

Display Date	7-14-99
Publication Date	7-15-99
Certifier	Michael W. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0077]

Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)." The draft guidance is intended to stimulate discussion about designing clinical programs for the development of drugs, devices, and biological products intended for the treatment of osteoarthritis (OA). This draft guidance reflects comments received in response to a previous draft version of the guidance available in February 1998.

DATES: Written comments on the draft guidance document may be submitted by (*insert date 60 days after date of publication in Federal Register*). General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance and appended questions are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>" or "<http://www.fda.gov/cber/guidelines.htm>". Submit written requests for single copies of the draft guidance and appended questions to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; FAX: 1-888-

CBERFAX or 301-827-3844, mail: the Voice Information System at 800-835-4709 or 301-827-1800. 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Submit written comments on the draft guidance to the Dockets Management Branch (HFD-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra N. Cook, Center for Drug Evaluation and Research (HFD-550), 9201 Corporate Blvd., Rockville, MD 20850, 301-827-2090.

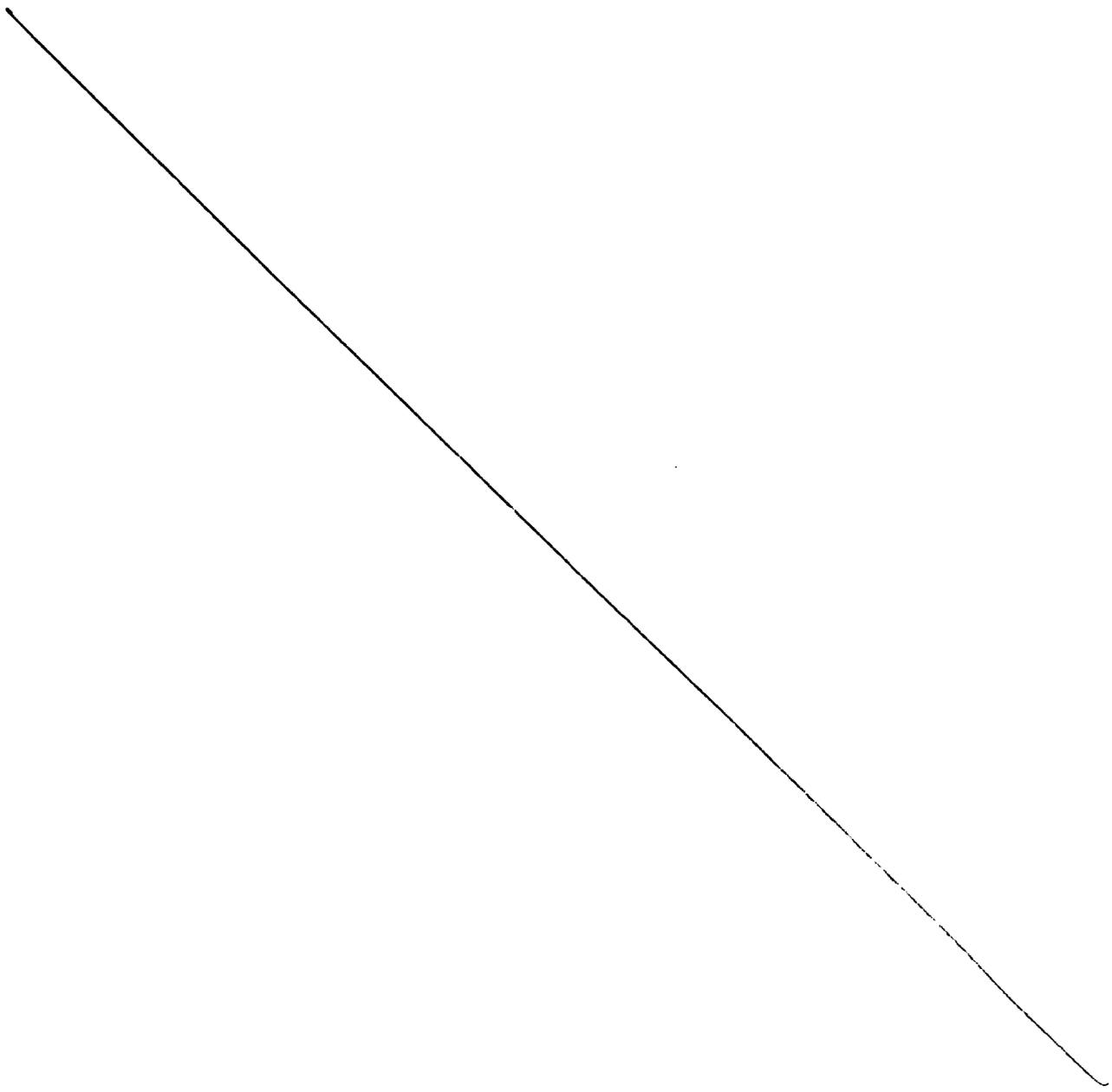
SUPPLEMENTARY INFORMATION: Currently, treatment for OA is fundamentally symptomatic, with no data available on long-term outcomes. Clinical trial experience with OA has been limited to short-term studies in patients with knee or hip OA and generalized OA normally has not been appropriate for assessing OA agents. A number of novel approaches are under study for the treatment of OA, as companies, clinicians, and patients search for more effective treatments. The design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA was the subject of a previous draft guidance issued in February 1998 (63 FR 8208, February 18, 1998). The February 1998 draft guidance generated several comments and was the subject of discussion at the Arthritis Advisory Committee meeting held on February 20, 1998.

The agency found the comments and the discussion at the advisory committee meeting very helpful in developing the recommendations to industry, contained in the guidance, on the design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA. However, the agency believes that more public input would be beneficial in preparing a final version of the guidance. Accordingly, the agency has decided to issue this revised version of the guidance as a draft.

This level 1 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 developing drugs, devices, or biological products intended for the treatment of OA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

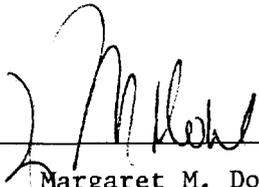
public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before (*insert date 60 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments on the draft document. 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 document, appended questions, and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/8/99
July 8, 1999



Margaret M. Dotzel
Acting Associate Commissioner for
Policy Coordination

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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