Surveillance and Epidemiology in the Center for Drug Evaluation and Research, or the Branch Chief at the Advertising and Promotion Labeling Branch of the Division of Case Management in the Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research, concerning any questions about their proposed submissions. For prescription products, applicants should inform the appropriate center at the 120-day pre-submission discussion if they plan to use alternative or additional methods to evaluate the safety of their proposed proprietary name. For nonprescription products, sponsors should discuss with FDA different protocols that could be used for their specific drug products prior to the submission of the proprietary name.

- Applicants should submit two separate sets of product name-related information to enable parallel reviews by FDA as follows: (1) A comprehensive evaluation of the proposed proprietary name including the information and data listed in Appendix B (''Proposed Template For A Pilot Program Submission'') of the concept paper; and (2) the proprietary name information that they would ordinarily submit under FDA's current practice. (Note: The proprietary name information ordinarily submitted under FDA's current practice is not included in the estimates in table 1 of this document because this information collection is already approved under OMB Control Numbers 0910–0001 and 0910–0338).
- After review of the proprietary name submissions, and if FDA informs the applicant that the proposed first-choice proprietary name is unacceptable, the applicant should confirm in writing that it would like its originally submitted second-choice name reviewed, or the applicant should submit an alternative second-choice name along with the information described in the concept paper. At that time, FDA will begin review of the second-choice name. If an applicant has submitted a complete proprietary name analysis for the second-choice name, the responsible center will use discretion to determine whether to review the applicant's analysis in addition to conducting its own analysis using the traditional approach. Although FDA would ideally review the applicant's completed proprietary name analysis for the second-choice name, factors such as staffing and timelines will be used in making this determination.

FDA estimates the burden of this collection of information in table 1 of this document. The ''hours per response'' is for all of the submissions and notifications to FDA described under the bulleted paragraphs above and is based on information provided by industry as well as FDA's familiarity with the time required for this information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pilot Project Proprietary Name Review	20	1	20	480	9,600

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30587 Filed 12–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0375] (formerly Docket No. 2004D–0555)

Guidance for Industry and Food and Drug Administration Staff; ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300.'' This guidance document describes a means by which male condoms made of natural rubber latex (latex condoms) may comply with the requirement of special controls for class II devices. FDA believes that the labeling recommendations contained in this guidance, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of latex condoms without spermicidal lubricant. In the **Federal Register** of November 10, 2008 (73 FR 66522), FDA published a final rule that amended the classification regulation for condoms from class II (performance standards) to class II (special controls) and designated this guidance document as the special control for male condoms made of natural rubber latex classified under that regulation.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for

information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paul Tilton, Center for Devices and Radiological Health (HFZ–332), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, Congress enacted Public Law 106–554, which directed FDA to ''* * * 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 conducted a review of scientific information and of existing latex condom labeling, and concluded that existing latex condom labeling was medically accurate in presenting the conclusion that, as an overall matter, condoms are effective in reducing the risk of sexually transmitted infections (STIs). To help consumers make appropriate choices for their particular needs, and therefore to ensure the safe and effective use of latex condoms, FDA issued a proposed rule to establish a labeling guidance as a special control to address some additional, more nuanced information about latex condoms and STIs, as well as to provide information about contraception, and about appropriate directions and precautions for use of latex condoms (the 2005 proposed rule) (70 FR 69102, November 14, 2005). The rule proposed to amend existing classification regulations to designate a labeling guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex'' as the special control for condoms made of natural rubber latex (latex condoms), classified under § 884.5300 (21 CFR 884.5300), and latex condoms with spermicidal lubricant containing nonoxynol-9, classified under § 884.5310 (21 CFR 884.5310). Also in the **Federal Register** of November 14, 2005 (70 FR 69156), FDA announced the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex'' (the 2005 draft guidance). FDA invited interested persons to comment on the 2005 proposed rule and 2005 draft guidance by February 13, 2006.

