the Act, 21 U.S.C. 352(f); 21 CFR 801.5). Adequate directions for use help ensure that the condom will be used correctly. (Section VI.3., includes an example of acceptable directions for use of latex condoms.)

FDA has included examples of labeling that incorporate the requirements of the Act and regulations and the recommendations made in this special controls guidance document in Section VII, below.

IV. Scope

The scope of this special controls guidance document is limited to male condoms made from natural rubber latex without spermicidal lubricant (latex condoms). Latex condoms are described in 21 CFR 884.5300 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.

Latex condoms are the subset of these condoms made of natural rubber latex and are assigned the product code HIS. (See 21 CFR 884.5300(b)(2).)

Exclusions from the Scope of this Guidance:

This guidance has not been established as a special control for male condoms with spermicidal lubricant (21 CFR 884.5310). Likewise, this guidance has not been established as a special control for male condoms made of natural membrane (skin) or synthetic materials that are classified under 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, this special control guidance does not address these products.

V. Issues Requiring Special Controls

FDA has identified the following issues requiring special controls associated with the use of latex condoms, which can be mitigated by the labeling recommended in the special controls guidance. The recommended mitigation measures (labeling) are intended to provide information to users about the extent of protection provided by latex condoms to help prevent pregnancy and help prevent the spread of various types of STIs. The labeling provides important information for condom users to assist them in determining whether latex condoms are appropriate for their needs, as well as instructions for optimal use.

Table 1 includes risks associated with sexual intercourse, i.e., unintended pregnancy and STI transmission, that latex condoms are intended to prevent. This special controls guidance document addresses how manufacturers can label their latex condoms to help assure that they will be safe and effective for these intended uses, which are of significant personal and public health concern. Labeling for latex condoms should follow the mitigation measures suggested in Table 1. All the labeling recommendations are discussed in more detail in Section VI.

A. Issues Requiring Special Controls and Recommended Mitigation Measures for Latex Condoms

Table 1. Identified Issues and Recommended Mitigation Measures

Identified issues*	Recommended mitigation measures
1. Risk of Unintended Pregnancy	Labeling should indicate that latex condoms are intended to prevent pregnancy. Labeling should indicate that condom use does not eliminate the risk of pregnancy and also indicate the importance of correct and consistent use. Labeling should indicate that consumers should consult a health care provider if they have questions about birth control options, particularly because of health reasons for avoiding pregnancy. Labeling should include information comparing the percentage of women experiencing unintended pregnancy during one year of use of latex condoms with rates experienced during one year of use of other contraceptive methods available in the U.S., including drugs, devices, and methods of permanent sterilization . The information should address, at minimum, typical use rates.
2. Risk of Transmission of Sexually Transmitted Infections (STIs) • Condoms reduce the overall risk of STI transmission (including transmission of HIV/AIDS and other STIs). • Degree of protection against different types of STIs varies.	Labeling should indicate that latex condoms are intended to prevent HIV/AIDS and other STIs. Labeling should indicate that condom use does not eliminate the risk of STIs and also indicate the importance of correct and consistent use. Labeling should indicate that latex condoms reduce the risk of transmission of STIs by providing a barrier against the source of the infection. Labeling should indicate that condoms are most effective against STIs such as HIV/AIDS and gonorrhea that are spread by contact with the head of the penis. Labeling should indicate condoms are less effective against STIs such as Human Papillomavirus (HPV) and herpes that can also be spread by contact with infected

	skin that is not covered by the condom. Labeling should indicate that consumers who believe they have an STI should contact a health care provider. Labeling should indicate that for more information on latex condoms or STIs, consumers should contact a health care provider or public health agency.
3. Incorrect or inconsistent use diminishing the effectiveness of latex condoms against the risks of unintended pregnancy and STI transmission.	Labeling should include adequate directions for use and precautions about incorrect or inconsistent use.

* Additional risks of (1) product deterioration due to aging and (2) allergic reactions to latex have been specifically addressed in labeling regulations that are discussed in Section III of this guidance.

VI. Labeling Recommendations

This section provides guidance on the labeling of latex condoms grouped according to the issues identified in Table 1 of Section V of this document. Generally, there are three different levels of packaging for latex condoms:

- the retail package (includes the principal display panel)
- the primary condom package (individual foil packet)
- the package insert.

