ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sexual Abuse Significant Incident Report Form	2,430	1 or more	0.5	1,215 or more.
Assessment of Risk Form	57,500	1	0.17	9,775.
Care Provider Incident Review Form	2,430	1	0.5	1,215.
Written policies	120	1	2	240.
Previous misconduct	7,479	1 or more	0.33	2,468.
Background checks	748	1 or more	0.1	74.8.
Reporting misconduct of former employees	75	1	0.33	25.
Reporting to investigating authorities	2,430	1 or more	0.33	802 or more.
MOUs with investigating authorities	120	2 or more	0.33	79 or more.
Training documentation	7,479	1	0.17	1,271.
Information for UCs	57,500	1	0.25	14,375.
MOUs with reporting entities	120	1	0.25	30.
Grievance procedures	120	1	0.5	60.
Agreements with local service providers	120	1 or more	1	120.
Third Party reporting	73 or more	1	0.25	18 or more.
Disclosure to parent/guardian	2,430	1	0.17	413.
Disclosure to atty of record	972	1	0.17	165.
Reporting staff, contractors, and volunteers to investigating authorities	25	1	0.25	6.
Annual reports	120	1	4	480.
Quarterly reports	120	4	2	960.
Other data	120	20 or more	0.25	600.
Audit report	40	1	8	320.

Estimated Total Annual Burden Hours: 34,713.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–01372 Filed 1–26–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0194]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

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 in Form FDA 3792, ''Biosimilars User Fee Cover Sheet''.

DATES: Submit either electronic or written comments on the collection of information by March 30, 2015.

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.

Biosimilars User Fee Cover Sheet; Form FDA 3792 (OMB Control Number 0910–0718)—Extension

The Patient Protection and Affordable Care Act (Pub. L. 111–148) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (Title VII Subtitle A) (BPCI Act) that amends the Public Health Service Act (42 U.S.C. 262) (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for fiscal years 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012.

FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

Respondents to this collection of information are manufacturers of biosimilar biological product candidates. Based on the number of Form FDA 3792s we have received, we estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilars User Fee Cover Sheet; Form FDA 3792 ..	20	1	20	0.50 (30 minutes) ...	10

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

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01404 Filed 1–26–15; 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; Submission for Office of Management and Budget Review; 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 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.

DATES: Fax written comments on the collection of information by February 26, 2015.

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 *oira_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: 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: 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 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