1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test.'' The guidance document is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test'' published in the **Federal Register** of August 27, 1998 (63 FR 45826).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a revised Form FDA 356h that will be used as a single harmonized application form for all drug and licensed biological products. Manufacturers may voluntarily begin using this form for an allergenic extract or allergen patch test. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This guidance document represents the agency's current thinking with regard to the content and format of the CMC and establishment description sections of a license application for an allergenic extract or allergen patch test. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: April 16, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10228 Filed 4–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–278]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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 this 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: New Collection;

Title of Information Collection: National Hospital Malpractice Insurance Survey;

Form No.: HCFA–R–278 (OMB# 0938–NEW);

Use: The Data collected from this survey will be used to collect two years of malpractice insurance costs data from a nationally representative sample of 800 hospitals. Along with the survey of hospitals, we will collect rate schedules from the commercial insurers and the offices of state insurance commissioners. As compared to the survey of hospitals which is a statistical sampling survey, the survey of the offices of state insurance commissioners and commercial insurance companies will not be a statistical sampling survey. We will match collected data in the rate schedules to the data from sampled hospitals in order to convert malpractice insurance costs of different level of coverage into costs of a constant level of coverage. The primary statistics will be used to rebase the input price index through weight adjustment and the annual percent change to update the operating prospective payment rates. Therefore, the NHMIS must allow estimates of the primary statistics for each hospital be adjusted by their rating basis, coverage elements, and types of coverage. The survey results will be used to estimate the weight of malpractice insurance costs in relation to goods and services hospitals purchase in order to furnish inpatient care and to calculate the malpractice insurance cost to change over time at the national level. The analytic results will be used to adjust Medicare operating reimbursement rates to Medicare participating hospitals and to prepare statistical summaries.;

Frequency: Annually;

Affected Public: Not-for-profit institutions, business or other for-profit, and State, Local, or Tribal Govt.;

Number of Respondents: 600;

Total Annual Responses: 600;

Total Annual Hours: 300.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your

request, including your address, phone number, OMB number, and HCFA document identifier, 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 Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 14, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–10280 Filed 4–22–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0416]

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

AGENCY: Health Care Financing Administration, HHS.

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 this 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: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) Participation Report and Supporting Regulations in 42 CFR 441.60; *Form No.:* HCFA–416 (OMB# 0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services to HCFA pursuant to section 1902(a)(43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs. It is also helpful in developing trend patterns, national projections, responding to inquiries, and determining a State's results in achieving its participation goal.; *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 15, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–10155 Filed 4–22–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration; Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Proposed Project: Feasibility Study To Evaluate the Positive Activities Campaign (PAC) (OMB No. 0930–0188 Revision)

The Center for Substance Abuse Prevention is conducting a feasibility study of the Positive Activities Campaign (PAC), an initiative aimed at the general public to encourage adults to become more involved in positive, skill-building activities with youth. The ultimate goal of the initiative is to reduce substance abuse among young people.

To determine the likely effectiveness of the campaign, CSAP's feasibility study consists of a process evaluation and an outcomes evaluation. The evaluation is assessing change in communities exposed to PAC, including change in adults' involvement with youth. Two treatment and two comparison communities have been selected for study. Data for the process evaluation are primarily from on-site interviews with key personnel in local youth-serving organizations (e.g, Boy Scouts, Boys and Girls Clubs); data for the outcomes evaluation are from baseline and 6-month followup telephone surveys of adults.

This revision to the currently approved information collection activities involves: (1) a third, 12-month followup telephone interview with the random sample of adults; and (2) because PAC is being expanded to serve civic membership organizations (e.g., Rotary Clubs, Lions Clubs, Kiwanis) application of the process evaluation activities with these groups, plus three telephone interviews with random samples of members of the civic organizations.

The table that follows shows the total response burden associated with this project. All of the currently approved burden will have been experienced by the time of OMB approval of the revision.