as part of this study to identify and assess the organizational structure and collaborative efforts that contribute to the ability of CBOs to access their target populations, deliver HIV prevention services, and provide referrals over a sustained period of time. For the purposes of this study, a CBO is defined as any not-for-profit organization that provides direct prevention services to persons at high risk for infection within a designated area. Evaluation is necessary to understand the impacts of CDC's expenditures and efforts to support CBOs, and for modifying and improving the prevention efforts of CBOs.

Interviews and document reviews will be conducted with community-based organizations, health departments, collaborating organizations, other organizations in the community, and community members in seven geographical areas at four different points in time. Four CBOs from each area will be included in the study. The first wave of data collection is planned for the summer 1998, and data collection will end during the winter of 2000. The total burden in hours is estimated at 10,080.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
CBOs	224	4	1	896
Health Department	56	4	1	224
Collaborating Organizations	840	4	1	3360
Other Community	840	4	1	3360
Community Members	560	4	1	2240
Total				10080

3. PHS Supplements to the Application for Federal Assistance SF 424 (0920–0428)—Extension—The Centers for Disease Control and Prevention (CDC) is requesting a three-year extension and revision of OMB approval for continued use of the Supplements to the Request for Federal Assistance Application (SF–424). We also plan on modifying the SF 424 form. The Checklist, Program Narrative, and the Public Health System Impact Statement (third party notification) (PHSIS) are a part of the standard application for State and local governments and for private non-profit and for-profit organizations when applying for financial assistance from PHS grant programs. The Checklist assists applicants to ensure that they have included all required information necessary to process the application. The Checklist data helps to reduce the time required to process and review grant applications, expediting the issuance of grant awards. The PHSIS Third Party Notification Form is used to inform State and local health agencies of community-based proposals submitted by non-governmental applicants for Federal funding.

The current OMB approval for the supplements was previously submitted by the Department of Health and Human Services, Office of the Assistant Secretary of Health (OASH) under OMB number 0937–0189. The total annual cost to the respondents is $1,184,452.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
State and local health departments; non-profit and for-profit organizations	7,643	1	4.215	32,215
Total				32,215

Dated: April 13, 1998.

Kathy Cahill,

Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–10195 Filed 4–16–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: National Directory of New Hires Reporting Results Survey.

OMB No.: New Collection.

Description: Pub. L. 104–193, the ''Personal Responsibility and Work Opportunity Reconciliation Act of 1996,'' required the Office of Child Support Enforcement (OCSE) to develop a National Directory of New Hires (NDNH) to improve the ability of State child support agencies to locate noncustodial parents and collect child support across State lines. In order to encourage continued and even improved cooperation with the requirements of the program, OCSE would like to conduct a brief telephone survey to solicit any information already collected by the States as to improve collection and other programmatic savings attributable to the program. That information would then be condensed into a report to be published through newsletters or press releases.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Hire Results Survey	54	4	.5	108

Estimated Total Annual Burden Hours: 108.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 13, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–10188 Filed 4–16–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0193]

Draft Guidance for Industry on Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients.'' This draft guidance is intended to provide guidance on current good manufacturing practices (CGMP's) for manufacturing, processing, packing, or holding active pharmaceutical ingredients (API's). The draft guidance is intended to help ensure the quality and suitability of API's for use in the manufacture of drug products.

DATES: Written comments may be submitted on the draft guidance by May 18, 1998. General comments on agency guidances are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Edwin M. Rivera, Center for Drug Evaluation and Research (HFD–322), 7520 Standish Pl., Rockville, MD 20855, 301–594–0095; John A. Eltermann, Center for Biologics Evaluation and Research (HFM–205), 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031; or Jose R. Laureano, Center for Veterinary Medicine (HFV–230), 7500 Standish Pl., Rockville, MD 20855, 301–594–1785.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients.'' It provides guidance on CGMP's for the manufacture, processing, packing, or holding (i.e., storage) of API's.

The draft guidance is a result of extensive efforts that began in July 1995 when FDA decided to develop an industry guidance for the manufacture and control of API's. An initial draft of this guidance for industry was widely distributed during 1996. It was reviewed at a September 1996 international conference on API's in Canberra, Australia, sponsored by the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Convention Scheme (PIC–PIC/S), and at the October 1996 annual FDA/Parenteral Drug Association Forum in Bethesda, MD. It also was distributed to numerous pharmaceutical trade associations in a letter from the Center for Drug Evaluation and Research's (CDER) Office of Compliance, dated November 8, 1996. The initial draft was posted on CDER's website on November 12, 1996, with a request for comments by December 10, 1996. On December 9, the deadline for comments was extended until January 31, 1997. This draft guidance incorporates recommendations received at the two conferences and comments from 27 organizations, including API manufacturers, dosage manufacturers, and pharmaceutical associations.

At a February 4 and 5, 1998, meeting of the International Conference on Harmonisation (ICH) Steering Committee in Tyson's Corner, VA, FDA supported the decision to develop internationally harmonized guidance on CGMP's for API's through the ICH process. The agency agreed to participate in an expert working group that will review numerous guidance documents developed by industry and regulatory bodies to develop a single harmonized ICH guidance. API/CGMP guidances to be reviewed by the working group include those prepared by the European Chemical Industry Council/European Federation of Pharmaceutical Industries' Association, the Pharmaceutical Research and Manufacturers of America, PIC–PIC/S, and the World Health Organization. This draft guidance will also be considered by the working group.

The draft guidance applies to the manufacture and control of drug and biologic API's for use in human and veterinary drug products. In addition, it applies to the later chemical isolation and purification steps of API's derived from biological or fermentation processes and to sterile API's, but only up to the point where the API is