inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 3, 1998.

A. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Morrill Bancshares, Inc., Sebetha, Kansas, and Morrill & Janes Bancshares, Inc., Hiawatha, Kansas, First Centralia Bancshares, Inc., Centralia, Kansas, Davis Bancorporation, Inc., Davis, Oklahoma, Onaga Bancshares, Onaga, Kansas; to acquire FBC Financial Corporation, Claremore, Oklahoma, and thereby indirectly acquire 1st Bank Oklahoma, Claremore, Oklahoma, and thereby engage in operating a savings association, pursuant to § 225.28(b)(4) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 11, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–3949 Filed 2–17–98; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 814]

Applied Research in Emerging Infections; Hepatitis C Virus Infection—Sexual Transmission

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for competitive cooperative agreements and/or grants to support applied research on emerging infections—epidemiologic studies of sexual transmission of hepatitis C virus (HCV) infection.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section **Where to Obtain Additional Information**.)

Authority

This program is authorized under Sections 301 and 317 of the Public Health Service Act, as amended (42 U.S.C. 241 and 247b).

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Pub. L. 103–227, the Pro-Children's Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private non-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private non-profit organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority-and/or women-owned non-profit businesses are eligible to apply.

Availability of Funds

Approximately $500,000 is available in FY 1998 to fund one or two awards. It is expected the awards will begin on or about August 10, 1998 and will be made for a 12-month budget period within a project period of up to three years. The funding estimate is subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Determination of Which Instrument To Use

Applicants must specify the type of award for which they are applying, either grant or cooperative agreement. CDC will review the applications in accordance with the evaluation criteria. Before issuing awards, CDC will determine whether a grant or cooperative agreement is the appropriate instrument based upon the need for substantial CDC involvement in the project.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Pub. L. 105–78) states in Section 503 (a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

No part of any appropriation shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

Once expected to be eliminated as a public health problem, infectious diseases remain the leading cause of death worldwide. In the United States and elsewhere, infectious diseases increasingly threaten public health and contribute significantly to the escalating costs of health care.

In partnership with other Federal agencies, State and local health departments, academic institutions, and others, CDC has developed a plan for revitalizing the nation's ability to identify, contain, and prevent illness from emerging infectious diseases. The plan, Addressing Emerging Infectious Disease Threats; A Prevention Strategy for the United States, identifies objectives in four major areas: surveillance; applied research; prevention and control; and infrastructure.

Under the objective for applied research, the plan proposes to integrate laboratory science and epidemiology to optimize public health practice in the United States. In FY 1996, CDC initiated the Extramural Applied Research Program in Emerging Infections (EARP).

This grant/cooperative agreement announcement specifically addresses the area of hepatitis c virus (HCV) infection.

In the United States, an estimated 3.9 million persons are chronically infected with HCV and are a potential source of transmission to others. In the absence of pre- or post-exposure prophylaxis, preventing infection is dependent on providing infected persons with specific information about the risk of transmission in different settings. This announcement addresses the sexual transmission of HCV infection.

Case-control studies have demonstrated an independent association between acquiring acute non-A, non-B hepatitis and a history of exposure to an infected sex partner or to multiple heterosexual partners. HCV seroprevalence studies of STD populations have generally demonstrated an increased risk associated with high-risk sexual behaviors, including multiple partners and failure to use a condom. In contrast, HCV seroprevalance studies of long-term partners of patients with chronic HCV infection have generally shown either very low or absent risk, but these studies had inadequate sample sizes to address the issue, most were not conducted in the United States, and in several of the studies in which transmission between long term sex partners was reported, a common parenteral exposure in the past could not be ruled out. Because of the limited and inconsistent data available, there are currently no specific recommendations for changes in sexual practices for infected persons and their steady partners. Definitive studies in this area are needed to determine if such recommendations need to be developed.

