

designated as the agency component with primary jurisdiction for the premarket review and regulation of MAS cell products. The products are subject to licensure as biological products under section 351 of the Public Health Service Act (42 U.S.C. 262).

The guidance document includes discussions on the following: (1) Background and recent events; (2) regulatory plan, including: A summary and discussions of products to be regulated, registration and inspection of establishments, clinical studies, investigational phase and requirements for premarket approval, cost recovery, marketing application, chemistry, manufacturing and controls section of a biologics license application, formulation of an intercenter working group, contracting of manufacture, lot release, and current good manufacturing practice requirements; (3) registration and application submission; and (4) submission of comments.

As with other procedural guidance documents, FDA does not intend this guidance to be all-inclusive. Alternative approaches could be warranted in specific situations, and certain aspects might not be applicable in all situations. If an applicant believed a procedure described in this guidance was inapplicable to a specific situation for a particular product, the applicant could provide, for CBER's consideration, information supporting an alternative process. If an applicant chooses to use an alternative process, the applicant may wish to discuss the matter further with the agency to prevent expenditure of money and resources on activities that later might be determined to be inappropriate to FDA. Although this guidance does not create or confer any rights for or on any person, and does not operate to bind FDA or the public, it does represent the agency's current thinking on the regulation of MAS cell products.

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and information 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.

Received comments on this document will be considered in determining whether revisions to the guidance are warranted.

Dated: May 22, 1996.
William K. Hubbard,
*Associate Commissioner for Policy
Coordination.*
[FR Doc. 96-13386 Filed 5-23-96; 11:13 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing; Notice of Proposed Information Collection for Public Comment

[Docket No. FR-3917-N-78]

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement, described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: July 29, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451—7th Street, SW., Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Betty Belin, Telephone number (202) 708-0614 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate

automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Multifamily Coinsurance Claims Package (f).

OMB Control Number: 2502-0420.

Description of the need for the information and proposed use: Under Statue 12 USC 1715z-9 and Title II, Section 244 of the National Housing Act authorizes the Secretary of HUD to coinsure eligible multifamily mortgages against default. In addition to complying with statutory requirements, the information collected is used by HUD to determine the claim amount due the mortgages. The main purpose for the forms is for lenders to file a claim for insurance benefits.

Agency form numbers: HUD 27008, 27009B, 27009D, 27009F.

Members of affected public: Mortgagees participating in Section 233(f).

An estimation of the total numbers of hours needed to prepare the information collection is 5, the number of respondents is 5, frequency of response is 1, and the hours of response is 5.

Status of the proposed information collection: Reinstatement with change.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: May 20, 1996.

Nicolas P. Retsinas,

A/S Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 96-13238 Filed 5-24-96; 8:45 am]

BILLING CODE 4210-27-M

[Docket No. FR-3917-N-81]

Office of Administration; Submission for OMB Review; Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: June 27, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should