CDC suggests the following to get more timely responses to any questions: use Internet/email, follow all instructions in this announcement, and leave messages on the contact person's voice mail.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: May 17, 1996.

Diane D. Porter,

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

[FR Doc. 96–13196 Filed 5–24–96; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 95N–0200]

Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction.'' The guidance was prepared by the Center for Biologics Evaluation and Research (CBER) in consultation with the Center for Devices and Radiological Health. The document is intended to provide guidance on FDA's approach to the regulation of living autologous cells manipulated ex vivo and intended for structural repair or reconstruction (Manipulated Autologous cells or MAS cells). The agency is also inviting comments on the guidance.

DATES: Written comments by August 26, 1996.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction'' to the Division of Congressional and Public Affairs (HFM–44), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail or FAX by calling the CBER Voice Information System at 1–800–835–4709.

Persons with access to the INTERNET may obtain the document in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators:

http://www.fda.gov/cber/cberftp.html

ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requestors should connect to FDA's FTP Server, FTP.FDA.GOV(192.73.61.21). CBER documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents that may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the guidance can be obtained by ''bounce-back e-mail''. A message should be sent to: GDEXV@al.cber.fda.gov''.

Submit written comments on the guidance to the Dockets Managements 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. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

FDA had recently become aware of the clinical use of MAS cell products. MAS cells are defined as cells derived from a patient's tissues, which are manipulated ex vivo, and then implanted locally into the same patient with the intent of providing repair or reconstruction of a structure. The repair and reconstruction does not involve systemic action by the MAS cell product. Examples of MAS cells include chondrocytes expanded ex vivo and implanted in focal cartilage defects (see 60 FR 36808 at 36809 for additional information and references). The commercialization and distribution of expanded cartilage cells to provide a potential solution to a relatively common medical injury suggested that numerous patients could be receiving these cells within a short period of time.

In light of the potential public health significance of the MAS cell products, the growth of a commercial industry potentially affecting a large number of patients, and the need to decide which existing regulatory authorities (e.g., device versus biologics) would be appropriate to apply or whether a new regulatory framework was required, the agency held a public hearing on November 16 and 17, 1995 (60 FR 36808). The intent of the meeting was to solicit information on the nature and diversity of these products, and to receive comments on the formulation and implementation of any new regulatory requirements. The public hearing had 8 panels with 24 speakers, and there was general consensus that the establishment, the production process, and the MAS cell products should be of the highest quality. The speakers and attendees also agreed that MAS cell products should benefit the patient, but there was little consensus on the appropriate mechanism that should be used to show this benefit.

In the Federal Register of March 7, 1996 (61 FR 9185), after reviewing the comments and further internal discussions, the agency published a notice announcing a Commissioner's roundtable to be held on March 15, 1996. The roundtable was held to present the elements of a planned regulatory framework intended to ensure patient safety and to demonstrate patient benefit, while accommodating the development of these therapies and the need for a flexible regulatory approach. Many of the concepts presented at the roundtable were derived from ongoing FDA Reinventing Government (REGO) initiatives. In the same Federal Register notice, FDA also invited the submission of written comments concerning FDA's draft plan for the regulation of MAS cells. Based on the discussions at the March 15, 1996, roundtable and on a review of all comments received, FDA has decided that, in light of the existing and increased flexibility provided by REGO initiatives, FDA will apply the regulatory framework as detailed and explained in the guidance. CBER is

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