

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.*

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#### 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 imposition of adverse actions, dates on which a laboratory corrects deficiencies, 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](mailto: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.*

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[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