SUPPORTING STATEMENT FOR
CLASS II SPECIAL CONTROLS GUIDANCE DOCUMENT:
LABELING FOR NATURAL RUBBER LATEX CONDOMS CLASSIFIED UNDER 21 CFR 884.5300

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, defined by the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Class II devices are defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. The natural rubber latex condoms without spermicidal lubricant are class II devices. Section 513(a)(1)(B) of the act defines those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, dissemination and development of guidelines, recommendations, and any other appropriate actions the agency deems necessary. The Food and Drug Administration (FDA) selected a special

controls guidance document as the most effective method for disseminating its labeling recommendations for condoms without spermicidal lubricant.

On December 21, 2000, Congress enacted Public Law 106-554, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ554.106, which required that FDA " * * * reexamine existing condom labels" and " * * * determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including [human papillomavirus]." Under this mandate, FDA undertook a review of the medical accuracy of condom labeling, which included an extensive review of the scientific information related to condoms. The special controls guidance document includes labeling recommendations based on this FDA review.

2. Purpose and Use of the Information Collection

The manufacturers of latex condoms would need to make changes to the present information on the retail package, including the principal display panel, the primary condom package (individual foil), and package insert.

The primary users of the information disclosed on the label or in the labeling for devices are the health professionals who use or prescribe the device or the lay consumers who use the device. The intent of these rules is that the labeling should contain sufficient information for these persons to use the device safely and effectively. FDA may use the information to determine whether there is reasonable assurance of the safety and effectiveness of the device for its intended use. Failure of the manufacturer, packer, or distributor to label its products in accordance with section 502 of the act may result in the

product being misbranded under the act and the firm and the product subject to regulatory action.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers and repackagers may use any appropriate forms of information technology to develop and distribute the recommended labeling.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency with jurisdiction that can recommend labeling changes to medical devices, which includes male condoms made of natural rubber latex.

5. Impact on Small Businesses or Other Small Entities

FDA helps to minimize the impact on small businesses through personalized assistance provided by the Center for Devices and Radiological Health's Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) and its technical and regulatory staff.

6. Consequences of Collecting the Information Less Frequently

This is a one-time burden for respondents, because once a label is redesigned, it can be used indefinitely.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection is consistent with the guidelines prescribed in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of July 8, 2011 (76 FR 40377), FDA solicited comments on this information collection, no comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information that is made available in labeling is, by its nature, public information. Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

TABLE 1. – ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

21 CFR Section	Number of Respondents	Number of disclosures per respondent	Total Annual Disclosures	Average burden per disclosure	Total Hours
884.5300	3	34	102	12	1,224

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA expects approximately three new manufacturers or repackagers to enter the market yearly, and collectively have a third-party disclosure burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA's database of premarket submissions. The remaining figures were derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging

requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to currently approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information under 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in part 801 (21 CFR part 801) have been approved under OMB control number 0910-0485.

The collection of information in 21 CFR part 801.437 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)).

12b. Annualized Cost Burden EstimateCost to Respondents

	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Design of Label	12	$44.17	$530.00

Using a wage rate of $44.17, the average incremental cost of the one time regulatory component cost to redesign the labels is $530.00.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The annualized cost for FDA to review the labels or any other action on the labels is approved under OMB control number 0910-0120; annual cost of $21,879.00

15. Explanation for Program Changes or Adjustments

There is a decrease in burden by 14,280 hours and a decrease in annual responses by 1,088. The previously approved collection, a newly implemented ICR, included reporting burden hours to respondents (then current manufacturers) in the first year as a one-time burden of 14,280 hours. The proposed ICR includes only the one-time (now third-party) burden for prospective new manufacturers. FDA continues to expect three new manufacturers or repackagers to enter the market yearly and collectively have a one-time burden of 1,224 hours; unchanged from the previously approved ICR.

Additionally, after a review under the PRA, the burden has been changed from reporting to third-party. FDA feels that regarding the burden as a third-party disclosure is more appropriate because it is a labeling item ultimately intended to inform the consumer, i.e., a third party.

16. Plans for Tabulation and Publication and Project Time Schedule

Labeling information collections are not collected as part of a statistical analysis.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking an exemption to not display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.