Purpose

The purpose of this grant/cooperative agreement program is to provide assistance for projects addressing the sexual transmission of HCV infection between steady partners. Specifically, applications are solicited for projects aimed at determining if there is an increased risk of HCV infection among steady sexual partners of HCV infected persons and identifying potential risk factors responsible for transmission.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for conducting activities for a cooperative agreement under B. (CDC Activities):

Research Project Grants

A research project grant is one in which substantial programmatic involvement by CDC is not anticipated by the recipient. Applicants for grants must demonstrate an ability to conduct the proposed research with minimal assistance, other than financial support, from CDC. This would include possessing sufficient resources for clinical, laboratory, and data management services and a level of scientific expertise to achieve the objectives described in their research proposal without substantial technical assistance from CDC.

Cooperative Agreements

A cooperative agreement implies that CDC will assist recipients in conducting the proposed research. The application should be presented in a manner that demonstrates the applicant's ability to address the research problem in a collaborative manner with CDC.

A. Recipient Activities

Determine if there is an increased risk of HCV infection among steady sexual partners of HCV infected persons and identify potential risk factors responsible for transmission.

1. Enroll a sufficient number of anti-HCV positive persons and their steady sexual partners (estimated at ≥1000 participants each) to evaluate low frequency events. A steady sexual partner is defined as one whose only partner was the index case during the previous 3 or more years.

a. Index cases should represent a broad spectrum of infection (e.g., asymptomatic persons identified through routine screening, symptomatic persons with various stages of chronic liver disease, etc.), a broad range of duration of infection (when it can be determined), and as broad an age range as possible.

2. Conduct an anti-HCV seroprevalence study of the sexual partners and a complete risk behavior history on cases and partners. All samples with anti-HCV repeatedly reactive results using enzyme immuno-assay should be tested using a supplemental anti-HCV assay.

3. Use nucleic acid detection methods to identify virus-specific factors in either the index case or the partner that may be responsible for transmission and to confirm the identity of virus strains in partner-pairs when both are infected.

4. Publish results.

B. CDC Activities (Cooperative Agreement)

1. Provide technical assistance in the design and conduct of the research.

2. Perform selected laboratory tests as appropriate and necessary.

3. Participate in data management, the analysis of research data, and the interpretation and presentation of research findings.

4. Provide biological materials as necessary for studies, etc.

Technical Reporting Requirements

An original and two copies of a narrative progress report are required semiannually. The first semiannual report is required with each year's non-competing continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project).

The second semiannual report and Financial Status Report (FSR) are due 90 days after the end of each budget period and should cover activities from the date of previous report. Progress reports should address the status of progress toward specific project objectives and should include copies of any publications resulting from the project. The final performance report and FSR are required no later than 90 days after the end of the project period.

All reports should be directed to the CDC Grants Management Officer at the address referenced in the following section.

Application Process

Notification of Intent To Apply

In order to assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit an application are requested to inform CDC of their intention to do so as soon as possible prior to the application due date but not later than 10 business days prior to the application due date. Notification should cite this Announcement number 814 and include: (1) Name and address of institution and (2) name, address, and phone number of contact person. Notification can be provided by facsimile, postal mail, or electronic mail (E-mail) to Sharron P. Orum, Grants Management Officer, Attn: Gladys T. Gissentanna, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–18, Atlanta, Georgia 30305, facsimile (404) 842–6513 or E-mail gcg4@cdc.gov.

Application Content

All applicants must develop their application in accordance with the PHS Form 398, information contained in this

grant/cooperative agreement announcement, and the instructions outlined below.

General Instructions

Due to the need to reproduce copies of the applications for the reviewers, ALL pages of the application must be in the following format:

1. The original and five (5) copies must be unstapled and unbound.
2. All pages must be clearly numbered, and a complete index to the application and its appendices must be included.
3. All materials must be typewritten, single-spaced, using a font no smaller than size 12, and on 8½″ by 11″ white paper.
4. Any reprints, brochures, or other enclosures must be copied onto 8½″ by 11″ white paper by the applicant. No bound materials will be accepted.
5. All pages must be printed on one side only, with at least 1″ margins, headers, and footers.

Special Instruction

The application narrative must not exceed 10 pages (excluding budget and appendices). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below.

1. Abstract

Provide a brief (two pages maximum) abstract of the project. Clearly identify the type of award that is being applied for: grant or cooperative agreement.

