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Dated: February 11, 1998.

Joseph R. Carter

*Acting Associate Director for Management
and Operations, Centers for Disease Control
and Prevention (CDC)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93P-0448]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling; Serving Sizes; Reference Amount for Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt)" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT:
Margaret R. Schlosburg, Office of
Information Resources Management
(HFA-250), Food and Drug
Administration, 5600 Fishers Lane,
Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 2, 1997 (62 FR 63647), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0362. The approval expires on January 31, 2001.

Dated: February 4, 1998.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

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Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA); Availability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

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and requesting comment on a draft guidance for industry entitled "Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)." The purpose of the draft guidance and the discussion questions appended to the draft guidance is to stimulate discussion and seek input about designing clinical programs for the development of drugs, devices, and biological products intended for the treatment of OA. The draft guidance and appended questions will be the topics of discussion at the Arthritis Advisory Committee meeting to be held on February 20, 1998.

DATES: Written comments may be submitted on the draft guidance document by April 20, 1998. General comments on the 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."

Written requests for single copies of the draft guidance and appended questions should be submitted 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 (HFD-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The February 20, 1998, meeting of the Arthritis Advisory Committee will be held at the Holiday Inn Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT:
Chin C. Koerner, Center for Drug
Evaluation and Research (HFD-550),
Food and Drug Administration, 9201

Corporate Blvd., Rockville, MD 20850,
301-827-2090.

SUPPLEMENTARY INFORMATION: Currently, treatment for OA is fundamentally symptomatic, with no data available on the impact 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 therapeutics. The focus of the discussion during the February 20, 1998, Arthritis Advisory Committee Meeting will be: (1) The appropriateness of the proposed claims for improvement of pain, function, structure, and durability, as well as delay in new OA and delay in joint replacement; and (2) trial designs and analyses to support those claims. Notice of the meeting of the Arthritis Advisory Committee appeared in the **Federal Register** of January 16, 1998 (63 FR 2682).

The purpose of the draft guidance and the appended questions is to stimulate discussion and seek input regarding the design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA. Discussion during the meeting will enable public participation and the exchange of ideas on developing and assessing new treatment modalities for OA, types of claims that might be reasonably pursued, and data necessary to support such claims. The discussions are not intended to result in consensus among participants; they are intended to contribute to the formulation of suggestions to drug, device, and biological product sponsors for designing appropriate study protocols and expediting product development.

Interested persons may submit written comments on the draft document to the Dockets Management Branch (address above). 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: February 11, 1998.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

[FR Doc. 98-3982 Filed 2-12-98; 1:39pm]

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