

classification framework presumes that the risk presented by a particular device depends on its intended purpose and the effectiveness of the risk management techniques applied during the design, manufacture, and use of that device. The document also suggests that the regulatory controls applied should be proportional to the level of risk associated with a medical device and should increase with the associated degree of risk presented by the medical device. The GHTF document suggests four global classifications of devices.

This document also presents a decision tree logic that may help regulatory authorities develop different parameters that might be used to classify specific devices.

When FDA discusses draft documents with representatives of other countries, we seek public comment on the resulting documents. We believe that it is important to publish draft documents for comment at the same time as other countries so we may review the public comments and resume discussions in a timely manner. Because other countries do not follow our good guidance practices (GGPs), we do not require draft documents that result from international discussions to comply with the format requirements of our GGP regulation. The GGP regulation does require that any final FDA guidance that results from international discussions will comply with the GGP regulation.

II. Electronic Access

In order to receive "Medical Devices Classification" 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 (1327) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including 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 civil money penalty guidance documents package, 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>.

III. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. FDA must submit its written comments to the GHTF by July 1, 2001. FDA will consider any comments that it receives in a timely manner, while preparing those comments. FDA will consider any public comments that it receives after preparation of its comments to GHTF in future discussions on this issue. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01-12226 Filed 5-15-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10041]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, 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 and 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.

Type of Information Collection Request: New collection; *Title of Information Collection:* Long Term Care Awareness Project; *Form No.:* HCFA-10041 (OMB# 0938-NEW); *Use:* HCFA needs to collect data to pilot test a national campaign to educate current and future Medicare beneficiaries and their families about long term health care needs, as requested in the Clinton Fiscal Year 2000 Budget, to design and implement a nationwide campaign. Respondents will be from two groups: 55-70 year-olds and 18-64 years old persons with disability; *Frequency:* Quarterly; *Affected Public:* Individuals or households; *Number of Respondents:* 7,800; *Total Annual Responses:* 3,900; *Total Annual Hours:* 800.

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. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Attn. 10041, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 8, 2001.

Julie Brown,

Acting Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01-12342 Filed 5-15-01; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: May 10, 2001.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jeanne N. Ketley, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435-1789.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 8, 2001.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-12260 Filed 5-15-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); National Institute of Environmental Health Sciences; NTP Announces the Release of the NTP Final Report From the Endocrine Disruptors Low-Dose Peer Review for Public Comment

Summary

The National Toxicology Program (NTP)/National Institute of Environmental Health Sciences (NIEHS) organized and conducted a scientific peer review at the request of the US Environmental Protection Agency (EPA) to evaluate reported low-dose reproductive and developmental effects and dose-response relationships for endocrine disrupting chemicals. The NTP is soliciting public comment prior to transmitting the final report to the US EPA. Public comments received in response to this solicitation will be included in the final transmittal. The final report is available on the NTP web

site at <http://ntp-server.niehs.nih.gov> or by contacting the NTP Office of Liaison and Scientific Review; 919-541-0530 (phone); 919-541-0295 (fax); liaison@starbase.niehs.nih.gov; 111 T.W. Alexander Drive, P.O. Box 12233, MD A3-01, Research Triangle Park, NC 27709.

Background

The NTP final report will be provided to the US EPA to help guide the agency in determining whether or not its guidelines for reproductive and developmental toxicity testing are adequate for endocrine active chemicals. For this meeting, "low-dose effects" referred to biological changes that occur in the range of human exposures or at doses lower than those typically used in the US EPA's standard testing paradigm for evaluating reproductive and developmental toxicity.

The peer review included plenary sessions and several subpanel meetings. The peer review panel was divided into five subpanels: Bisphenol A, Other Environmental Estrogens and Estradiol, Androgens and Anti-Androgens, Biological Factors and Study Design, and Statistics and Dose-Response Modeling. The Panel examined data from major, selected studies (excluding studies on phthalates and dioxin and dioxin-like compounds) supporting the presence or absence of low-dose effects in laboratory animals that could be relevant for human health assessments. The Panel was also asked to evaluate the shape of the dose-response curve for endocrine active substances in the low-dose region. Prior to the peer review, members of the Statistics and Dose-Response Modeling Subpanel analyzed the raw data on selected parameters for 38 studies and provided its analyses to the other subpanels. At the peer review, members from this subpanel participated in other subpanels.

Request for Public Comment on the Final Report

Interested parties are encouraged to submit written comments on the NTP Endocrine Disruptors Low-Dose Peer Review Final Report. Comments should include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any). The NTP invites written public comment on the final report through July 16, 2001. Comments should be submitted to the NTP Office of Liaison and Scientific Review; 919-541-0530 (phone); 919-541-0295 (fax); liaison@starbase.niehs.nih.gov; 111 T.W. Alexander Drive, P.O. Box 12233,

MD A3-01, Research Triangle Park, NC 27709.

Additional Information About the Endocrine Disruptors Low-Dose Peer Review

For additional information about the Endocrine Disruptors Low-Dose Peer Review including the peer review's program, list of participants, literature reference lists, and **Federal Register** notices, visit the NTP web site at: <http://ntp-server.niehs.nih.gov>

Previously three **Federal Register** notices were published about this peer review: January 6, 2000, Volume 65, Number 4, pages 784-787; April 17, 2000, Volume 65, Number 74, pages 20478-20479; September 27, 2000, Volume 65, Number 188, pages 58097-58099.

Dated: May 8, 2001.

Kenneth Olden,

Director, NIEHS, Director, NTP.

[FR Doc. 01-12261 Filed 5-15-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4655-N-13]

Notice of Proposed Information Collection: Comment Request; Hospital—Section 242, Application for Project Mortgage Insurance

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 Date:* July 16, 2001.

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: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Building, Room 8202, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Roger Miller, Director, Office of Insured Health Care Facilities, U.S. Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone number (202) 708-