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

Dated: May 22, 1995.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 95–17979 Filed 7–20–95; 8:45 am]

BILLING CODE 4120–01–P

**[HSQ–228–N]**

## CLIA Program; Approval of the American Association of Blood Banks

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the approval of the American Association of Blood Banks (AABB) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that a laboratory accredited by it meets the conditions required by Federal law and regulations. Consequently, laboratories that are voluntarily accredited by the AABB and continue to meet the AABB requirements will be deemed to meet the CLIA condition level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys conducted by HHS or its designee.

**EFFECTIVE DATE:** This notice is effective for the period July 21, 1995 through July 21, 1997.

**FOR FURTHER INFORMATION CONTACT:** Tracey Mummert, (410) 597–5906.

**SUPPLEMENTARY INFORMATION:**

### I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA replaced in its entirety section 353 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS and Federal regulation whether or not it participates in the Medicare or Medicaid program. New section 353 requires HHS to establish requirements for any laboratory that performs tests on human specimens and certify, through issuance of a certificate, that those laboratories meet the requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs, or both. Laboratories that are accredited by an accreditation organization approved under section 353(e) of the PHSA will automatically be eligible for Medicare and Medicaid participation as long as they meet applicable State requirements.

On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002–7243) that implemented the amendments to section 353 of the PHSA. Specifically, regulations were established at 42 CFR part 493 that:

- Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates and to fund activities to determine compliance with our performance requirements.
- Specify the performance requirements that apply to laboratories subject to CLIA and list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver.
- Set rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, we issued final rules (57 FR 33992), under authority in section 353(e)(2) of the PHSA, that permit us to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to, or more stringent than, the applicable CLIA program requirements established at part 493 of our regulations. Therefore, a laboratory accredited by an approved organization that meets and continues to meet all of the accreditation organization's requirements is deemed to meet CLIA condition level requirements. Subpart E of part 493 specifies the requirements an accreditation organization must meet in order to be approved. We may approve an accreditation organization under § 493.501(d) of our regulations for a period not to exceed 6 years.

In general, the accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS;
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by HHS when taken as a whole;
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HHS, within 30 days, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;
- Notify HHS at least 30 days prior to changing its standards; and
- If HHS withdraws its approval, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA requires HHS to annually evaluate the performance of an approved accreditation body for compliance with the CLIA requirements by inspecting a sufficient number of laboratories accredited by the organization as well as by any other means that HCFA determines appropriate. Under section 353(o) of the PHSA, the Secretary may, by agreement, use the services or facilities of any other Federal, State or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

### II. Notice of Approval of AABB as an Accrediting Organization

In this notice, we approve the AABB as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the following specialty/subspecialty areas:

- Immunohematology
- Diagnostic Immunology
- Hematology
- Histocompatibility
- Routine Chemistry
- Toxicology

As a result of this determination, any laboratory that is accredited by AABB during the effective time period for an approved specialty/subspecialty is deemed to meet the CLIA requirements

for laboratories found in part 493 of our regulations for that specialty or subspecialty and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by HCFA, or by any other Federal or State or local public agency or nonprofit private organization which acts in conformance to an agreement with the Secretary.

**III. Evaluation of the AABB Request for Approval as an Accreditation Organization under CLIA**

The AABB formally applied to HCFA for approval as an accreditation organization under CLIA for the specialties of immunohematology, histocompatibility, hematology, diagnostic immunology and the subspecialties of routine chemistry and toxicology. We evaluated the AABB application to determine equivalency with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules. We also verified the organization's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of part 493 as explained below:

*Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program.*

The AABB submitted a list of all specialties and subspecialties that it would accredit, a comparison of individual accreditation and condition level requirements, a description of its inspection process, proficiency testing (PT) monitoring process, and its data management and analysis system, a listing of the size, composition, education and experience of its inspection teams, its investigative and complaint response procedures, its notification agreements with HCFA, its removal or withdrawal of laboratory accreditation procedures, its current list of accredited laboratories, and its announced or unannounced inspection process.

The AABB has additional requirements pertaining to waived testing. The AABB will routinely inspect laboratories that perform waived tests that are normally associated with blood centers and transfusion services. These laboratories will be inspected for good manufacturing practices and to verify that tests are performed according to manufacturer's instructions. In addition, the AABB requires that there be appropriately qualified personnel, that is, director, supervisor, testing personnel, for waived testing. Section 493.15 of the CLIA regulations requires only that a laboratory follow manufacturer's instructions and does not require routine inspections of waived testing.

We have determined that the AABB has complied with the general requirements under § 493.501, the applicable parts of § 493.506, and the CLIA requirements for approval as an accreditation organization under various subparts of part 493.

*Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both*

The AABB requires that its accredited laboratories performing histocompatibility testing participate in a local, State, or national PT program or cell exchange for all tests. The CLIA regulations do not require laboratories that perform histocompatibility testing to participate in a HCFA-approved PT program. Apart from this more stringent requirement for PT, the AABB has revised its requirements to be equivalent to the CLIA requirements at §§ 493.801 through 493.865 on an overall basis.

*Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both*

The AABB has revised its requirements to be equivalent to the CLIA requirements at §§ 493.1101 through 493.1111 on an overall basis.

*Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both*

The quality control (QC) requirements of the AABB have been evaluated against the requirements of the CLIA regulations. The AABB has modified its survey process and made revisions to its standards encompassing general QC requirements as well as specialty and subspecialty QC in order to address some of the more general QC requirements of CLIA. As such, we have determined that the AABB's requirements, when taken as a whole, are equal to or more stringent than the CLIA requirements. The specific areas of QC that are more stringent are:

- The requirement that laboratories meet the AABB's QC requirements for all waived testing they perform;
- The requirement that laboratories maintain histocompatibility records for 5 years;
- The requirement for compliance with standards for parentage testing;
- The application of all requirements for moderate complexity testing to testing categorized as provider-performed microscopy procedures, as of April 25, 1995.

*Subpart M—Personnel for Moderate and High Complexity Testing*

The AABB has revised its requirements to equal the CLIA requirements at §§ 493.1403 through 493.1495 on an overall basis. The AABB states, as general policy under its personnel standards, that the laboratory must meet CLIA requirements for personnel qualifications. The CLIA requirements for personnel responsibilities are encompassed in the revisions made to the AABB standards.

*Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both*

The AABB has revised its requirements to be equivalent to the CLIA requirements at §§ 493.1701 through 493.1721 on an overall basis. One specific area of quality assurance that is more stringent is the requirement that laboratories maintain quality assurance records for 5 years.

*Subpart Q—Inspections*

We have determined that the AABB's requirements for inspections are at least equivalent to the requirements of §§ 493.1775 through 493.1780 of this subpart.

*Subpart R—Enforcement Procedures for Laboratories*

The AABB meets the requirements of subpart R to the extent it applies to accreditation organizations. The AABB policy stipulates the action it takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the AABB will deny, suspend or revoke accreditation in a laboratory using the AABB accreditation to meet the CLIA requirements and report that action to HCFA within 30 days. The AABB also provides an appeals process for laboratories that have had accreditation denied, suspended or revoked.

Some specific actions the AABB takes in response to non-compliance or violation of its requirements or standards for accreditation include:

- When the AABB determines that a serious risk of harm (immediate jeopardy) exists in an AABB-accredited laboratory, the laboratory must immediately correct the problem that poses the risk. Failure to do so will result in a recommendation to the AABB area chairman to suspend or revoke that facility's accreditation. In

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