Number of Respondents: 2,000;
Total Annual Responses: 2,000;
Total Annual Hours: 500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–14319 Filed 6–4–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases: Opportunity for Cooperative Research and Development Agreements (CRADAs) in Conjunction With a Major Multicenter Clinical Trial—the Study of Health Outcomes of Weight Loss (SHOW)

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

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) seeks capability statements from parties interested in entering into a potential Cooperative Research and Development Agreement (CRADA) to provide anti-obesity agents for treating subjects in the Study of Health Outcomes of Weight Loss (SHOW).

Collaborator applicants developing capability statements may also include proposals to provide funding for assessment of outcomes of interest to the Collaborator. The availability of provide sector support may increase the feasibility of particular aspects of the final SHOW design, but the primary criterion for selecting potential collaborator(s) is the scientific merit of proposals for use of anti-obesity agents.

The control of the SHOW clinical trial shall reside entirely with the Institute and the scientific participants of the trial. In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communications with the FDA, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as an NIDDK endorsement of the drug under study.

DATES: Only written CRADA capability statements received by the NIDDK on or before September 1, 1999 will be considered during the initial design phase, confidential information must be clearly labeled. Potential collaborators may be invited to meet with the Selection Committee at the Collaborator's expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design of the trial if circumstances change or if the trial design alters substantially.

FOR FURTHER INFORMATION AND QUESTIONS: Capability statements should be submitted to Dr. Michael W. Edwards, Office of Technology Development, National Institute of 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; Email: mels@nih.gov.

SUPPLEMENTARY INFORMATION: SHOW will be conducted as a cooperative agreement among the SHOW Clinical Centers (approximately fifteen centers), a Data Coordinating Center, and the NIH. SHOW will address two primary research questions: (1) Do interventions designed to produce sustained weight loss in obese individuals with type 2 diabetes improve health? (2) How do the benefits and risks of interventions designed to produce weight loss compare with the benefits and risks related to treatment of obesity-related comorbid conditions in the absence of weight loss intervention?

SHOW is expected to recruit approximately 6000 obese diabetic patients over a three-year period with four additional years of treatment and follow-up (average treatment duration 5.5 years). It is anticipated that two-thirds of the patients recruited to the study will be randomly assigned to enrollment in weight loss interventions and one-third to community care. The SHOW trial is likely to have three arms, as follows:

(1) Community Care—Patients will receive medical care for their obesity and obesity-related comorbid conditions (e.g., diabetes, hypertension, dyslipidemia) from their primary care physician. The primary care physician will be given standard of care recommendations for treatment of obesity and comorbid conditions (e.g., guidelines from the American Diabetes Association) and will be provided with results of diagnostic tests carried out at study sites.

(2) Intensive Lifestyle Intevention—Patients will under go a long-term behavioral treatment program that includes dietary modification, increased physical activity, and behavioral therapies designed to enhance weight loss and weight maintenance. This intervention is anticipated to be conducted in groups. Obesity-related comorbid conditions will be treated by the primary care physician as in Group 1.

(3) Intensive Lifestyle Intervention plus Weight-Loss Medication—Medication will be added to the intensive lifestyle intervention in an attempt to enhance long-term weight maintenance. Comorbid conditions will be treated by the primary care physician as in Group 1.

The SHOW RFAs may be accessed at:
http://www.nih.gov/grants/guide/rfa–files/RFA–DK–98–019.html for Clinical Centers RFA
http://www.nih.gov/grants/guide/rfa–files/RFA–DK–98–020.html for the Data Coordinating Center RFA

Capability Statements

The design concept described above is not final. The final design will be developed over the course of the first year of the trial by the SHOW Steering Committee (which will include the Principal Investigators of the Clinical Centers, the Principal Investigator of the Data Coordinating Center, and the NIDDK Project Coordinator). It is possible that the final design for SHOW may include no anti-obesity agents, or may include more than one anti-obesity agent.

A Selection Committee will utilize the information provided in the ''Collaborator Capability Statements'' received in response to this announcement to help in its deliberations. The Selection Committee will interact with the Steering Committee to develop the most appropriate design, based on a thorough understanding of the efficacy and side effects associated with all agents proposed.

It is the intention of the NIDDK that all qualified collaborators have the

opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

(1) The statement should provide specific details regarding the safety and efficacy of the proposed anti-obesity agency for long-term use in obese diabetic patients with a description how it might be utilized in SHOW.

(2) The statement should include a detailed plan demonstrating the ability of the Collaborator to provide sufficient quantities of the agent in a timely manner for the duration of the study.

