ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396A	54	4	8	1,728
OCSE–34A	54	4	8	1,728

Estimated Total Annual Burden Hours: 3,456.

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.

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 ACF.

Dated: April 22, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–10456 Filed 4–28–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: 45 CFR 1304 Head Start Program Performance Standards.

OMB No.: 0970–0148.

Description: Head Start Performance Standards require Head Start and Early Head Start Programs and Delegate Agencies to maintain program records. The Administration for Children and Families is proposing to renew the authority to require certain record keeping in all programs as provided for in 45 CFR 1304 Head Start Performance Standards. These standards prescribe the services that Head Start and Early Head Start programs provide to enrolled children and their families.

Respondents: Head Start and Early Head Start grantees and delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
	2,590	16	41.8	1,737,618

Estimated Total Annual Burden Hours: 1,737,618.

In compliance with the requirements of section 3506 (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 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.

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.

Dated: April 22, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–10457 Filed 4–28–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0016]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; MedWatch: The FDA Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 information collection provisions by May 29, 2003.

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 electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

MedWatch: The FDA Medical Products Reporting Program (OMB Control Number 0910–0291)—Extension

Under sections 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b, 360c, 360e, and 393); and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. A drug or device is misbranded under section 502(f)(1) of the act if its labeling does not bear adequate warnings for use, and under section 502(j) of the act if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) (21 U.S.C. 341), section 402 of the act (21 U.S.C 342) is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event, product problem or medication error occurs. Only if FDA is provided with such information, will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action ranging from labeling changes to the rare product withdrawal. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR parts 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56.

To implement these provisions for reporting of adverse events, product problems and/or medication error with medications, devices, biologics, and special nutritional products, as well as any other products that are regulated by FDA, two very similar forms are used. Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events, product problems and medication errors by health professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation).

Respondents to this collection of information are health professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, and manufacturers, packers, distributors, and importers of biological and drug products and medical devices.

II. Use of the Voluntary Version (FDA Form 3500)

The voluntary version of the form is used to submit all adverse event, product problems, and medication error reports not mandated by Federal law or regulation.

Individual health professionals are not required by law or regulation to submit adverse event, product problem, or medication error reports to the agency or the manufacturer, with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Those mandatory reports are submitted by physicians to the joint FDA/Centers for Disease Control and Prevention Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form (see http://www.vaers.org/pdf/vaers for pdf version), rather than the FDA 3500 or 3500A forms.

Hospitals are not required by Federal law or regulation to submit adverse event reports, product problems, or medication errors associated with medications, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device related deaths and serious illnesses or injuries.

Manufacturers of dietary supplements do not have to prove safety or efficacy of their products prior to marketing, nor do they have mandatory requirements for reporting adverse reactions to FDA. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. The agency is dependent on the voluntary reporting by health professionals and consumers of suspected adverse events associated with the use of dietary supplements.

III. Use of the Mandatory Version (FDA Form 3500A)

A. Drug and Biologic Products

In sections 505(j) and 704 (21 U.S.C. 374) of the act, Congress has required that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biologics). Parts 310, 314, and 600 mandate the use of the FDA Form 3500A form for reporting to FDA on adverse events that occur with drugs and biologics.

(Note: Most pharmaceutical manufacturers already use a 1-page modified version of the 3500A form where section G from the back of the form is substituted for section D on the front of the form.)

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers, packers and distributors and importers of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990 amended section 519 of the act to require that user facilities, such as hospitals, nursing homes, ambulatory surgical facilities and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 requires the use of the FDA Form 3500A for mandatory reporting to FDA on medical devices.

The Food and Drug Administration Modernization Act of 1997 eliminated the reporting requirements for domestic

distributors of medical devices. In addition, section 303 of the Medical Device User Fee and Modernization Act of 2002 directs FDA to modify the MedWatch mandatory and voluntary forms to facilitate the reporting of information by user facilities or distributors as appropriate relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

C. Other Products Used in Medical Therapy

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center/(21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500	20,074	1	20,074	0.5	10,037
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	600	463.86	278,315	1.0	278,315
CDRH					
Form 3500	3,252	1	3,252	0.5	1,626
Form 3500A (part 803)	1,935	33	63,623	1.0	63,623
§ 803.10	2,845	2.4	6,828	.17	1.160
CFSAN					
Form 3500	895	1	895	0.5	448
Form 3500A (no mandatory requirements)	0	0	0	1.0	0
Total Hours					355,209
Form 3500					13,271
Form 3500A					343,098

(NOTE: CBER = Center for Biologics Evaluation and Research; CDER = Center for Drug Evaluation and Research; CDRH = Center for Devices and Radiological Health; and CFSAN = Center for Food Safety and Applied Nutrition. FDA Form 3500 is for voluntary reporting; FDA Form 3500A is for mandatory reporting.)