The recommendations in this section indicate the level(s) of packaging where the labeling should appear and provide examples of labeling statements that adequately address the issues identified in Table 1. Example statements appear in the guidance in italics to make them easier to identify, but FDA is not recommending italic font be used in actual labeling.

Labeling Recommendations for Latex Condoms

1. Unintended Pregnancy

1a. The principal display panel, the primary condom package (individual foil packet) and the package insert should identify contraception as one of the principal intended actions of the latex condom (along with preventing transmission of HIV/AIDS and other STIs, as described in section VI.2a.)[2] The following is an example of an acceptable statement addressing both intended actions:

"Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections."

1b. The back of the retail package should contain a **box** entitled *Important Information.* The first statements in this box should indicate that latex condom use does not completely eliminate the risk of pregnancy and highlight the importance of correct and consistent use. (These statements should also include the information described in Section VI.2b of this guidance.) The following is an example of such statements:

"Latex condoms do not completely eliminate the risks of pregnancy and sexually transmitted infections (STIs).

To get the most protection from a latex condom, use one correctly every time you have sex. Please see directions for use inside the package."

1c. The package insert should include a statement that consumers should consult a health care provider if they have questions about birth control options, particularly because of health reasons for avoiding pregnancy. The following is an example of such a statement:

"If you have questions about birth control options, particularly because of health reasons for avoiding pregnancy, consult a health care provider."

The package insert should also contain contraceptive effectiveness information comparing the percentage of women experiencing unintended pregnancy during one year of use of latex condoms with rates experienced during one year of use of other contraceptive options available in the U.S. including drugs, devices, and methods of permanent sterilization . This information should at minimum include typical use rates. This information is intended to enable contraceptive users to compare alternatives and make appropriate choices. We recommend that you develop your contraceptive effectiveness information from Hatcher, Trussell, et al. (Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive Technology: Nineteenth Revised Edition. New York NY: Ardent Media, 2007), or its updates.

2. Sexually Transmitted Infections (STIs)

Condoms reduce the overall risk of STI transmission (including transmission of HIV/AIDS and other STIs):

2a. The principal display panel, the primary condom package (individual foil packet), and the package insert should identify preventing transmission of HIV/AIDS and of other STIs as a principal intended action of the latex condom (along with preventing pregnancy, as described in section VI.1a).[3] The following is an example of a statement addressing both uses.

"Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections."

2b. The back of the retail package should have a **box** entitled *Important Information.* The first statements in this box should indicate that latex condom use does not completely eliminate the risk of STIs and highlight the importance of correct and consistent use. (These statements should also include the information described in Section VI.1b of this guidance.) The following is an example of such statements:

"Latex condoms do not completely eliminate the risks of pregnancy and sexually transmitted infections (STIs).

To get the most protection from a latex condom, use one correctly every time you have sex. Please see directions for use inside the package."

Degree of protection against different types of STIs varies:

STIs can be transmitted in various ways, including transmission to or from the head of the penis and transmission by contact with infected skin not covered by the condom. The degree of protection provided by latex condoms depends on whether the condom provides a barrier against the source of the infection.

2c. To reflect this, the *Important Information***box** on the back of the retail package should contain the following information. The first statement, after the statements addressing the information discussed in sections VI.1b and 2b should state that there are many STIs, and address the differential effectiveness of condoms for various STIs. This message should also refer consumers to the location in the labeling of additional information on STI protection. Another statement should suggest that consumers who believe they have an STI should contact a health care provider and that for more information on latex condoms or STIs, consumers should contact a health care provider or public health agency.

The following is an example of an acceptable set of statements addressing 1b, 2b, and 2c:

Important Information

- *Latex condoms do not completely eliminate the risks of pregnancy and sexually transmitted infections (STIs).*
- *To get the most protection from a latex condom, use one correctly every time you have sex. Please see directions for use inside the package.*
- *There are many STIs. A latex condom can reduce the risk of STI transmission to or from the head of the penis. However, some STIs can also be spread by other sexual contact. For additional information on STI protection, please read the information inside the package.*
- *If you believe you have an STI, contact a health care provider. For more information on condoms or STIs, contact a health care provider or public health agency.*

2d. The package insert of latex condoms should contain a section stating that latex condoms reduce the risk of STIs by providing a barrier against the source of infection. The section should also explain that latex condoms are most effective against STIs, such as HIV infection (AIDS) and gonorrhea, that are spread by contact with the head of the penis. The section should also explain that condoms are less effective against STIs, such as HPV and herpes, that can also be spread by contact with infected skin not covered by the condom. The following is an example of an acceptable statement:

"Degree of STI Protection

Latex condoms reduce the risk of transmitting STIs by providing a barrier against the source of the infection.

