

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of Exclusive License: Treatment of Cancer Using Human Chorionic Gonadotropin (hCG)****AGENCY:** National Institutes of Health, Public Health Service, DHHS.**ACTION:** Notice.

**SUMMARY:** This notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(I) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in U.S. Patent Application Serial Number 08/286,299, and entitled: "Treatment of Cancer Using Human Chorionic Gonadotropin (hCG)", and corresponding U.S. and foreign patent applications to Serono Laboratories, Inc., of Norwell, Massachusetts. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. The field of use for this prospective exclusive license may be limited to "Treatment of Cancer".

**SUPPLEMENTARY INFORMATION:** Clinical observations of the regression of Kaposi's sarcoma (KS) in women during pregnancy and its return after birth has suggested the existence of a naturally-occurring KS therapeutic. Research performed at the National Cancer Institute suggested the cause of this phenomena was hCG. hCG is a hormone which is naturally produced by the placenta during pregnancy. In the male, hCG stimulates the development of accessory organs. hCG is composed of an alpha chain that is identical in structure to several other hormones and a unique beta chain. The beta chain of hCG was found to induce apoptosis, or programmed cell death in primary cultures of KS cells. Studies performed in KS tumors in nude mice confirmed the anti-KS effect of hCG.

The above captioned patent application describes the use of various hormones in the treatment of cancer. In particular, the use of hCG or the  $\beta$

subunit thereof and luteinizing hormone or the  $\beta$  subunit thereof in the treatment of cancer, including breast, prostate, ovary and stomach carcinomas and, in particular, KS are described. KS is the most common neoplasm in HIV-infected patients and hCG has been used to treat KS patients (Gill, et al., "The Effects of Preparations of Human Chorionic Gonadotropin on AIDS-related Kaposi's Sarcoma", New Eng. J. Med. 1996 Oct. 24:335(17):1261-69).

**ADDRESSES:** Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Raphe Kantor, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; Telephone: 301/496-7735 ext. 247; Facsimile: 301/402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications. Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated licenses. Only written comments and/or applications for a license which are received by NIH on or before June 30, 1997 will be considered. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 16, 1997.

**Barbara M. McGarey,**

*Deputy Director, Office of Technology Transfer.*

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405(c)(4) of the Tribal Self-Governance Act.

**DATES:** This notice expires on September 30, 1998.

**ADDRESSES:** Inquiries or comments regarding this notice may be directed to the Office of Self-Governance, 1849 C Street NW, 2548 MIB, Washington, DC 20240. Telephone (202) 219-0240 or to the bureau points of contact listed below.

**SUPPLEMENTARY INFORMATION:****I. Background**

Title II of the Indian Self-Determination and Education Assistance Act Amendments of 1994 (P.L. 103-413, the "Self-Governance Act" or the "Act") instituted a permanent tribal self-governance program at the Department of the Interior (DOI). Under the self-governance program certain programs, functions, services, and activities or portions thereof in Interior bureaus other than BIA are eligible to be planned, conducted, consolidated, and administered by a self-governance tribal government.

Under section 405(c) of the Self-Governance Act, the Secretary of the Interior is required to publish annually: (1) A list of non-BIA programs, services, activities, and functions or portions thereof, that are eligible for inclusion in agreements negotiated under the self-governance program; and (2) programmatic targets for these bureaus.

Under the Self-Governance Act, two categories of non-BIA programs are eligible for self-governance funding agreements. Under section 403(b)(2) of the Act, any non-BIA program, service, function or activity that is administered by Interior that is "otherwise available to Indian tribes or Indians," can be administered by a tribal government through a self-governance agreement. The Department interprets this provision to authorize the inclusion of not only programs eligible for self-determination contracting under Title I of the Indian Self-Determination and Education Assistance Act (P.L. 93-638), but also other programs which the Department determines are appropriate and to the extent available under other laws for contracting out or including in cooperative agreements.

Section 403(b)(2) also specifies that "nothing in this subsection may be construed to provide any tribe with a preference with respect to the opportunity of the tribe to administer programs, services, functions and activities, or portions thereof, unless such preference is otherwise provided for by law." Under section 403(c) of the

**DEPARTMENT OF THE INTERIOR****Office of the Secretary****List of Programs Eligible for Inclusion in Fiscal Year 1998 Annual Funding Agreements To Be Negotiated With Self-Governance Tribes by Interior Bureaus Other than the Bureau of Indian Affairs****AGENCY:** Office of the Secretary, Interior.**ACTION:** Notice.

**SUMMARY:** This notice lists programs or portions of programs that are eligible for inclusion in Fiscal Year 1998 annual funding agreements with self-governance tribes and lists programmatic targets for each of the non-BIA bureaus, pursuant to section