analytical method will be determined on a case-by-case basis.

The comment asked: ''Will this rule apply to old approved drugs or just new approvals ?'' This rule applies to the extralabel use in animals of currently approved new animal and human drugs and new approvals of human and new animal drugs.

The comment asked: ''Who pays to have the analytical method developed ?'' As stated previously, the sponsor may be willing to provide the methodology for assay of residue in some cases, while in others, FDA, the sponsor, USDA, States, or a consortium of interested parties may negotiate a cooperative arrangement to development the methodology. Conceivably, a third party who might submit such data could include a distributor or group of distributors who wish to make a drug available for extralabel use.

The comment asked: ''To what extent will it have to be validated and how many tissues will it have to be validated for?'' As stated in the preamble to the final rule, methods validation is anticipated to be necessary. The number of tissues for which method validation might be required would be determined on a case-by-case basis.

The comment asked: ''If [there are] multiple approvals of [the] same active [ingredient], will they force all manufacturers to do the same work because of a different salt? If not, how will they decide who does the work?'' As was stated in the preamble to the final rule, the sponsor may be willing to provide the methodology for residue detection in some case, while in others, FDA, the sponsor, States, USDA, or a consortium of interested parties could negotiate a cooperative arrangement to develop the methodology. The third party could conceivably include a group of drug sponsors who might cooperatively submit data on behalf of all drugs with a particular active drug ingredient.

The comment asked: ''What will they do to generic approvals? Force the originator to pay?'' FDA does not comtemplate requiring a sponsor or any other person to collect data to establish a safe level for extralabel use if the sponsor or other person is not willing to do so. If the agency determines that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, or if no required acceptable analytical method has been developed, the agency would be permitted to prohibit extralabel use of the drug.

The comment asked: ''If it is FDA's plan to demand this data for all existing drug[s] that might be used in food animals, please announce your intentions.'' FDA has no plan to require the submission of data for extralabel use for all existing drugs that might be used in food-producing animals. The respondents may be sponsors of new animal drugs, State(s) or Federal Government or individuals.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on agency records and experience, the agency estimates that two methods of intermediate difficulty will be developed per year and each method may take up to two person years to develop.

Dated: June 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–16593 Filed 6–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier HCFA–R–288]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), 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 of the 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.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. In particular, a statutory deadline has been missed and public harm may occur, as the result of unnecessary loss of Medicare trust fund dollars.

The Balanced Budget Act of 1997 requires the Secretary to implement up to seven competitive pricing demonstrations. Advisory committees, authorized under the Federal Advisory Committee Act (FACA), have been responsible for recommending the design of the demonstration, the sites for the demonstrations, and the manner in which the demonstrations are to be implemented. As such, this information collection was developed under the direction of the two committees and is intended for the Kansas City competitive pricing demonstration since its design is final.

Congress directed HCFA to implement the competitive pricing demonstration through the use of two FACA-compliant advisory committees composed of health care experts. Consistent with FACA requirements, all advisory committee meetings were open to the public and all affected parties were present and able to provide input. Notice of the five meetings of the Competitive Pricing Advisory Committee (CPAC) and the four meetings of the Kansas City Area

Advisory Committee were published in the **Federal Register**.

Throughout the planning process for this demonstration which began in May 1998, all entities impacted by the demonstration including health plans, providers, employers and beneficiaries have been educated on the types of specific information required in the bid solicitation package. In response, written comments and recommendations have been received from the public on all aspects of the demonstration design and implementation during our Federal Advisory Committee meetings. This information collection package could not be prepared until several specific decisions were made by the advisory committees. These included the formula for determining the government contribution, the standard benefit package upon which plans bid, the county or counties upon which the bid is based, and the service included in the demonstration. Final decisions occurred on May 12, 1999, and, as a result, HCFA could not reasonably comply with the normal clearance procedures. Also, due to the fact that the Kansas City demonstration is scheduled to begin on January 1, 2000, at the direction of the CPAC, HCFA must have the collection approved by July 1, 1999 to allow potential bidders enough time to plan for, and submit their applications.

The Bid Solicitation Package for Kansas City will be used to determine the government's contribution to premiums for Medicare+Choice plans that are participating in the Competitive Pricing Demonstration. HCFA will use the information to determine the higher of the weighted average or median of all submitted bids.

HCFA is requesting OMB review and approval of this collection within 2 days of publication, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, within 2 days of publication.

During this 180-day period, HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.

Type of Information Collection Request: New Collection;

Title of Information Collection: Medicare Competitive Pricing Demonstration Bid Solicitation Package for Kansas City;

Form No.: HCFA–R–0288;

Use: This information collection ''Medicare Competitive Pricing Demonstration Bid Solicitation Package for Kansas City'' will be used to determine the government's contribution to premiums for Medicare+Choice plans that are participating in the Competitive Pricing Demonstration. HCFA will use the information to determine the higher of the weighted average or median of all submitted bids;

Frequency: One time;

Affected Public: Business or other for-profit;

Number of Respondents: 9;

Total Annual Responses: 9;

Total Annual Hours: 360.

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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and record keeping requirements must be mailed and/or faxed to the designee referenced below within 2 days of publication:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–0262 Attn: John Burke HCFA–R–0288

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167 Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: June 22, 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. 99–16615 Filed 6–29–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4410–C–04]

FY 1999 Super Notice of Funding Availability (SuperNOFA); Modifications and Clarifications Regarding Funding Under the Fair Housing Initiatives Program

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: On February 26, 1999, HUD published its Fiscal Year (FY) 1999 Super Notice of Funding Availability (SuperNOFA) for HUD's Housing, Community Development, and Empowerment programs. This notice advises of certain modifications and clarifications to funding provided under the Fair Housing Initiatives Program (FHIP).

DATES: The FHIP application due date of June 30, 1999, is not changed by this notice.

FOR FURTHER INFORMATION CONTACT: For the FHIP, please contact the office or individual listed in the ''For Further Information'' portion of the section of the individual programs that are part of the SuperNOFA, published on February 26, 1999 at 64 FR 9618.

SUPPLEMENTARY INFORMATION:

I. Background

On February 26, 1999 (64 FR 9618), HUD published its FY 1999 SuperNOFA for HUD's Housing, Community Development, and Empowerment programs. The FY 1999 SuperNOFA announced the availability of approximately $2.4 billion in HUD program funds covering 32 grant programs and program components administered by the following HUD offices: the Office of Community Planning and Development (CPD); the Office of Housing-Federal Housing Administration (FHA); the Office of Public and Indian Housing (PIH); the Office of Policy Development and Research (PD&R); the Office of Fair Housing and Equal Opportunity (FH&EO); and the Office of Lead Hazard Control.

On April 27, 1999 (64 FR 22634), HUD published a notice that extended the application deadlines of two programs (HOPE VI and FHIP) and made certain corrections and clarifications to four programs (FHIP, Lead-Based Hazard Control Program, Section 202 Supportive Housing for the Elderly Program; and Section 811 Supportive Housing for Persons with Disabilities Program).

On May 8, 1999 (64 FR 27120), HUD published a notice that, among other things, extended the deadline for certain programs in the SuperNOFA to accommodate areas that were designated disaster areas as a result of the tornados in early May 1999.

The purpose of this notice is to advise of certain modifications and clarifications to funding under the FHIP Program. These changes do not alter the selection factors of the FHIP NOFA.