addition, the AABB will notify HCFA within 10 days of this determination.

• When an AABB laboratory is unsuccessful in PT participation for a Federally-required analyte, subspecialty, and/or specialty, the laboratory will be contacted by the AABB and required to initiate corrective actions. Failure to submit an acceptable plan of remedial action to correct the problem may result in a focused, onsite survey or limitation of the laboratory's scope of accreditation for the particular analyte, specialty, and/or subspecialty. As applicable, to regain accreditation, the laboratory must provide the AABB with evidence that it has successfully participated in two consecutive PT events.

We have determined that the AABB's laboratory enforcement and appeal policies are essentially equivalent to the requirements of this part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections and continuing oversight of the AABB accredited laboratories will be conducted based on the regulations at §§ 493.507 and 493.509.

V. Removal of Approval as an Accrediting Organization

Our regulations at § 493.511 provide that we may rescind the approval of an accreditation organization, such as that of the AABB, for cause, prior to the end of the effective date of approval. If we determine that the AABB failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed one year, to allow the AABB to adopt comparable requirements.

Should circumstances result in our withdrawal of the AABB's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: June 29, 1995

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–17981 Filed 7–20–95; 8:45 am]

BILLING CODE 4120–01–P

National Institutes of Health

Prospective Grant of Exclusive License: Delta-Like Gene Expressed in Neuroendocrine Tumors

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

ACTION: Notice.

SUMMARY: This is 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 07/989,537 and corresponding foreign patent applications entitled, ''Delta-Like Gene Expressed in Neuroendocrine Tumors'' to ImClone Systems Incorporated of New York, NY. 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 present patent application covers a novel gene, delta-like, dlk and its corresponding protein. The protein contains EGF-like repeats and a transmembrane domain and appears to be a novel member of the family of EGF-like neurogenic genes. Such genes were initially found in Drosophila and are involved in embryonic developmental decisions to differentiate into epidermal or neuronal cells. One of these genes in Drosophila is termed, ''Delta'', hence the name of the current gene. dlk can be employed in genetic assays for detection of a primary or secondary pheochromocytoma, neuroblastoma, and small cell lung cancer or identification of a stage of these tumors.

Although dlk may have utility as a cancer marker, recent research indicates another important application of this technology, as a hematopoietic stem cell growth factor. The adult bone marrow is the site of hematopoiesis with an estimated 0.01% of the cells being stromal cells. It is thought that the stem cells are found in micro-environments associated with stromal cells which produce factor(s) which allows the maintenance and self-renewal of the stem cells. One or more stromal cell produced factor(s) may be required to keep the stem cells in an uncommitted state. When stem cells leave this micro-environment they would no longer be in contact with this factor(s) and, consequently, they would differentiate toward one of the hematopoietic cell lineages.

Delta is a 43 kDa protein which belongs to the epidermal growth factor-like superfamily. Delta was cloned by another group from a mouse stromal cell line PA–6, a cell line which has been reported to support the growth of hematopoietic stem cells. Delta may function as a ligand by binding to the extracellular domain of a Drosophila protein called Notch. Notch encodes a transmembrane protein with a large extracellular domain, is widely expressed including by hematopoietic cells, and its activation may keep cells in an uncommitted state.

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 September 19, 1995 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: July 11, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95–17983 Filed 7–20–95; 8:45 am]

BILLING CODE 4140–01–P

Public Health Service

Agency Forms Undergoing Paperwork Reduction Act Review

Each Friday the Public Health Service (PHS) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call