

Jefferson Street, Whiteville, NC

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 13⁷/₈% for the quarter ended June 30, 2000. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: July 25, 2000.

George Strader,

Deputy Assistant Secretary, Finance.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-54-00]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the

Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

Interstate Control of Communicable Diseases—New—The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are planning to consolidate regulations related to controlling the spread of communicable diseases, thereby increasing their efficiency and effectiveness. Currently, the regulations contained in Part 1240 of Title 21, Code of Federal Regulations, which pertain to interstate control of communicable diseases, are administered by FDA. Regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States are separately promulgated in Part 71 of Title 42, Code of Federal Regulations and are administered by the CDC. FDA is transferring to CDC certain sections of 21 CFR Part 1240 that relate to restrictions on interstate travel of any person who is in the communicable period of cholera, plague, smallpox, typhus, or yellow fever, or who, having been exposed to any such disease, is in the incubation period thereof.

Of the regulations being transferred, 21 CFR 1240.50 (Certain communicable diseases; special requirements), contains a requirement for reporting certain information to the Federal government. Specifically, this regulation requires any person who is in the communicable period of cholera, plague, smallpox, typhus or yellow fever, or who, having been exposed to any such disease, is in the incubation period thereof, to apply for and receive a permit from the Surgeon General or his authorized representative in order to travel from one State or possession to another.

Control of disease transmission within the States is considered to be the province of State and Local health authorities, with Federal assistance being sought by those authorities on a cooperative basis, without application of Federal regulations. The regulations formerly administered by FDA and being assumed by CDC were developed to facilitate Federal action in the event

of large outbreaks of disease requiring a coordinated effort involving several States, or in the event of inadequate local control. While it is not known whether, or to what extent, situations may arise in which these regulations would be invoked, contingency planning for domestic emergency preparedness is not uncommon. Should this occur, the reporting and record keeping requirements contained in the regulations will be used by CDC to carry out quarantine responsibilities as required by law.

Because of the uncertainty about whether a situation will ever arise precipitating CDC's enforcement of this rule, the following data collection burden estimate was prepared using the article Smallpox: An Attack Scenario, Tara O'Toole; Emerging Infectious Diseases, Vol. 5, No. 4, Jul-Aug 1999. This article describes the aftermath of a hypothetical domestic public health emergency situation involving smallpox virus. Of the potentially 15,000 persons infected with smallpox, the data collection assumes that one-fourth of these would apply for a permit to move from one state to another while in the communicable period of or having been exposed to smallpox, under the requirements set forth in 42 CFR 70.5. During such an event, it is assumed that an additional 2,000 persons not infected with smallpox may, as a precautionary measure, be required to obtain a State permit in order to move from one State to another, and that 8 States would be involved, under the requirements set forth in 42 CFR 70.3.

Further, it is assumed that during such an event, the master of a vessel or person in charge of a conveyance may be required to notify a local health authority of as many as 1,500 suspected cases of communicable disease developed and/or observed during transit, involving as many as 20 State or local jurisdictions, under the requirements set forth in 42 CFR 70.4.

In such a scenario, it would be likely that CDC would obtain for followup and analysis any information it requires to be delivered to a State or local health authority. Accordingly, an additional burden may be imposed upon said authority to copy and transmit that information. We assume that the burden would apply to 100% of the information submitted under both 42 CFR 70.3 and 42 CFR 70.4.

The annualized burden is estimated to be 3,600 hours.

Regulation	Respondent	Number of applicants	Number of responses per applicant	Average Burden per Response (in minutes)
42 CFR 70.3	Traveler	2,000	1	15/60
42 CFR 70.3	Attending physician	2,000	1	15/60
42 CFR 70.3	State Health Authority	8	250	6/60
42 CFR 70.4	The Master of a vessel or person in charge of a conveyance engaged in interstate traffic.	1,500	1	15/60
42 CFR 70.4	State or local Health authority	20	75	6/60
41 CFR 70.5	Traveler	3,750	1	15/60
41 CFR 70.5	Attending physician	3,750	1	15/60

Dated: July 26, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers, Supplemental Awards under Program Announcement 98047

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting. This notice is published less than 15 days in advance of the meeting due to administrative delays.

NAME: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers, Supplemental Awards under Program Announcement 98047, meeting.

TIMES AND DATES: 1 p.m.–1:30 p.m., August 9, 2000 (Open). 1:30 p.m.–4 p.m., August 9, 2000 (Closed).

PLACE: The teleconference call will originate in the National Center for Chronic Disease Prevention and Health Promotion, Prevention Research Centers Program, Koger Center, Rhodes Building, 3005 Chamblee Tucker Rd., Atlanta, Ga 30341. Open access to the call will be available from 1–1:30 p.m. EDT, only. Interested parties may access the teleconference at 877/331-6867. The participant code is 949464.

STATUS: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4)

and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

MATTERS TO BE DISCUSSED: The meeting will include the review, discussion, and evaluation of supplemental award applications received in response to Program Announcement 198047.

CONTACT PERSON FOR MORE INFORMATION: David Elswick, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway m/s K30, Atlanta, GA., 30341. Telephone 770/488-5395, email dce1@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 25, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00-19462 Filed 7-28-00; 10:36 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1418]

International Conference on Harmonisation; Draft Guidance on Good Manufacturing Practice for Active Pharmaceutical Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a draft guidance entitled “Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document is intended to provide guidance regarding current good manufacturing practice (CGMP) for manufacturing of active pharmaceutical ingredients (API’s). The recommendations in the draft guidance are intended to assist in the manufacture of API’s that meet the standards for quality and purity they purport or are represented to possess.

DATES: Submit written comments by October 2, 2000.

ADDRESSES: Copies of the draft guidance 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, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests.

To facilitate the submission and review of comments on this draft guidance, the agency has developed two methods for submitting electronic comments. Interested persons may submit comments to the Dockets Management Branch (HFA-305) online or offline by downloading a comments template. Both methods are accessible on the FDA web site at <http://www.fda.gov/ohrms/dockets>. The agency encourages the submission of electronic comments and anticipates that widespread use of these methods