

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-14947 Filed 6-13-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1307]

Draft Guidance for Industry on Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis." Parathyroid hormone (PTH) is being studied for use in the prevention and treatment of osteoporosis. In response to preclinical studies submitted to FDA in which osteosarcomas developed in rats and mice following administration of PTH and related peptides, the agency is developing guidance for the development of PTH as a drug for osteoporosis. This guidance is intended to improve the benefit to risk ratio of treatment with PTH and related peptides.

DATES: Submit written comments on the draft guidance by August 14, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management

Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric Colman, Center for Drug Evaluation and Research (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6371.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis." This draft guidance is being issued in response to information submitted to the agency regarding the development of osteosarcomas in two strains of rats and one strain of mice following treatment with PTH and related peptides from weaning to 18 months. Given the uncertain clinical relevance of the findings in rodents, and in an effort to improve the benefit to risk ratio of PTH when used in studies of the prevention and/or treatment of osteoporosis, the draft guidance recommends that special consideration be given to the design and conduct of clinical trials evaluating the safety and effectiveness of PTH. These special considerations relate to inclusion and exclusion criteria, patient followup, and patient informed consent.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the development of parathyroid hormone in the prevention and treatment of osteoporosis. 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 requirements of the applicable statutes, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, 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 draft 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.

Dated: June 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-14986 Filed 6-13-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review: Comment Request: National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 19, 2000, pages 2967-1968 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey. *Type of Information Request:* NEW. *Need and Use of Information Collection:* NIDDK will conduct a survey to evaluate the efficiency and effectiveness of services provided its three information clearinghouses: National Diabetes Information Clearinghouse, National Digestive Diseases Information Clearinghouse, National Kidney and Urologic Diseases Information Clearinghouse. The survey responds to Executive Order 12862, "Setting Customer Services Standards," which requires agencies and departments to identify and "survey their customers to determine the kind and quality of service they want and their level of satisfaction with existing service." *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; clinics or doctor's offices. *Type of Respondents:* Physicians, nurses, patients, family.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 12,000; *Estimated Number of Responses per Respondent:* 1; *Estimated Average Burden Hours Per Response:* 0.1671; and *Estimated Total Annual Burden Hours Requested:* 2,000.

The annualized cost to respondents is estimated at \$39,000. There are no Capital Costs to report. There are no

Operating or Maintenance Costs to report.

Type of respondents	Number of respondents	Frequency of response	Estimated average response time	Estimated annual burden hours
Patients/Family	3,600	1.0	0.167	600
Phys. Asst	7,200	1.0	0.167	1,200
Physicians	1,200	1.0	0.167	200
Totals	12,000	2,000

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Kathy Kranzfelder, Project Officer, NIDDK Information Clearinghouses, NIH, Building 31, Room 9A04, MSC2560, Bethesda, MD 20852, or call non-toll-free number (301) 435-8113 or E-mail your request, including your address, to: kranzfeldk@hq.nidDK.nih.gov

Comments Due Date

Comments regarding this information are best assured of having their full effect if received within 30 days following the date of this publication.

Dated: May 25, 2000.

L. Earl Laurence,

Executive Officer, NIDDK.

[FR Doc. 00-14956 Filed 6-13-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel, NCI Transition Career Development Award (K22 applications).

Date: June 16, 2000.

Time: 4:00 PM to 8:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, N.W., Washington, DC 20007.

Contact Person: Mary Bell, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8058, Bethesda, MD 20892.

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. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention

Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer control, National Institutes of Health, HHS)

Dated: June 6, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-14962 Filed 6-13-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

National Cancer Institute; 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 meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 U.S.C., as amended. The discussions could reveal information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy and the premature disclosure of discussions related to personnel and programmatic issues would be likely to significantly frustrate the subsequent implementation of recommendations.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee B—Basic Sciences.

Date: July 10, 2000.

Time: 8:00 AM to 5:30 PM.

Agenda: Chair's Remarks; Division Director's Report and Discussion of personnel and programmatic issues; Site Visit Reports; Review and evaluate individual Principal Investigators.

Place: National Cancer Institute, Building 31, C Wing, 6th Floor, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.