records to trace patients, and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These requirements are to be performed only by those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMA's are eventually approved and 75 percent of those have original clinical trial data. Therefore, about 27 PMA's a year would be subject to these requirements. Also, because the requirements apply to all active PMA's, all holders of active PMA applications must maintain these records. PMA's have been required since 1976, so there are around 567 active PMA's that could be subject to these requirements (21 years x 27 per year). Each study has about approximately 200 subjects, and, at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 16.7 hours. The aggregate burden for all 567 holders of approved original PMA's, therefore, is 9,469 hours (567 approved PMA's with clinical data x 16.7 hours per PMA).

The applicant determines what records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the Current Good Manufacturing Practices for medical devices regulation part 820 may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

With the additional 9,469 hours or recordkeeping, the total annual burden is 104,020 hours.

Dated: September 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25938 Filed 9-29-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part D, Chapter DE, Office of External Affairs (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56605, November, 9, 1995, and in pertinent part at 56 FR 29484, June 27, 1991) is amended to reflect the title change of the Industry and Small Business Liaison Staff. The title is being changed to more accurately reflect the expanding concerns and community issues in the jurisdictions containing various FDA headquarter facilities. The Industry and Small Business Liaison Staff will be retitled as the Industry, Small Business and Community Affairs Staff. The current functions remain the same with the addition of two new functions.

Delete the **Industry and Small Business Liaison Staff** (DE–1) in its entirety and insert the following:

Industry, Small Business and Community Affairs Staff (DE–1). Advises and assists the Commissioner and other Agency officials on industry-related issues which have an impact on policy, directions, and goals.

Serves as the Agency focal point for overall industry liaison and communication activities within FDA, including FDA Centers, and between FDA and FDA-regulated industry, industry trade associations, and scientific associations.

Serves as liaison with other Agency components to provide advice and assistance to small manufacturers and scientific associations to promote their understandings of and compliance with FDA regulations.

Develops and maintains effective channels of communication with regulated industry, professional societies, and trade and scientific associations.

Serves as liaison with local civic organizations in jurisdictions containing or contiguous to the various FDA headquarters facilities.

Provides official contact point within the Agency for discussion and resolution of community issues and concerns arising in connection with the construction, renovation, or ongoing operation of FDA's widely dispersed physical point.

Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: September 2, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–25782 Filed 9–29–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–211]

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: Revision of a currently approved collection; *Title of Information Collection:* State Child Health Plan and Supporting Information Collection Requirements Referenced in Title XXI of the Social Security Act; *Form No.:* HCFA–R–211, OMB # 0938–0707; *Use:* This Model template will enable states to apply for funds under Title XXI of the Social Security Act, to initiate and expand the provision of child health insurance to uninsured, low income children in a effective and efficient manner that is coordinated with other sources of health coverage for children; *Affected Public:* State, Local or Tribal Government; Number of Respondents: 56; *Total Annual Responses:* 56; *Total Annual Hours:* 8,960.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, 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: