product pill appearance change. These surveys are intended to further our understanding of the relationship between changes in pill appearance and non-adherence to prescribed therapeutic regimens. The surveys may enable us to investigate factors that may explain the association between changes in pill appearance and non-adherence, including which factors could be modified to improve the safe and effective use of generic drugs.

We intend to survey a national cohort of pharmacists about their experiences with dispensing generic drug pills that differ in appearance from previous refills of the same medication and dosage level (e.g., when pharmacies switch generic suppliers). A stratified, random sample of U.S.-licensed pharmacists will be obtained based on a master list from KM Lists. The target sample includes pharmacists with active licenses who practice in traditional community pharmacy settings and will be proportionally allocated across the United States in relation to the number of pharmacists in each state. Based on an 11 percent undeliverable rate and a 52 percent response rate, 2,161 questionnaires will be mailed to pharmacists to obtain the 1,000 responses required for adequate statistical power. The pharmacists' survey will consist of a mailed questionnaire rather than a telephone survey or an email survey. Prior experience conducting surveys has shown that it is easier to guarantee respondent anonymity using an impersonal, mailed questionnaire with no individual identifying information. The pharmacists will be asked about the frequency with which their pharmacy changes suppliers that lead to variations in the appearance of the generic drugs that they dispense, as well as strategies they use with patients to address the transition to pills that have a different appearance (e.g., alert stickers on pill bottles, verbal warnings, and other strategies). They will also be asked about patient responses to changes in pill appearance, including what types of appearance changes seem to affect patients most often (shape/color/size), how often patients report confusion about pill appearance, and how often patients ultimately refuse to accept the new product. Participation is expected to take approximately 20 minutes.

We also intend to survey two different patient samples using two methodologies. The first is a telephone survey of patients who are 50 years and older and who take one or more generic medications for at least one of the following chronic conditions: Epilepsy, diabetes, hypertension, hyperlipidemia, depression, and HIV. The telephone survey will be generalizable and will consist of well-defined methods to minimize sampling bias such as use of random phone numbers for both landlines and mobile phones, as well as small-batch sampling to ensure a high response rate that meets demographic diversity goals. For the second patient survey, patients will be selected from a proprietary research database of commercially insured patients containing medical and pharmacy claims linked to health insurance enrollment information. A nationally representative sample of patients with at least one chronic condition and who experienced a change in physical appearance of a generic pill will be identified by the research team using medical and pharmacy claims data. Both patient surveys will consist of questions covering topics similar to those asked in the survey of pharmacists and is intended to provide answers to the same topic areas from patients' perspectives. As before, topic areas will include beliefs about generic drugs, outcomes related to changes in generic drug pill appearance, and strategies used by pharmacists or doctors to alert patients to the possibility of changes in appearance. Participation is expected to take approximately 20 minutes.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Surveys of pharmacists and patients on variations in the physical characteristics of generic drug pills and patients' perceptions	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey of Pharmacists	1,000	1	1,000	0.333 (20 minutes)	333
Survey of Patients #1	1,000	1	1,000	0.333 (20 minutes)	333
Survey of Patients #2	1,000	1	1,000	0.333 (20 minutes)	333
Total					999

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

Dated: October 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24365 Filed 10–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0078]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Animal Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Animal Drug User Fee Cover Sheet'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 8, 2014, the Agency submitted a proposed collection of information entitled ''Animal Drug User Fee Cover Sheet'' to OMB for review and clearance under 44

U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0539. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24444 Filed 10–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1414]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling of 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 the information collection for the labeling of natural rubber latex condoms.

DATES: Submit either electronic or written comments on the collection of information by December 15, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

With respect to the following collection 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 0910–0633)—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 before the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101–629), which 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 expects approximately 5 new manufacturers or repackagers to enter the market yearly and to collectively have a third-party disclosure burden of 60 hours. The number of respondents cited in table 1 of this document is based on FDA's database of premarket submissions and the electronic registration and listing database. The average burden per disclosure was 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 previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.