- *Latex condoms are most effective against STIs such as HIV infection (AIDS) and gonorrhea that are spread by contact with the head of the penis.*
- *Latex condoms are less effective against STIs such as Human Papillomavirus (HPV) and herpes. These STIs can also be spread by contact with infected skin that is not covered by the condom."*

2e. The package insert should also refer consumers to health care providers if they believe they have an STI. The following is an example of an acceptable statement:

"If you believe you have an STI, contact a health care provider."

2f. The package insert should notify the consumer that for additional information on latex condoms and STIs a health care provider or public health agency should be contacted.

The following is an example of an acceptable statement:

"For more information on latex condoms or STIs, contact a health care provider or a public health agency."

3. Incorrect or Inconsistent Use

Latex condoms must include adequate directions for use to avoid being misbranded (section 502(f) of the Act, 21 U.S.C. 352(f); 21 CFR 801.5). Adequate directions for use will also help address the issue of incorrect or inconsistent use. Precautions should also address this issue. We provide examples of appropriate directions for use and precautions for latex condoms below. Manufacturers may have additional directions for use, precautions, or other information that they believe is necessary for proper use of their products. Such additional information is acceptable as long as it does not conflict with or detract from the statements recommended in this guidance (or equivalent statements) or any other applicable requirements (see Section III).

3a. Directions for Use:

The following set of statements is an example of acceptable directions for use for latex condoms:[4]

Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections.

1. *Use a new condom for each act of sex.*
2. *Tear open the package carefully. Do not use fingernails, teeth, or anything that can damage the condom.*
3. *Before any sexual contact, place the condom on the head of the erect penis with the rolled side out.*
    - *Lesions, pre-ejaculate secretions, semen, vaginal secretions and blood can all transmit infectious organisms.*
4. *Unroll or pull the condom all the way to the base of the erect penis. If the condom doesn't unroll easily, it may be on backwards, damaged or too old. Throw it away and start over with a new condom.*
5. *Immediately after ejaculation, hold the rim of the condom in place and withdraw the penis while it is still erect.*
    - *Avoid spilling semen.*
6. *Dispose of a used condom by wrapping it in tissue and throwing it into the trash. Wash your hands with soap and water.*

Pictorial representations of each direction for use are recommended. Line art attracts and keeps a reader's interest and is often remembered longer than words. Properly chosen and placed illustrations re-emphasize the text, make it more meaningful, and reduce the burden of details in the text. Graphics should:

- be simple and clearly drawn, without clutter, unneeded background, or extraneous detail
- be placed next to corresponding text
- use cues such as circles or arrows to point out key information
- be clearly labeled
- be easy to understand
- be recognizable to the audience

3b. Precautions

The following set of statements is an example of acceptable precautions regarding condom use:

- *Do not reuse latex condoms.*

- *Store latex condoms in a cool, dry place (below 100ºF) and avoid exposure to direct sunlight.*
- *If the rubber material is sticky or brittle or obviously damaged, do not use the condom.*
- *If the color is uneven or changed, do not use the condom.*
- *Make sure there is adequate lubrication. If you add lubricant, use a water-based lubricant. [Manufacturers may identify one or more examples.] DO NOT USE OIL-BASED LUBRICANTS, such as those made with petroleum jelly (e.g., Vaseline ®), mineral oil, vegetable oil, or cold cream, as these may damage the condom.*

VII. Examples of Condom Labeling that Follow the Recommendations in the Guidance

Label statements appearing in *italics* are those recommended in Section VI of the current guidance. Other label statements, discussed in Section III of this guidance, appear in regular font. This difference in font styles is used only to identify the labeling recommended by this guidance as a special control. FDA is not recommending italic font for the actual label statements provided by manufacturers.

In recognition of the variety of ways that manufacturers may configure their labeling to satisfy their statutory and regulatory labeling obligations as well as incorporate the recommendations of this guidance, this section does not include a full mock-up of a package insert, but gives only selected examples of recommended language. Please consult the body of this guidance, 21 CFR Part 801, and the Act, for other information on the full content of labeling.

