

Development of Systemic Drugs; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for

Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Dawn Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5168, Silver Spring, MD 20993–0002, 301–796–5376; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs.” This draft guidance addresses FDA’s current thinking about the relevant age groups to study and how early in the drug development pediatric patients should be incorporated during development of systemic drugs for AD.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the timing of pediatric studies during development of systemic drugs for atopic dermatitis. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

**II. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: April 2, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–1414]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls Guidance Document: Labeling Natural Rubber Latex Condoms**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

**DATES:** Fax written comments on the collection of information by May 9, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0633. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms—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. Accordingly, FDA has established the above captioned Special Controls Guidance Document regarding the labeling of natural rubber latex condoms.

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 permits 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 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 five 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 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 part 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.

The collection of information under 21 CFR 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)).

In the **Federal Register** of November 9, 2017 (82 FR 52056) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

We therefore retain the currently approved burden estimate for the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300 .....	5	1	5	12	60

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

Dated: April 3, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
 [Docket No. FDA-2018-N-1011]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of

certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 reporting requirements contained in existing FDA regulations governing petitions to request an exemption from 100 percent identity testing of dietary ingredients.

**DATES:** Submit either electronic or written comments on the collection of information by June 8, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2018. The <https://www.regulations.gov>