(3) The statement should outline outcome measures proposed by the Collaborator which support the aims of SHOW. The specifies of the proposed outcome measures and the proposed support could include, but not be limited to the following: Specific funding commitment to support the advancement of scientific research, personnel, services, facilities, equipment, or other resources that would contribute to the conduct of the trail.

(4) The statement must address willingness to promptly publish research results and ability to be bound by PHS intellectual property policies (see CRADA: http://www.nih.gov/od/ott/crada198.htm).

Dated: May 26, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99–14245 Filed 6–4–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Acylated Oligopeptide Derivatives Having Cell Signal Inhibiting Activity

Terrence R. Burke, Jr. (NCI)

Serial No. 09/236,160 filed 22 Jan 99

Licensing Contact: Richard Rodriguez; 301/496–7056, ext. 287; e-mail: rr154z@nih.gov

The invention is directed to pharmaceutically active compounds comprising an N-oxalyl peptide structure. These compounds have the ability to disrupt the interaction between SH2 domain (e.g., Grb2) containing proteins, and proteins with phosphorylated moieties, especially phosphorylated tyrosine moieties on protein tyrosine kinase (PTK) receptors. The effect of inhibiting the association of SH2 domain-containing proteins with PTKs is to inhibit downstream signaling through one or more specifically targeted effector proteins. Examples of these SH2-containing proteins include, but are not limited to, Src, Lck, Fps, ras-GTPase activating protein, Fyn, Lyk, Fgr, Fes, Zap-70, Bcr-Abl, JAK1 and JAK2. These compounds could prove highly useful for the treatment of some cancers. In particular, Grb2 SH2 domains afford an ideal target because they provide a critical link between growth factor receptor PTKs and downstream signaling events involving ras-proteins which have been directly implicated with oncogenic processes. Examples of this include: members of the epidermal growth factor receptor PTK family (ErbB-2) which are found in many breast cancers; the hepatocytes growth factor/scatter factor (Met) PTK which is overexpressed in many human tumors; and the Bcr-Abl PTK which is necessary for Philadelphia chromosome positive leukemia. The development of this technology could therefore provide for the design and use of powerful therapeutics for disease states where signal transduction becomes deregulated.

Water-Insoluble Drug Delivery System

E Tabibi, E Ezennia, BR Vishnuvajjala, S Gupta (NCI)

Serial No. 60/113,423 filed 22 Dec 98

Licensing Contact: Girish Barua; 301/496–7056, ext. 263; e-mail: gb18t@nih.gov

This technology describes an improved, stable drug delivery system for water-soluble drugs, in particular 17-allylaminogeldanamycin (17–AAG) and a pharmaceutical composition comprising such a drug delivery system, as well as methods for preparing the drug delivery system. The water-insoluble drug is dissolved in a water miscible organic solvent that forms a continuous phase with water and a surface active agent. The application of this technology enables the more effective delivery of drugs such as geldanamycin and 17–AAG, with preparation of the system requiring less complex processing steps.

Nucleosides for Imaging and Treatment Applications

Jerry M. Collins, Raymond W. Klecker, Aspandiar G. Katki, Lawrence Anderson (FDA).

DHHS Reference No. E–058–97/1 filed 30 Oct 98; PCT/US98/23109

Licensing Contact: John Fahner-Vihtelic; 301/496–7735 ext. 270; e-mail: jf36z@nih. gov

The present application describes recently developed nucleosides that provide for (1) external imaging of tumor cell proliferation, (2) noninvasive determination of which tumors would be sensitive to drug therapy, and (3) potential utility as a novel antitumor treatment approach. No comparable procedures are available to determine, prior to treatment, which tumors are likely to respond to a given therapeutic approach. This invention also has the ability to rapidly evaluate the success or failure of treatment, during the course of therapy. As imaging agents, these nucleosides are directly targeted towards specific events, rather than broad measures of effect such as fluorodeoxyglucose. There is no currently available treatment for tumors with high levels of drug resistance, specifically due to overexpression of the key enzyme, thymidylate synthase. The utility of these inventions has been demonstrated in cultured human tumor cells, and preclinical toxicology studies have been conducted which permit entry into initial human testing.

Virally Mediated Gene Therapy for the Control of Chronic or Persistent Pain

MJ Iadarola, RM Caudle, AA Finegold, AJ Mannes (NIDCR)

DHHS Reference No. E–044–98/0 filed 23 Sep 98 Licensing Contact: Kai Chen; 301/496–7056 ext. 247; e-mail: kc169a@nih.gov