Front panels of condom retail package:

Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections. **Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**
When used correctly every time you have sex, latex condoms help prevent pregnancy and reduce the risk of transmitting HIV/AIDS, and other sexually transmitted infections.[5]
XYZ Brand Latex Condoms **# (net quantity) Latex Condom**

Rear panel of condom retail package

Important Information • *Latex condoms do not completely eliminate the risks of pregnancy and sexually transmitted infections (STIs).* • *To get the most protection from a latex condom, use one correctly every time you have sex. Please see*

directions for use inside the package.

- *There are many STIs. A latex condom can reduce the risk of STI transmission to or from the head of the penis. However, some STIs can also be spread by other sexual contact. For additional information on STI protection, please read the information inside the package.*
- *If you believe you have an STI, contact a health care provider. For more information on condoms or STIs, contact a health care provider or public health agency.*

Distributed by XYZ Corporation Rockville, Maryland	EXP. Date: Jan 20XX

Primary condom package (individual foil packet):

Front of packet	Back of packet
One XYZ Brand Latex Condom *Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections.* **Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**	Before using, please see directions for use inside the package. Distributed by XYZ Corporation Rockville, Maryland EXP Date: Jan 20XX

Examples of information to be included in package insert:

Directions for Use

Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections.

1. *Use a new condom for each act of sex.*
2. *Tear open the package carefully. Do not use fingernails, teeth, or anything that can damage the condom.*
3. *Before any sexual contact, place the condom on the head of the erect penis with the rolled side out.*
    - Lesions, pre-ejaculate secretions, semen, vaginal secretions and blood can all transmit infectious organisms.
4. *Unroll or pull the condom all the way to the base of the erect penis. If the condom doesn't unroll easily, it may be on backwards, damaged or too old. Throw it away and start over with a new condom.*
5. *Immediately after ejaculation, hold the rim of the condom in place and withdraw the penis while it is still erect.*
    - Avoid spilling semen.
6. *Dispose of a used condom by wrapping it in tissue and throwing it into the trash. Wash your*

hands with soap and water.

Package insert (cont.)

Precautions:

- Do not reuse latex condoms.
- Store latex condoms in a cool, dry place (below 100ºF) and avoid exposure to direct sunlight.
- If the rubber material is sticky or brittle or obviously damaged, do not use the condom.
- If the color is uneven or changed, do not use the condom.
- Make sure there is adequate lubrication. If you add lubricant, use a water-based lubricant. [Manufacturers may identify one or more examples.] DO NOT USE OIL-BASED LUBRICANTS, such as those made with petroleum jelly (e.g., Vaseline®), mineral oil, vegetable oil, or cold cream, as these may damage the condom.

Degree of STI Protection

Latex condoms reduce the risk of transmitting STIs by providing a barrier against the source of the infection.

- Latex condoms are most effective against STIs such as HIV infection (AIDS) and gonorrhea that are spread by contact with the head of the penis.
- Latex condoms are less effective against STIs such as Human Papillomavirus (HPV) and herpes. These STIs can also be spread by contact with infected skin that is not covered by the condom.

If you believe you have an STI, contact a health care provider. For more information on latex condoms or STIs, contact a health care provider or a public health agency.

VIII. 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:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov (mailto:PRAStaff@fda.hhs.gov)

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 801, including those in 21 CFR 801.435, referenced in the guidance, have been approved under OMB control number 0910-0485. The latex allergy caution required by 21 CFR 801.437 and referenced in the guidance does not constitute a "collection of information" under the PRA. Rather, it 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)).

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 May 31, 2018).

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[1] As discussed in section IV of this guidance, male condoms made of natural rubber latex with spermicidal lubricant (21 CFR 884.5310), which includes lubricant that contains nonoxynol-9 (N-9), are not within the scope of this guidance.

[2] In the package insert, this statement may be included in the directions for use, to satisfy the requirements of 21 CFR 801.5(a).

[3] In the package insert, this statement may be included in the directions for use, to satisfy the requirements of 21 CFR 801.5(a).

[4] Adequate directions for use must contain a statement of indications for use. (21 CFR 801.5(a)). As indicated in the example below, the statement recommended under sections 1a and 2a may be incorporated into the instructions for use to fulfill this requirement.

[5] You may add this statement to the “top shelf” of the condom retail package (the front panels also include the hanger and main box front).

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)