

the appropriate salary structure and salary adjustments for Federal Reserve employees.

Board of Governors of the Federal Reserve System, December 1, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98-32462 Filed 12-7-98; 8:45AM]

Billing Code 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

State Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children Pre-application Workshop; Correction

SUMMARY: The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) published a notice in the **Federal Register**, Volume 63, Number 228, Page 65598, on November 27, 1998, announcing the State Childhood Lead Poisoning Prevention and Surveillance of Blood Levels in Children Pre-application Workshop. The meeting name was incorrect in the notice. Please note the correct meeting name, as follows:

NAME: State Childhood Lead Poisoning Prevention and Surveillance of Blood Levels in Children New and Competing-continuation Grantees Pre-application Workshop.

CONTACT PERSON FOR MORE INFORMATION: Claudette Grant-Joseph, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F-42, Atlanta, Georgia 30341-3724, telephone 770/488-7330.

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: December 2, 1998.

Carolyn J. Russell,

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

[FR Doc. 98-32490 Filed 12-7-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-1022]

COPA Distributors, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that COPA Distributors, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of pyrogallol and ferrous sulfate as a color additive in hair dyes.

FOR FURTHER INFORMATION CONTACT:

Aydin Örtan, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3076.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 8C0263) has been filed by COPA Distributors, Inc., c/o Research It!, Inc., 116 Huckleberry Lane, Henderson, NV 89014. The petition proposes to amend the color additive regulations to provide for the safe use of pyrogallol and ferrous sulfate as a color additive in hair dyes.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 10, 1998.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-32507 Filed 12-7-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995.

Proposed Project: Ryan White CARE Act Dental Reimbursement Program—0915-0151—Revision

This is a request for approval of a revision of the application and instructions used by accredited dental schools and post-doctoral dental programs requesting reimbursement for documented uncompensated costs for providing oral health care for HIV infected individuals. Awards are authorized under section 776(b) of the PHS Act (42 U.S.C. 294n).

The HIV/AIDS Bureau needs to collect this information to determine the amount of the reimbursement award that is made to each institution. The information will also assist the Health Resources and Services Administration in understanding: (1) the extent to which dental programs are involved in the treatment of HIV infected individuals; (2) the type of individuals seeking care; (3) the scope and extent of HIV oral health services provided; (4) the time and costs involved in providing these services; and (5) how the funds used by the institutions are allocated.

The hourly burden estimate has increased substantially based upon the experience of the grantees in completing the information required. The burden estimate is as follows:

Type of information	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	105	1	17.5	1838

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 2, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98-32514 Filed 12-7-98; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Licensing Opportunity and/or Cooperative Research and Development Agreement (CRADA) Opportunity to Develop a Hepatitis C virus (HCV) Vaccine Based Upon the Synthesis and Purification of Non-infectious HCV-like Particles Containing HCV Structural Proteins

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) is seeking licensees and/or capability statements from parties interested in entering into a Cooperative Research and Development Agreement (CRADA) to develop a hepatitis C virus (HCV) vaccine based on in the synthesis, large scale production and purification of non-infectious HCV-like particles containing HCV structural proteins (Baumert, TF et al. 1998, J. Virol. 72:3827-3836).

The invention claimed in DHHS Reference No. E-009-97/0, "Synthesis and Purification of Hepatitis C Virus-Like Particles In Vitro" (TJ Liang, TF Baumert), field 08 Nov 96, is available for licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under one or more CRADAs in the clinically important applications described below in the **SUPPLEMENTARY INFORMATION** section.

DATES: Only written CRADA capability statements received by the NIDDK on or before March 1, 1999 will be considered. There is no deadline by

which license applications must be received.

ADDRESSES: Capability statements should be submitted to Dr. Michael W. Edwards, Office of Technology Development, National Institute Diabetes and Digestive and Kidney Diseases, National Institutes of Health, BSA Building, Suite 350 MSC 2690, 9190 Rockville Pike, Bethesda, MD 20814-3800; Tel: 301/496-7778, Fax: 301/402-0535; Electronic mail: mels@nih.gov.

Questions about the licensing opportunity, copies of the patent application, or requests for license applications should be addressed to Carol Salata, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852-3804; Tel: 301/496-7057 ext. 232; Fax: 301/402-0220; Electronic mail: cs253n@nih.gov.

SUPPLEMENTARY INFORMATION: HCV is a major causative agent of post-transfusion and community-acquired non-A, non-B hepatitis world-wide. About 4 million people in the U.S. and probably more than 100 million worldwide are infected with HCV. The majority of HCV infected individuals become persistently infected and many develop chronic hepatitis which progresses eventually to liver cirrhosis and hepatocellular carcinoma.

HCV is a member of the flavivirus family. The HCV viron contains a positive-strand RNA genome of 9.5 kilobases including a highly conserved 5' non-coding region followed by a long open reading frame of 9030 to 9099 nucleotides that is translated into a single polypeptide about 3,010 to 3030 amino acids long. Although the viral genomic organization has been characterized in detail, morphologic analysis of hepatitis C virus has been hampered by low levels of HCV particles in infected patients and the inability to propagate efficiently the virus in cultured cells. The levels of the viral particles present in infected patient plasma and/or liver tissues are very low, making it difficult to visualize the virus. Studies of HCV infection in chimpanzees, a reliable animal model for hepatitis C, have provided evidence that HCV is inactivated by chloroform, indicating that it contains lipids and therefore is probably enveloped. Filtration studies have estimated the viron particle size to be about 30-60 nm in diameter.

Under the CRADA the synthesis, large scale production, and purification of HCV virus-like particles will be optimized and the agent evaluated in a

series of preclinical studies in animals as well as initial safety testing in humans. Positive outcomes of these studies will indicate continued clinical development aimed at supporting regulatory approval of a product to be labeled for use in humans.

NIDDK's principal investigator has extensive experience with recombinant technology as applied to the synthesis, purification and testing of HCV-like particles. The Collaborator in this endeavor is expected to assist NIDDK in evaluating its current system for producing HCV vaccine formulation and to develop and optimize adjuvants, if necessary, to manufacture sufficient quantities of the product for preclinical testing in animals and initial safety studies in humans. The Collaborator must have experience in the manufacture of vaccine formulations according to applicable FDA guidelines and Points to Consider documents to include Good Manufacturing Procedures (GMP). In addition, it is expected that the Collaborator would provide funds to supplement the NIDDK PI's research budget for the project and to support the preclinical and initial human testing.

The capability statement should include detailed descriptions of: (1) Collaborator's expertise in vaccine formulation and development, (2) Collaborator's ability to manufacture sufficient quantities of the product according to FDA guidelines and Points to Consider documents, (3) the technical expertise of the Collaborator's principal investigator and laboratory group in preclinical safety testing (e.g., expertise in in vitro and in vivo toxicity, efficacy and pharmacology studies) and initial human safety studies, and (4) Collaborator's ability to provide adequate funding to support preclinical and initial human safety studies required for marketing approval.

The Public Health Service (PHS) has filed patent applications both in the U.S. and internationally related to this technology. Notice of the availability of the patent applications for licensing was first published in the **Federal Register** on January 28, 1998 (63 FR 4274). Information about the patent applications and pertinent information not yet publicly described may be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to