stated. The extent to which the applicant provides proof of the involvement of partners/stakeholders (e.g., agricultural workers, agricultural organizations, agribusiness) in the development of this proposal. (7 points)

5. Evaluation (20 points)

The extent to which the proposed evaluation system is detailed and will document program process, effectiveness, impact, and outcome. The extent to which an evaluation plan has been developed to determine both the success of the pilot intervention or demonstration project(s) and to determine its utility as a public health prevention strategy with broader application in other communities. The extent to which the applicant demonstrates potential data sources for evaluation purposes, and documents staff availability, expertise, and capacity to perform the evaluation. The extent to which a feasible plan for reporting evaluation results and using evaluation information for programmatic decisions is included.

6. Budget and Justification (not scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

7. Human Subjects Review (not scored)

The applicant must clearly state what precautions exist to protect human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. annual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Sheryl Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E13, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 20(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970, [29 U.S.C. 669(a) and 671(e)(7)]. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

Please refer to Program Announcement 99039 when you request information. To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

See also the CDC home page on the Internet:

http://www.cdc.gov

If you have questions after reviewing the contents of all the documents, please contact: Sheryl Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99039, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E–13,Atlanta, GA 30341, telephone (404) 842–6814, Email address SLH3@cdc.gov

For program technical assistance, contact Janet Ehlers, R.N., M.S.N., Occupational Health Nurse, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Division of Surveillance, Hazard Evaluations and Field Studies, 4676 Columbia Parkway, R–21, Cincinnati, OH 45226, Telephone (513) 841–4208, fax (513) 841–4489, e-mail: jje0@cdc.gov; or Teri Palermo R.N. Public Health Advisor, NIOSH/CDC, Division of Respiratory Disease Studies, Office of the Director, 1095 Willow dale Road, Mailstop 127 Morgantown, WV 26505–2888, telephone (304) 285–5836, fax (304)285–5861, e-mail: btp0@cdc.gov.

Dated: February 4, 1999.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health,Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–3197 Filed 2–9–99; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0383]

Guidance for Industry on Population Pharmacokinetics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Population Pharmacokinetics.'' This guidance provides recommendations to pharmaceutical industry scientists, who have long been interested in the application of population pharmacokinetics, during the new drug development, safety and efficacy evaluation, and approval processes.

DATES: Written comments on the guidance may be submitted at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''Population Pharmacokinetics'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Copies of this guidance may also be obtained by fax from 1–888–CBERFAX or 301–827–3844 or by mail from the Voice Information System at 800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

He Sun, Center for Drug Evaluation and Research (HFD–880), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2205, or

Martin D. Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville

Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Population Pharmacokinetics.'' Pharmaceutical industry scientists and FDA have long been interested in the application of population pharmacokinetics and pharmacodynamics to the evaluation of drug safety and efficacy. Although several special data collection and analysis methodologies are available for use, this guidance provides recommendations regarding the use of population pharmacokinetics in new drug development and evaluation.

In addition to summarizing the scientific and regulatory issues that should be addressed when conducting population pharmacokinetic studies and analyses, the guidance: (1) Presents an overview of population methods, including when to perform a population study/analysis; (2) discusses how to design and execute a population pharmacokinetic study; (3) describes how to handle and analyze population pharmacokinetic data; (4) summarizes what model validation methods are available; and (5) explains how to provide appropriate documentation for population pharmacokinetic reports intended for submission to FDA. Although the information provided in this document focuses primarily on population pharmacokinetics, the principles discussed are equally applicable to population pharmacodynamic and toxicokinetic studies.

Because population analysis is a rapidly evolving area of drug development and regulation, frequent communication throughout the entire process between the sponsor and the FDA review staff is encouraged.

In the **Federal Register** of September 18, 1997 (62 FR 49016), FDA announced the availability of a draft version of this guidance entitled ''Population Pharmacokinetics.'' The September 18, 1997, document gave interested persons an opportunity to submit comments through November 17, 1997. All comments received have been carefully reviewed and incorporated, where appropriate, in this revised guidance.

This guidance is being issued as a Level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on population pharmacokinetics. 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 requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. 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. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3156 Filed 2–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–243]

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: New Collection; *Title of Information Collection:* Medicare Agreement Application, Health Care Prepayment Plan and Supporting Regulations in 42 CFR, Section 417; *Form No.:* HCFA–R–243; *Use:* An organization must meet certain requirements to be a Health Care Prepayment Plan that is eligible for a Medicare 1833 agreement. The application is the collection form used to obtain information from an organization that would allow HCFA staff to determine compliance with the regulations. This form includes requests for information about: the management of the applicant organization; arrangements for providing health care to beneficiaries; meeting Medicare requirements for appeals, hearings, advance directives, health benefits; risk sharing with other entities; the fiscal soundness of the applicant; the cost budget, which forms the basis for HCFA payment; prevention of duplicate payment; and the applicant's marketing strategy. *Frequency:* Other (One time); *Affected Public:* Business or other for-profit institutions, Not-for-profit institutions, and State, Local or Tribal Governments.; *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 1,125.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or 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 Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 1, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 99–3273 Filed 2–9–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–250]

Agency Information Collection Activities: Submission for OMB Review; 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, has submitted to the