On March 4, 1996, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On May 28, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Under section 519(e) of the act (21 U.S.C. 360i(e)) as amended by the Safe Medical Devices Act of 1990, manufacturers of certain types of devices are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. FDA has identified the above device as a new generic type of device requiring tracking. FDA is providing a 30-day period for interested persons to submit to the Dockets Management Branch (address above) written comments regarding the agency's position that this new generic type of device requires tracking.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 24, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 16, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–4228 Filed 2–20–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–462 A/B]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Adverse Action Extract; *Form No.:* HCFA–462A/B; *Use:* This form is used by HCFA surveyors (State Health Department surveyors and other HCFA agents) to record which types of adverse actions are imposed against laboratories. The form will also serve to track dates of the impostion of adverse actions, dates on which a laboratory corrects deficiences, and all appeals activity. *Frequency:* Biennially; *Affected Public:* Not-for-profit institutions, Federal Government, State, Local or Tribal Govt; *Number of Respondents:* 2,500; *Total Annual Responses:* 2,500; Total Annual Hours: 5,625

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Rudolph, Room C2–25–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 13, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–4338 Filed 2–20–97; 8:45 am]

BILLING CODE 4120–03–P

[HCFA–841–853]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated

burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

3. HCFA–841–853 *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity; *Form Nos.:* HCFA–841–853 (formally HCFA–R–182); *Use:* A Certificate of Medical Necessity is a standardized format used to communicate information provide by an attending physician and a supplier of medical equipment and supplies. The information is used by carriers to determine the medical necessity of an item or service covered by the Medicare program and being used for the treatment of the Medicare beneficiary's condition. The CMNs being submitted for OMB review are necessary in order for HCFA to determine the medical necessity of the item or service. The information needed to make this determination requires application of medical judgment that can only be provided by a physician or other clinician who is familiar with the condition of the beneficiary; *Frequency:* On Occasion; *Affected Public:* Suppliers and physicians, business or other for-profit, federal government; *Number of Respondents:* 140,000; *Total Annual Responses:* 6.8 million; *Total Annual Hours Requested:* 1.7 million.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC. 20503.

Dated: February 18, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–4339 Filed 2–20–97; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

''Low Income Levels'' for Health Professions and Nursing Programs

The Health Resources and Services Administration (HRSA) is updating income levels used to identify a ''low income family'' for the purpose of providing training for individuals from disadvantaged backgrounds under various health professions and nursing programs included in titles VII and VIII of the Public Health Service Act (the Act).

The Department periodically publishes in the Federal Register low income levels used for grants and cooperative agreements to institutions providing training for individuals from disadvantaged backgrounds. A ''low income level'' is one of the factors taken into consideration to determine if an individual qualifies as a disadvantaged student for purposes of health professions and nursing programs.

The programs under the Act that use ''low income levels'' as one of the factors in determining disadvantaged backgrounds include the Health Careers Opportunity Program, section 740, the Program of Financial Assistance for Disadvantaged Health Professions Students, section 740 (a)(2)(F), and Nursing Education Opportunities for Individuals from Disadvantaged Backgrounds, section 827. Loans to Disadvantaged Students, section 724, Scholarships for Health Professions Students from Disadvantaged Backgrounds, section 737, Disadvantaged Health Professions Faculty Loan Repayment and Fellowships Program, section 738 were added to title VII by the Disadvantaged Minority Health Improvement Act of 1990 (Pub. L. 101–527) and are also using the low income levels. Other factors used in determining ''disadvantaged backgrounds'' are included in individual program regulations and guidelines.

Health Careers Opportunity Program (HCOP), Section 740

This program awards grants to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, chiropractic and public or nonprofit private schools which offer graduate programs in clinical psychology, and other public or private nonprofit health or educational entities to assist individuals from disadvantaged backgrounds to enter and graduate from health professions schools.

Financial Assistance for Disadvantaged Health Professions Students (FADHPS), Section 740 (a)(2)(F)

This program awards grants to accredited schools of medicine, osteopathic medicine, and dentistry to provide financial assistance to individuals from disadvantaged backgrounds who are of exceptional financial need, to help pay for their health professions education. The provision of these scholarships shall be subject to section 795 relating to residency training and practice in primary health care.

Nursing Education Opportunities for Individuals From Disadvantaged Backgrounds, Section 827

This program awards grants to public and nonprofit private schools of nursing and other public or nonprofit private entities to meet costs of special projects to increase nursing education opportunities for individuals from disadvantaged backgrounds.

Loans to Disadvantaged Students, Section 724

This program makes awards to certain accredited schools of medicine, osteopathic medicine, dentistry, optometry, pharmacy, podiatric medicine, and veterinary medicine for financially needy students from disadvantaged backgrounds.

Scholarships for Health Professions Students From Disadvantaged Backgrounds, Section 737

This program awards grants to schools of medicine, nursing, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, allied health, or public health, or schools that offer graduate programs in clinical psychology for the purpose of assisting such schools in providing scholarships to individuals from disadvantaged backgrounds who enrolled (or are accepted for enrollment) as full-time students.

Disadvantaged Health Professions Faculty Loan Repayment and Fellowship Program, Section 738

This program awards grants to repay the health professions education loans of disadvantaged health professionals who have agreed to serve for at least 2 years as a faculty member of a school of medicine, nursing, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, public health, or a