

guidances,<sup>4</sup> the CRG will concentrate on specific identified risk areas and related compliance program best practices.

The CRG will include an additional section relating to risk areas associated with the Medical Assistance or Medicaid program requirements. The OIG intends to broadly address the Medicaid risks in light of the fact that the coverage and reimbursement rules differ among the various Medicaid programs. In order for the OIG to adequately incorporate the most prevalent Medicaid risk areas, we are requesting comments and suggestions from the various State agencies providing Medicaid services and from those ambulance providers and suppliers that furnish a significant level of services to Medicaid beneficiaries.

The OIG would also appreciate specific comments related to compliance regarding the proposed Medicare ambulance fee schedule.<sup>5</sup> As appropriate, we ask that commenters please provide detailed justifications and empirical data supporting such comments.

Dated: August 11, 2000.

**Michael F. Mangano,**

*Principal Deputy Inspector General.*

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**BILLING CODE 4152-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request, NCI Cancer Information Service Demographic/ Customer Service Data Collection

**SUMMARY:** Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 7, 2000, Vol. 65, No. 25, page 5873-5874 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

#### Proposed Collection

**Title:** NCI Cancer Information Service Demographic/Customer Service Data Collection. **Type of Information Collection Request:** Revision. OMB No. 0925-0208 expires October 2000. **Need and Use of Information Collection:** The Cancer Information Service (CIS)

provides the general public, cancer patients, families, health professionals, and others with the latest information on cancer. Essential to providing the best customer service is the need to collect data about callers and web users and how they found out about the service. This effort involves a telephone survey and a web survey. The telephone survey involves asking seven questions to five categories of callers for an annual total of approximately 500,430 callers. Three of the seven questions will be asked to 100% of five categories of callers for an annual total of approximately 333,620 callers; four questions will be asked to 50% of the same five categories of callers for an annual total of approximately 166,810 callers. The web survey involves asking eight questions to an annual total of approximately 75,266 voluntary users of the CIS web site. **Frequency of Response:** Single time. **Affected Public:** Individuals or households. **Type of Respondents:** Patients, relatives, friends, and general public. The annual reporting burden is as follows: **Estimated Number of Respondents:** 500,430 callers and 75,266 web users; **Estimated Number of Responses per Respondent:** 1; **Average Burden Hours per Response:** Telephone—.00328 and .0083 and Web—.0137; and **Estimated Total Annual Burden Hours Requested:** Telephone—2,479 and Web—1,031. The annualized cost to respondents is estimated at: \$42,120. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Individuals or households				
Telephone:				
—3 questions (100%) .....	333,620	1	0.00328	1,094
—4 questions (50%) .....	166,810	1	0.0083	1,385
Web:				
—8 questions (100%) .....	75,266	1	0.0137	1,031
<b>Annualized Totals</b> .....	<b>575,696</b>	.....	.....	<b>3,510</b>

#### Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of

the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)

Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other

<sup>4</sup> The seven elements of an effective compliance program include: (1) The development of written policies and procedures; (2) the designation of a compliance officer and other appropriate bodies; (3) the development and implementation of effective training and education programs; (4) the

development and maintenance of effective lines of communication; (5) the enforcement of standards through well-publicized disciplinary guidelines; (6) the use of audits and other evaluation techniques to monitor compliance; and (7) the development of

procedures to respond to detected offenses and to initiate corrective action.

<sup>5</sup> The Health Care Financing Administration's proposed Medicare ambulance fee schedule is expected to be published in the **Federal Register** shortly.

technological collection techniques or other forms of information technology.

#### Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Chris Thomsen, Chief, Cancer Information Service Branch, OC, OD, NCI, Building 31, Room 10A16, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496-5583 ext. 239 or E-mail your request, including your address to: thomsenc@mail.nih.gov.

#### Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before September 18, 2000.

Dated: August 7, 2000.

Reesa Nichols,

OMB Clearance Liaison.

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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 contacting Dennis Penn, at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 211;

fax: 301/402-0220; e-mail: pennd@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Preparation and Use of Androgenic Compounds

Richard P. Blye and Hyun K. Kim (NICHD) DHHS Reference Nos. E-069-00/0 filed 31 Mar 2000 and E-069-00/1 filed 04 Apr 2000.

