

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Ongoing Study Sites				
Baseline:				
Youth interview	98	1	1.5	147
Caseworker survey	4	19	.5	38
First Follow Up:				
Youth interview	177	1	1.5	266
Caseworker survey	4	36	.5	72
Program site visit	50	1	1.5	75
Second Follow Up:				
Youth interview	370	1	1.5	555
New (5th) Study Site				
Baseline:				
Youth interview	250	1	1.5	375
Program site visit	80	1	1.5	120
First Follow Up:				
Youth interview	213	1	1.5	320
Program site visit	50	1	1.5	75
Second Follow Up:				
Youth interview	200	1	1.5	300

Estimated Total Burden Hours: 2,343.

Estimated Annual Burden Hours (average over three years): 781.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACR, E-mail address: Katherine_T._Astrich@omb.eop.gov.

Dated: July 18, 2006.

Robert Sargis

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0123]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Need for Online Medical Device Survey

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 23, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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.

Survey of Need for Online Medical Device Information

Executive Order 12862 directs agencies to identify the customers who are, or should be, served by the agency, and to survey customers to determine the kind and quality of services they want.

This proposed survey will collect data about the information customers want when looking up medical devices on the Internet. It will focus on the ways individuals find, use, and rate existing sources of online medical device information. FDA will use this data to understand more about its customers and to make improvements to its own Web site.

FDA will administer this survey to individuals who use the Internet to look for information about medical devices. The survey will consist of three components: A screening tool of 5,000 to identify appropriate respondents, an online survey of 500 customers, and a telephone followup interview with 50 customers.

In the **Federal Register** of April 20, 2005 (70 FR 20573), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR (Or FDA Form #)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening Tool	5,000	1	5,000	0.05	250
Online Survey	500	1	500	0.25	125
Telephone ² Follow-Up	-	-	-	-	-
Total					375

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

²This was listed in the FEDERAL REGISTER announcement but is no longer required in the survey.

Dated: July 17, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0279]

Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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 bar code label requirements for human drug and biological products.

DATES: Submit written or electronic comments on the collection of information by September 22, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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 Management Programs (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.

Bar Code Label Requirement for Human Drug and Biological Products

In the **Federal Register** of February 26, 2004 (69 FR 9120), we issued a new rule that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Center for Biologics Evaluation and Research Director as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR 9120 at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated