

## II. Electronic Access

Persons with access to the Internet may obtain the summaries at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: April 16, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0122]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems." This guidance document describes a means by which computerized labor monitoring systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify computerized labor monitoring systems into class II (special controls). This guidance document is being immediately implemented as the special control for computerized labor monitoring systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax

your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Glenn Bell, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4100.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying computerized labor monitoring systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for computerized labor monitoring systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the time frames established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately implemented. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

##### II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation

(§ 10.115). The guidance represents the agency's current thinking on computerized labor monitoring systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1625 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

##### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 13, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E7-7700 Filed 4-23-07; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on

proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The necessity of the proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

#### **Proposed Project: The National Health Service Corps Loan Repayment Program (OMB No. 0915-0127)—Extension**

The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health care professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. Under this program, the Department of Health and Human Services agrees to repay the educational loans of the primary care health professionals. In return, the health professionals agree to serve for a specified period of time in a federally-designated HPSA approved by the Secretary for LRP participants.

The NHSC LRP forms provide information that is needed for selecting participants and repaying qualifying loans for education. The LRP forms include the following: The NHSC LRP Application, the Loan Information and Verification form, the Community Site Information form, the Request for Method of Advanced Loan Repayment form, the Applicant Checklist, the Payment Information form, and the Authorization to Release Information form.

The estimated annual burden is as follows:

Type of form	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
NHSC LRP Application .....	1920	1	1920	.5	960
Community Site Information form .....	1920	1	1920	.25	480
Loan Information and Verification form .....	1920	3	5760	.25	1440
Authorization to Release Information .....	1920	1	1920	.1	192
Applicant Checklist .....	1920	1	1920	.2	384
Lenders .....	80	1	80	.25	20
Total .....	2000		13520		3476

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 16, 2007.

**Caroline Lewis,**

*Acting Associate Administrator for Administration and Financial Management.*

[FR Doc. E7-7762 Filed 4-23-07; 8:45 am]

**BILLING CODE 4165-15-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Request for Nominations**

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill 11 vacancies on the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

**AUTHORITY:** 42 U.S.C. 294f, Section 756 of the Public Health Service Act, as amended. The Advisory Committee is

governed by provisions of Public Law (Pub. L.) 92-463, as amended (5 U.S.C. Appendix 2) which sets forth standards for the formation and use of advisory committees.

**DATES:** The Agency must receive nominations on or before June 30, 2007.

**ADDRESSES:** All nominations are to be submitted to Louis D. Coccodrilli, Designated Federal Official, ACICBL, Bureau of Health Professions (BHP), HRSA, Parklawn Building, Room 9-05, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Vanessa Saldanha, Public Health Fellow, AHEC Branch, Division of State, Community, and Public Health, BHP,