2. Background and Need

Discuss the background and need for the proposed project. Demonstrate a clear understanding of the purpose and objectives of this program.

3. Capacity and Personnel

Describe applicant's past experience in conducting projects/studies similar to that being proposed. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project. Provide *in an appendix* letters of support from all key participating non-applicant organizations, individuals, etc., which clearly indicate their commitment to participate as described in the operational plan. Do not include letters of support from CDC personnel. Letters of support from CDC will not be accepted. Award of a cooperative agreement implies CDC participation as outlined in the Program Requirements section of this announcement.

4. Objectives and Technical Approach

Present specific objectives for the proposed project which are measurable and time-phased and are consistent with the Purpose and Recipient Activities of this Program Announcement. Present a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses these objectives (if proposing a multi-year project, provide a detailed description of first-year activities and a brief overview of subsequent-year activities). Clearly identify specific assigned responsibilities for all key professional personnel. Include a clear description of applicant's technical approach/methods which are directly relevant to the above objectives. Describe specific study protocols or plans for the development of study protocols. Describe the nature and extent of collaboration with CDC (if applying for a cooperative agreement) and/or others during various phases of the project. Describe in detail a plan for evaluating study results and for evaluating progress toward achieving project objectives.

5. Budget

Provide a line-item budget and accompanying detailed, line-by-line justification that demonstrates the request is consistent with the purpose and objectives of this program. If requesting funds for contracts, provide the following information for each proposed contract: (a) Name of proposed contractor, (b) breakdown and justification for estimated costs, (c) description and scope of activities to be performed by contractor, (d) period of performance, and (e) method of contractor selection (e.g., sole-source or competitive solicitation).

Note: If indirect costs are requested from CDC, a copy of the organization's current negotiated Federal indirect cost rate agreement or cost allocation plan must be provided.

6. Human Subjects

Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, describe adequate procedures for the protection of human subjects. Also, ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (10 Points)

Extent to which applicant demonstrates a clear understanding of the subject area and of the purpose and objectives of this grant/cooperative agreement program.

2. Capacity (45 Points)

Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. If applicable, extent to which applicant includes letters of support from non-applicant organizations, individuals, etc., and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 Points Total)

a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and goals of this grant/cooperative agreement program and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all ''Recipient Activities.'' Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the approach/methods are appropriate and adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. Extent to which applicant describes adequate and appropriate collaboration with CDC (if applying for a cooperative agreement). Extent to which women, racial and ethnic minority populations are appropriately represented in applications involving human research. (30 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives.

If the proposed project involves notifiable conditions, the degree to which applicant describes an adequate process for providing necessary information to appropriate State and/or local health departments. (5 points)

4. Budget (Not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant/cooperative agreement funds.

5. Human Subjects (Not Scored)

If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHHS) regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the ORG has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 Review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the grant/cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If an American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, Hispanic or Latino and White. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of each application PHS Form 398 should be submitted to Sharron Orum, Grants Management Officer, Attn: Gladys T. Gissentanna, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–18, Atlanta, Georgia 30305, on or before May 15, 1998.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group.

(Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement 814. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, telephone (404) 842–6801, facsimile (404) 842-6513, E-mail gcg4cdc.gov.

Programmatic technical assistance may be obtained from Miriam J. Alter, Ph.D., National Center for Infectious Diseases, Division of Viral and Rickettsial Diseases, Hepatitis Branch, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G–37, Atlanta, Georgia 30333, telephone (404) 639–2709, E-mail address: mja2@cdc.gov.

Please refer to Announcement 814 when requesting information regarding this program.

You may also obtain this and other CDC announcements from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov, or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the **Introduction** through the Superintendent of Documents, Government Printing Office,

Washington, D.C. 20402–9325, telephone (202) 512–1800.

Dated: February 11, 1998.

Joseph R. Carter

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

[FR Doc. 98–3981 Filed 2–17–98; 8:45 am]

BILLING CODE 4163–18–P

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.

[FR Doc. 98–3985 Filed 2–17–98; 8:45 am]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F