The figures shown in table 1 of this document are based on actual calendar year 2002 reports and respondents for each center and type of report.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

FDA Center/21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
CDRH					
803.10	2,845	2.4	6,828	.17	1,160
Total					1,160

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

In the **Federal Register** of February 10, 2003 (68 FR 6752), FDA published a 60-day notice requesting public comment on the information collection provisions. Two comments from organizations (Health Industry Manufacturers Association and Baxter Healthcare Corp.) were submitted. In general, the comments supported the reinstatement of the 3500A form with little or no modification since most manufacturers had made investments in systems that produce computer facsimiles of the form. Both organizations also questioned the need for a medical device ''Baseline Report,'' saying that most of the information is already provided to FDA on either the 3500A form or through the Medical Device registration and listing process.

FDA recognized the impact that a major modification of the 3500A form would have on computerized systems in place across the pharmaceutical and medical device industry. In addition, the agency agreed that there is redundancy of certain data elements among the 3500A, Baseline Report and the Medical Device Registration and Listing Process. However, the agency also felt that certain elements found on the baseline form and not duplicated elsewhere were essential. At that time,

experience with the use of the 3500A for mandatory medical device reporting and the need to collect information found only on the baseline report led the agency in 1998 to propose a major modification to the medical device sections of the 3500A form.

Dated: April 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10616 Filed 4–25–03; 11:16 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0158]

Specification for Annotated Electrocardiographic Waveform Data in Electronic Format; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on proposed specifications for annotated electrocardiographic (ECG) waveform data in electronic format. The proposed specifications are described in a Health Level Seven (HL7) informative document.

DATES: Submit written or electronic comments on the specifications by May 29, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the specifications are available on the Internet at http://www.hl7.org/V3AnnECG/index.htm. Submit written comments on the specifications to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5329, or e-mail: *stockbridgen@cder.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA considers the results of ECG tests in evaluating the safety and efficacy of certain new drugs, biologics, and devices. Traditionally, FDA has reviewed only summary representations of ECG data for the analysis of the safety and efficacy of products. The agency is interested in improving the evaluation of specific drug induced cardiac toxicity by reviewing ECG waveform data with detailed, sponsor generated annotations from the full spectrum of ECG devices, including 12-lead standard ECG, holter monitors, and implanted devices. On November 19, 2001, FDA held a public meeting to collect information regarding the content and format of annotated ECG waveform data that could be submitted to the agency in support of product applications.

Following the meeting, the Regulated Clinical Research Information Management Technical Committee (RCRIM) in HL7[1], in association with the Clinical Data Interchange Standards Consortium (CDISC)[2], investigated the technology necessary for the submission and review of this ECG data. The RCRIM then developed a model electronic format for the transportation of digital ECG waveform data, including annotations in the data message. The specifications on this annotated ECG waveform data message are provided in a proposed HL7 informative document. The document can be found on the HL7 Web site at http://www.hl7.org/V3AnnECG/index.htm.

II. Comments

We are interested in comments on the use of the proposed HL7 electronic format in providing annotated waveform ECG data to FDA in support of submissions for regulated products. Specifically, does the proposed message capture the appropriate level of detail about ECGs for assessment? Are there additions needed to the proposed controlled terminology? What are the issues concerning the creation of the HL7 message?

After FDA reviews any such comments concerning the HL7 proposal, the agency intends to issue a draft guidance setting forth its recommended electronic format for the submission of digital ECG waveform data. In those instances when the agency requests that a regulated entity submit ECG data electronically concerning a product, the draft guidance would describe an appropriate electronic format for the submission. Interested parties would have an opportunity to submit comments on this recommended format in response to the draft guidance. FDA would consider any such comments before publishing a guidance.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the proposed specification. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The proposed specifications and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the proposed specifications at http://www.hl7.org/V3AnnECG/index.htm.

Dated: April 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10475 Filed 4–28–03; 8:45 am]

BILLING CODE 4160–01–S

[1]Founded in 1987, Health Level Seven, Inc., (HL7) (www.HL7.org), is a nonprofit, ANSI-Accredited Standards Developing Organization that provides standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Its 2,200 members represent over 400 corporate members, including 90 percent of the largest information systems vendors serving healthcare. HL7 international affiliates are active in Europe, Japan, Australia, Canada, New Zealand, and Southern Africa.

[2]CDISC, (www.cdisc.org), is an open, multidisciplinary, nonprofit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA–03–097 Fiscal Year 2003 Competitive Application Cycle for the Nurse Education, Practice and Retention Grant Program Grants for Career Ladder Programs (CARL)—CFDA 93.359

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Nurse Education, Practice and Retention Grant Program; Grants for Career Ladder Programs for Fiscal Year 2003.

Purpose: Grants will be awarded to eligible entities for programs—

(A) To promote career advancement for nursing personnel in a variety of training settings, cross training or specialty training among diverse