In response to FDA's requests for comments, more than 100 commenters submitted information and comments to the docket for the 2005 proposed rule and the docket for the 2005 draft guidance. Because of the intertwined nature of the 2005 proposed rule and the 2005 draft guidance, and because of the significant overlap in comments, FDA considered all comments in preparing both the final rule and special controls guidance. The analysis of comments is contained in the final rule.

In the **Federal Register** of November 10, 2008 (73 FR 66522), FDA issued a final rule which amended the classification regulation for condoms in § 884.5300 and designated the guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300,'' which is the subject of this notice, as the special control for latex condoms classified under that regulation. This guidance is based on the draft guidance proposed as a special control in November 2005 entitled ''Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex.'' FDA assigned a new title to the final special control guidance document designated as a special control by § 884.5300 in order to avoid confusion with the 2005 draft guidance, which remains available (but not for implementation) as the proposed special control for latex condoms with spermicidal lubricant (classified under § 884.5310) in association with the proposal to amend that classification regulation. FDA is continuing to study the issues surrounding latex condoms with spermicidal lubricant and has not yet issued a new final rule regarding those devices.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the labeling recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of latex condoms classified under § 884.5300. The final rule establishing this guidance document as a special control will be effective January 9, 2009. Following the effective date of the final rule, latex condoms classified under § 884.5300 must comply with the requirement of special controls; manufacturers must address the issues requiring special controls as identified in the guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document 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.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. 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 (the PRA) (44 U.S.C. 3501–3520). The new collections of information in this guidance were approved under OMB control number 0910–0633.

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)).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30586 Filed 12–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0644]

SEQC—The Sequencing Quality Control Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation.

SUMMARY: The Food and Drug Administration (FDA) is soliciting volunteers to participate in the SEQC (Sequencing Quality Control) project to objectively assess the technical performance of different next-generation sequencing technologies in DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) analyses and to evaluate the advantages and limitations of various bioinformatics solutions in handling and analyzing the massive new data sets. The SEQC project is a natural extension of the MicroArray Quality Control (MAQC) project (*http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/*) and is being coordinated by the FDA. This project is open to the public. Vendors of next-generation sequencing technologies and institutions interested in the generation, management, analysis, and interpretation of the resulting sequence data are welcome to participate.

DATES: Requests to participate in the SEQC project at the National Center for Toxicological Research (NCTR) should be submitted on or before 4:30 p.m., CST, January 9, 2009, or be postmarked on or before January 9, 2009.

ADDRESSES: Requests to participate in the SEQC project should be sent to Leming Shi, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7387, FAX: 870–543–7854; e-mail: *leming.shi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA's Critical Path Initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*) identifies pharmacogenomics as a key opportunity in advancing medical product development and personalized medicine. FDA has issued the ''Guidance for Industry: Pharmacogenomic Data Submissions'' (*http://www.fda.gov/cder/guidance/6400fnl.pdf*) to facilitate scientific progress in the field of pharmacogenomic data integration in drug development and medical diagnostics.

Microarrays represent a core technology in pharmacogenomics and toxicogenomics; however, next-generation sequencing technologies promise to provide some unique advantages in DNA and RNA analyses and are expected to be adopted by the pharmaceutical and medical industries for advancing personalized nutrition and medicine.

The SEQC project, with broad participation from scientists and reviewers within FDA and collaborators across the public, academic, and private sectors, is expected to help prepare FDA for the next wave of submission of genomic data generated from the next-generation sequencing technologies.

Dated: December 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30410 Filed 12–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict Panel for BGES and BMRD.

Date: January 7, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Scott Osborne, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435–1782, *osbornes@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, IMM Member Application Review.

Date: January 9, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Cathleen L. Cooper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, 301–435–3566, *cooperc@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Epidemiology of Chronic and Acute Outcomes.

Date: January 15, 2009.

Time: 10:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.