

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	6-13-00
Publication Date	6-14-00
Certifier	S. Reese

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Draft Guidance for Industry on Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis."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DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

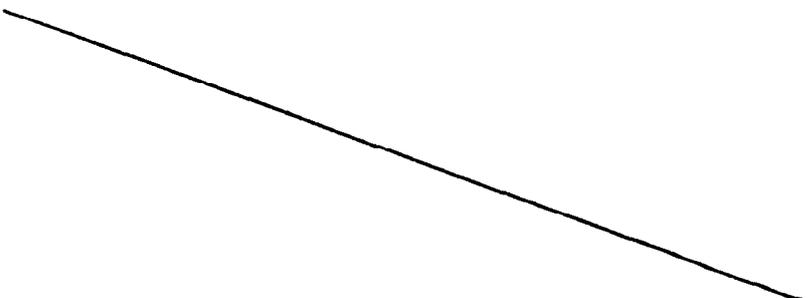
ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis." This draft guidance is being issued in response to information submitted to the agency regarding the development of osteosarcomas in two strains of rats and one strain of mice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.

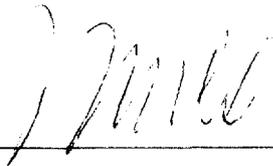
This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the development of parathyroid hormone in the prevention and treatment of osteoporosis. It does not create or confer any rights 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
June 6, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

