Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was developed as a special controls guidance to support the reclassification of three anesthesiology devices from class III (premarket approval) to class II (special controls). The three devices are:

- Indwelling blood carbon dioxide partial pressure (Pco_2) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (Po_2) analyzer (21 CFR 868.1200).

The guidance document combines and supersedes the guidances entitled ''Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions'' and ''Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions'' which, in turn, incorporated the special controls listed separately in the March 15, 1999 (64 FR 12774), proposal to reclassify these devices. In the **Federal Register** of November 22, 2000 (65 FR 70357), FDA announced the availability of the two guidance documents that were intended to serve as special controls and invited interested persons to comment on the guidances by February 20, 2001. In that same issue of the **Federal Register** (65 FR 70325), FDA reopened the comment period for 90 days to allow comments regarding the proposed reclassification of the three anesthesiology devices from class III into class II. FDA received no comments on the proposed reclassification of the three devices.

FDA received one comment on the document entitled ''Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions'' that was proposed as a special control for the devices. The comment, submitted by Diametrics Medical Ltd., disagreed that all clinical studies should be designated ''significant risk'' and be conducted under an investigational device exemption (IDE).

FDA agrees with the comment and has modified the guidance. With the exception of devices employing new technology, studies of the device are nonsignificant risk. These nonsignificant risk studies are exempt from IDE requirements in accordance with § 812.2(c)(2) (21 CFR 812.2(c)(2)), but must be performed in accordance with parts 50 and 56 (21 CFR parts 50 and 56). However, if the device employs new technology (i.e., technology different from that used in a legally marketed indwelling blood gas analyzers), FDA has determined that studies of this device are significant risk, as defined in 21 CFR 812.3(m)(4) and, therefore, do not qualify for the abbreviated requirements of § 812.2(b). In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (part 56) and informed consent (part 50).

Designation of this guidance as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate indwelling blood gas analyzer should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurance of safety and effectiveness.

II. Significance of Guidance

This guidance document represents the agency's current thinking concerning indwelling blood gas analyzers. 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 applicable statute and regulations.

The agency has adopted good guidance practices (GGPs) and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This guidance document is issued as a level 2 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1126) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. 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 the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page 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 Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance at any time. Submit two copies of any comments, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 5, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–28562 Filed 11–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–82]

Notice of Submission of Proposed Information Collection to OMB; Automated Clearing House (ACH) Program Application—Title I Insurance Charge Payments System

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The propose information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 17, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0512) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, and extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Automated Clearing House (ACH) Program Application—Title I Insurance Charge Payments System.

OMB Approval Number: 2502–0512.

Form Numbers: HUD–56150.

Description of the Need for the Information and Its Proposed Use: This information collection is used to collect data to establish an electronic premium payment method for the Title I Program. This information collection is designed to process the collection of Title I insurance charges electronically in lieu of sending checks and other payments instruments by mail.

Respondents: Business or other for-profit, Individuals or households.

Frequency of Submission: On occasion upon application.

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Reporting burden	750		1		0.25		188

Total Estimated Burden Hours: 188.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: November 6, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–28558 Filed 11–14–01; 8:45 am]

BILLING CODE 4210–72–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–83]

Notice of Submission of Proposed Information Collection to OMB; Preauthorized Debits, HUD PAD Authorization

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 17, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0424) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed uses; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Preauthorized Debits, HUD PAD Authorization.

OMB Approval Number: 2502–0424.

Form Numbers: HUD–92090.

Description of the Need for the Information and Its Proposed Use: The information collection is used to establish a direct electronic transfer of payment form a financial institution to HUD when debtors have established a repayment plan and desire an automated transfer of funds.

Respondents: Business or other for-profit, Individuals or households.

Frequency of Submission: On occasion upon application.