

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).*

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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#### Draft Guidance for Industry on Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis; Availability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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis."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**DATES:** Submit written comments on the draft guidance by August 14, 2000.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**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at 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 Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management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]

**BILLING CODE 4160-01-F**

## 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.