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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.

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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 Willingham, 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.

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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