implementing direct notices and parental consent mechanisms will account for the remaining 300 hours.

Website operators that have previously created or adjusted their sites to comply with the Rule will incur no further burden associated with the Rule, unless they opt to change their policies and information collection in ways that will further invoke the Rule's provisions. Moreover, staff believes that existing COPPA-compliant operators who introduce additional sites beyond those they already have created will incur minimal, if any, incremental PRA burden. This is because such operators already have been through the start-up phase and can carry over the results of that to the new sites they create.

(b) *Voluntary Reporting Requirements for Safe Harbor Participants*: 100 hours (rounded to the nearest hundred)

Operators can comply with the Rule by meeting the terms of industry self-regulatory guidelines that the Commission approves after notice and comment.[3] While the submission of industry self-regulatory guidelines to the agency is voluntary, the Rule includes specific reporting requirements that all safe harbor applicants must provide to receive Commission approval. Staff retains its estimate that it would require, on average, 265 hours per new safe harbor program applicant to prepare and submit its safe harbor proposal in accordance with Section 312.12(c) of the Rule. Industry sources have confirmed that this estimate is reasonable and advised that all of this time would be attributable to the efforts of lawyers. Given that several safe harbor programs are already available to website operators, FTC staff believes that it is unlikely that more than one additional safe harbor applicant will submit a request within the next three years of PRA clearance sought. Thus, annualized burden attributable to this requirement would be approximately 85 hours per year (260 hours ÷ 3 years) or, roughly, 100 hours. Staff believes that most of the records submitted with a safe harbor request would be those that these entities have kept in the ordinary course of business, and that any incremental effort associated with maintaining the results of independent assessments or other records under Section 312.10(d)(3) also would be in the normal course of business. In accordance with the regulations implementing the PRA, the burden estimate excludes effort expended for these activities. 5 CFR 1320.3(b)(2).

Accordingly, FTC staff estimates that total burden per year for disclosure requirements affecting new web entrants and reporting requirements for safe harbor applications would be approximately 2,000 hours, rounded to the nearest thousand.

Labor costs: Labor costs are derived by applying appropriate hourly cost figures to the burden hours described above. Staff conservatively assumes hourly rates of $150 and $35, respectively, for lawyers or similar professionals and computer programmers.[4] Based on these inputs, staff further estimates that associated annual labor costs for new entrants would be $235,000 [(1,500 hours x $150 per hour for legal) + (300 hours x $35 per hour for computer programmers)] and $15,000 for safe harbor applicants (100 hours per year x $150 per hour), for a total labor cost of $250,000.

Non-labor costs: Because websites will already be equipped with the computer equipment and software necessary to comply with the Rule's notice requirements, the sole costs incurred by the websites are the aforementioned estimated labor costs. Similarly, industry members should already have in place the means to retain and store the records that must be kept under the Rule's safe harbor recordkeeping provisions, because they are likely to have been keeping these records independent of the Rule.

William J. Blumenthal

General Counsel

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[3] *See* Section 312.10(c). Approved self-regulatory guidelines can be found on the FTC's website at *http://www.ftc.gov/privacy/privacyinitiatives/childrens_shp.html.*

[4] FTC staff estimates average legal costs at $150 per hour, which is roughly midway between Bureau of Labor Statistics (BLS) mean hourly wages shown for attorneys (approximately $55) in the most recent whole-year data available online (2006) and what staff believes may more generally reflect hourly attorney costs ($250) associated with Commission information collection activities. The $35 estimate for computer programmers is also conservatively based on the most recent whole-year data available online from the BLS (2006 National Compensation Survey and 2006 Occupational Employment and Wage Statistics).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0168]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

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 provisions relating to FDA's electronic records and electronic signatures.

DATES: Submit written or electronic comments on the collection of information by May 27, 2008.

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: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Electronic Records; Electronic Signatures—21 CFR Part 11 (OMB Control Number 0910–0303)—Extension

The FDA regulations in 21 CFR part 11 (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 (§§ 11.10, 11.30, 11.50, and 11.300) require 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.

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	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0169]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.