information in the ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater'' issued on October 14, 1999. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by January 21, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

At a public meeting held on September 16 and 17, 1999, the Neurological Devices Panel (the Panel) recommended that human dura mater be classified into class II. The Panel also commented on the information in the ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater'' that was issued on July 31, 1999, and was subsequently reformatted and reissued with the same title on October 14, 1999. The draft guidance entitled ''Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA'' was developed as a special controls guidance to support the classification of human dura mater into class II and to update and supersede the information in the October 14, 1999, guidance document. Following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket notification for human dura mater will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on special controls for human dura mater. 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 applicable statutes and regulations. This draft guidance document is issued as a level 1 guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive a copy of the ''Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (054) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information, including the text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the human dura mater guidance document, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 3 and 7 through 12 of this guidance were approved under OMB control number 0910–0120.

V. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on ''Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA.'' You must submit three copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26817 Filed 10–21–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP)

National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH) Notice of Availability of an Expert Panel Report on the Current Validation Status of *In Vitro* Endocrine Disruptor Screening Methods and a Proposed List of Substances for Validation of *In Vitro* Endocrine Disruptor Screening Methods; Request for Comments.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of a report entitled, ''The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Expert Panel Report on the Current Status of *In Vitro* Test Methods for Detecting Endocrine Disruptors'' and a list of substances proposed by the ICCVAM Endocrine Disruptor Working Group (EDWG) for the validation of in vitro endocrine disruptor screening methods. Final versions of the Background Review Documents (BRDs) reviewed at the May 21–22, 2002 expert panel meeting and the summary minutes of this meeting are also available. The NICEATM invites public comment on the expert panel report and the proposed list of substances for validation.

Availability of Expert Panel Report, Proposed List of Substances for Future Validation, and Final Background Review Documents

Copies of the expert panel report, the EDWG proposed list of substances for validation, and each BRD may be obtained on the ICCVAM/NICEATM Web site at *http://iccvam.niehs.nih.gov*, or by contacting NICEATM, NIEHS, PO Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) (919) 541–3398, (fax) (919) 541–0947, (email) *niceatm@niehs.nih.gov.*

Request for Comments

NICEATM invites the submission of written comments on the expert panel report and the proposed list of substances for validation of *in vitro* endocrine disruptor methods. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable). Written comments and additional information should be sent by mail, fax, or email to Dr. William S. Stokes, Director of NICEATM, at the address listed above by noon, December 6, 2002. All written comments received before this deadline will be posted on the ICCVAM/NICEATM Web site and made available to ICCVAM agency representatives for their consideration prior to the development by ICCVAM of final recommendations on these test methods and the proposed list of substances for validation.

The expert panel report, the final list of proposed substances for validation, and the ICCVAM recommendations will be compiled into a report and forwarded to the Director of the NIEHS and the heads of appropriate Federal agencies and posted on the ICCVAM/NICEATM Web site. The NIEHS and the Federal agencies will consider these recommendations and comments to determine if and how (chemicals and laboratories) additional validation studies will be conducted. If a decision is made to conduct validation studies on *in vitro* ER and AR assays, an independent peer review panel will be convened to review the results of these studies and to propose minimum performance criteria.

Background on the Evaluation of *In Vitro* Endocrine Disruptor Screening Methods and Development of the Proposed List of Substances for Future Validation

A request for data supporting the performance and reliability of endocrine disruptor screening methods and for the nomination of expert scientists for an independent scientific review panel was previously published (**Federal Register**, Vol. 66, No. 57, pp. 16278–16279, March 23, 2001, available at *http://iccvam.niehs.nih.gov/methods/endocrine.htm*). This notice also announced that NICEATM in collaboration with the ICCVAM would hold an independent peer review panel meeting to assess the current validation status of *in vitro* estrogen receptor (ER) and androgen receptor (AR) binding and transcriptional activation assays, and to review proposed minimum performance criteria for defining an acceptable screening assay. During development of Background Review Documents (BRDs) for *in vitro* ER and AR assays, ICCVAM and NICEATM determined that no validation studies using standardized protocols had been completed. As a result, NICEATM in collaboration with the ICCVAM held an expert panel meeting on May 21–22, 2002, to evaluate the current status of ER and AR binding and transcriptional activation assays and to develop recommendations for their future validation (**Federal Register**, Vol. 67, No. 66, pp. 16415–16416, April 5, 2002, available at *http://iccvam.niehs.nih.gov/methods/endocrine.htm*). At this meeting, the panel reviewed each of four BRDs (Estrogen and Androgen Receptor Binding and Transcriptional Activation Assays) and developed conclusions and recommendations on the following:

- The relative priority that should be given to specific assays recommended for further evaluation in validation studies.
- The adequacy of the specific protocols recommended for validation studies.
- The adequacy of the minimum procedural standards recommended for each type of assay.
- The adequacy and appropriateness of substances recommended for validation studies.

The expert panel's conclusions and recommendations are included in the report described above.

Based on the recommendations of the expert panel and in consultation with the EDWG, a combined list of proposed substances for future validation was developed. This list is proposed by the EDWG to facilitate future validation of *in vitro* endocrine disruptor screening methods and is available as described in this notice.

Background Information on ICCVAM and NICEATM

ICCVAM was authorized as a permanent interagency committee of the NIEHS, under the NICEATM, on December 19, 2000, by the ICCVAM Authorization Act of 2000 (P.L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*). ICCVAM is composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information. P.L. 106–545 directs the ICCVAM to coordinate the technical review of new, revised, and alternative test methods of interagency interest. The committee also coordinates cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. ICCVAM promotes the scientific validation and regulatory acceptance of toxicological test methods that enhance agencies' ability to make decisions on health risks, while refining, reducing, and replacing animal use wherever possible. NICEATM provides operational and scientific support for ICCVAM and collaborates with ICCVAM to evaluate new and alternative test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: *http://iccvam.niehs.nih.gov*.

Dated: October 9, 2002.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 02–26733 Filed 10–21–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4734–N–62]

Notice of Submission of Proposed Information Collection to OMB: Capital Advance Program Submission Requirements for Section 202 Housing for the Elderly and Section 811 Housing for Persons With Disabilities

AGENCY: Office of the Chief Information Officer, 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:* November 21, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to