

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0035]

Draft Guidance for Industry on the Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on a draft guidance entitled “Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis.” The guidance was issued in 1994 (1994 draft guidance). During the past decade, a significant body of data related to the diagnosis, prevention, and treatment of osteoporosis has been published. Much of this information is relevant to osteoporosis drug development and, in particular, relates to issues surrounding clinical trial design and duration. The agency is preparing to develop an updated draft guidance on the same topic and is seeking comment on the 1994 draft guidance.

DATES: Submit written or electronic comments on the 1994 draft guidance by *[insert date 60 days after date of publication in the **Federal Register**]*.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ADDRESSES: Submit written requests for single copies of the 1994 draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,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 Submit written comments on the 1994 draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document

FOR FURTHER INFORMATION CONTACT: Randy Hedin, Center for Drug Evaluation and Research (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6392.

SUPPLEMENTARY INFORMATION:

I. Background

FDA, with input from an ad hoc workshop and an advisory committee, first issued guidance on osteoporosis drug development in 1979. The guidance was issued in response to the need for effective and safe drugs to prevent and treat osteoporosis. The agency revised the guidance in 1984. Most recently, FDA issued the 1994 draft guidance entitled “Guidelines for Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis.”

The 1994 draft guidance recommends study designs, patient populations for study, and techniques for evaluating skeletal mass and fracture frequency that are considered central to demonstrating the efficacy and safety of drugs used to treat and prevent osteoporosis. Since issuance of the 1994 guidance, a number of drugs have been approved for the prevention and treatment of osteoporosis. In general, approval of these drugs was based on favorable bone

mineral density and decreased fracture incidence from 2- and 3-year placebo-controlled trials.

Results from these trials and other published data have raised a number of issues and questions that the agency plans to address in an updated draft osteoporosis guidance. To aid in the development of the draft guidance, FDA is requesting comment on the 1994 draft guidance. The agency seeks specific comment on the following questions:

- Is it appropriate to continue to use placebo controls in fracture end-point trials?
- Do fracture end-point trials need to be 3 years in duration, or could shorter studies provide adequate evidence of a new osteoporosis drug's effectiveness and safety?

The 1994 draft guidance was issued before the 1997 publication of FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). In accordance with the GGPs, the agency will take into account any comments received on the 1994 draft guidance, develop a new draft guidance, and make it available for comment. When finalized, that guidance will represent the agency's current thinking on the preclinical and clinical evaluation of agents used in the prevention or treatment of postmenopausal osteoporosis. Agency guidance 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 and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the 1994 draft guidance. Two copies of mailed 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 1994 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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