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 (192.73.61.1). 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,w6p), 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 Management 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.


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 revisit the regulatory framework as detailed and explained in the guidance. CBER is
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).

Dated: May 22, 1996.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 96–13386 Filed 5–23–96; 11:13 am]

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

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[FR Doc. 96–13386 Filed 5–23–96; 11:13 am]

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