The technology describes the finding of the orally active androgenic compound, 7 $\alpha$ , 11 $\beta$ -dimethyl-19-nortestosterone 17-bucyclate (Also known as CDB-4386A). This 17-bucyclate androgen compound is orally bioavailable and possesses greater potency than Methyltestosterone, the only oral androgen commercially available in this country. Too, this compound may be injected as an aqueous suspension, whereas other injectable androgens require an oil diluent. Androgens find use in the treatment of male hypogonadism regardless of the cause. Consequently they are used for the treatment of hypogonadotropic hypogonadism, as the androgenic component of male hormonal contraceptives and for androgen supplementation in hormone replacement therapy (HRT) in both men and women.

#### Process for Preparing 17-Alpha-Acetoxy-11-Beta-[4-(N,N-Dimethylamino)phenyl]-21-Methoxy-19-Norpregna-4,9-Diene-3,20-Dione, Intermediates Useful in the Process, and Processes for Preparing Such Intermediates

Hyun K. Kim (NICHD), and Pemmaraju Rao, James Cessac, and Anne Marie Simmons of the Southwest Foundation for Biomedical Research DHHS Reference No. E-013-00/0 filed 29 Dec 1999.

This invention relates to a process for preparing 17-alpha-acetoxy-11-beta-[4-(N,N-dimethylamino)phenyl]-21-methoxy-19-norpregna-4,9-diene-3,20-dione. This method substantially increases the yield over existing methods and will substantially reduce the cost of production of this compound. Other advantages include: (1) Use of smaller quantities of solvent and reagent; (2) use of intermediates, reagents, or byproducts which are relatively safe to handle and dispose of, no use of chromatography; (3) a purification procedure easier to practice on large scale from kilograms to multi-kilograms, including no use of chromatography if possible; and (4) in some cases, recycling the by-products was successfully achieved.

#### Novel Anti-thrombin Peptide From Mosquito Salivary Gland

Jesus G. Valenzuela, Jose M.C. Ribeiro, and Ivo Francischetti (NIAID) DHHS Reference No. E-143-99/0 filed 29 Jun 1999.

Currently, treatment and prophylaxis of thrombotic diseases involve therapeutic agents which act in one of two different ways. The first type inhibits a-thrombin activity or a-thrombin formation, thus preventing clot formation. The second category accelerates thrombolysis and dissolves the blood clot, thereby removing it from the blood vessel and unblocking the flow of blood. Heparin is an example of the first class and is widely used; however, heparin is less effective in treating patients with an anti-thrombin III deficiency. Hirudin is an example of the second class of anti-thrombotic drugs.

This invention relates to an anti-thrombin (*Anophelin*) isolated from the salivary glands of the mosquito *Anopheles albimanus*. The purified peptide inhibits thrombin induced platelet aggregation, thrombin esterolytic activity, and thrombin cleavage of fibrinogen. This peptide has no homologies to proteins of known function in GenBank, and is a novel, specific, and tight binding inhibitor of  $\alpha$ -thrombin.

#### Ichthyosiform Skin Diseases

Peter M. Steinert, Nemes Zoltan and Lyuben Marckov (NIAMS) DHHS Reference No. E-149-99/0 filed 23 Jun 1999.

Many inherited autosomal recessive ichthyoses (ARI) are caused by improper or incomplete lipid barrier function in the skin due to genetic errors of either protein or lipid synthesis. It is previously known that the mutations in the transglutaminase 1 gene resulting in inactive enzyme is the cause of one ARI disease termed lamellar ichthyosis. This relates to the discovery that a principal function of the enzyme is to attach ceramide lipids for complete protein/lipid barrier function in the skin. This invention also describes how to: (1) Make large quantities of this enzyme that can be stored in a stable form which can be readied for use at short notice; (2) a simple way to make synthetic ceramide lipid analogs that function the same way as normal skin ceramides; and (3) make synthetic lipid vesicles that can carry, in a stable fashion, both the enzyme and synthetic ceramide so that it might be applied to affected ARI skin in order to provide ameliorative therapy.