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) (Attachment 1) 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. <u>Purpose and Use of the Information Collection</u>

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

On November 14, 2005 (70 FR 69159), FDA solicited comments on this information collection contained in the draft special controls guidance document then entitled "Labeling for Male Condoms Made of Natural Rubber Latex." FDA has subsequently retitled the special controls guidance document containing these information collection provisions to avoid confusion between the guidance established as a special control for condoms classified under 21 CFR 884.5300 by the final rule published elsewhere in this issue of the FEDERAL REGISTER and the November 2005 draft guidance, which remains available (but not for implementation) in conjunction with the pending proposal to amend another classification. There were no comments received on the information collection provisions in response to the 60-day notice.

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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

FDA estimates the burden of this collection as follows:

TABLE 1. – ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 513 of the FD&C Act	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
First Year	35[2]	34	1,190	12	14,280
Second and Third Year	3[3]	34	102	12	1,224
Total					15,504

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Current manufacturers for year one.
[3]New Manufacturers for years two and three.

The reporting burden to respondents in the first year is a one-time burden of 14,280 hours. FDA expects three new manufacturers or repackagers to enter the market yearly with a total one-time burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in Table 1 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 redesign the labeling for OTC drugs is an approximate proxy for the estimated costs to redesign condom labeling. Cost estimates were adjusted to account for inflation using the producer price index (PPI).

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 No. 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910-0073; and the collections of information in 21 CFR part 801 have been approved under OMB Control No. 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)).

Cost to Respondents

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**

This is a new collection of information.

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 approval to not display the OMB expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.