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]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

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 August 8, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0303. Also include the FDA 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., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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.

Electronic Records; Electronic Signatures—(OMB Control Number 0910–0303)—Revision

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (21 CFR part 11) (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

In the **Federal Register** of February 16, 2011 (76 FR 9024), FDA published a 60-day notice requesting public comment on the proposed collection of

information. FDA received one comment which was related to the Paperwork Reduction Act burden associated with this collection of information.

The comment indicated that table 2 in the 60-day notice was not clear if it represented burden for all respondents, or just one respondent. In addition, the commenter noted that if table 2 represented the estimated burden for all respondents, that they did not agree with the accuracy of FDA's estimate, as the table appears to assume that each respondent creates one SOP per each 21 CFR section listed. The commenter felt that this assumption is not correct for large companies, who could possibly have several thousand systems, each requiring their own SOPs. If this were the case, the recordkeeping burden in Table 2 would be severely understated.

FDA's response is to note that the recordkeeping burden in table 2 is an estimate of both large and small firms, and the burden represented in the table is an average of the burden for all forms. In addition, the recordkeeping requirements ask each respondent to this collection maintain a set of SOPs which could help the company and FDA in the future determine the methodology the company employed in its systems to ensure that the electronic signatures for its employees on documents submitted to the FDA were valid, if needed. Over the years, FDA developed this recordkeeping burden by listening to feedback from its staff and external stakeholders, and feels that the burden adequately represents the average burden a firm might expend to complete the recordkeeping requirements for this collection.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records. The respondents will be businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
11,100	4,500	1	4,500	1	4,500
Total					4,500

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
11.10	2,500	1	2,500	20	50,000
11.30	2,500	1	2,500	20	50,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					280,000

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

Dated: July 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17155 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Study Logistic Formative Research Methodology Studies for the National Children's Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NIHCD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23605–23606, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection

Title: Study Logistics Formative Research Methodology Studies for the National Children's Study (NCS).

Type of Information Collection Request: Generic Clearance.

Need and Use of Information Collection: The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and