compliance with the requirements in section 801(e)(1) of the FD&C Act. In the Federal Register of December 6, 2010 (75 FR 75677), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Annual frequency per response</th>
<th>Total annual responses</th>
<th>Hours per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.101 (d)</td>
<td>400</td>
<td>3</td>
<td>1,200</td>
<td>15</td>
<td>18,000</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of record-keepers</th>
<th>Annual frequency of recordkeeping</th>
<th>Total annual records</th>
<th>Hours per recordkeeper</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.101(b), (c), (e)</td>
<td>320</td>
<td>3</td>
<td>960</td>
<td>22</td>
<td>21,120</td>
</tr>
</tbody>
</table>

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

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN**

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN**

Dated: July 1, 2011.

Leslie Kux, Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17140 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2011–N–0492]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the labeling of natural rubber latex condoms.

DATES: Submit either electronic or written comments on the collection of information by September 6, 2011.

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

5156, 3 960 22 21,120
5156, 3 960 22 21,120

With respect to the following classification of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300—(OMB Control Number 0910–0632)—Extension

Under the Medical Device Amendments of 1976 (Pub. L. 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance.

Condoms without spermicidal lubricant containing nonoxynol-9 are classified in class II. They were originally classified by the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101–629) that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide...
reasonable assurance of the safety and effectiveness of such devices. In December 2000, Congress enacted Public Law 106–554, which among other provisions, directed FDA to “reexamine existing condom labels” and “determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases * * *.” In response, FDA recommended labeling intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant.

FDA estimates the burden of this collection of information 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 under § 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)).

Dated: July 5, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2011–17156 Filed 7–7–11; 8:45 am]