

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent 5,167,956 entitled "Immunotoxin with in-vivo T-Cell suppressant activity and Methods of Use" [HHS Ref. E-012-1991/0-US-01], U.S. Patent Application 60/037,196 entitled "Novel Vectors and Expression Methods for Producing Mutant Proteins" [HHS Ref. E-043-1997/0-US-01], U.S. Patent Application 60/039,987 entitled "Novel Immunotoxins and Methods of Inducing Immune Tolerance" [HHS Ref. E-044-1997/0-US-01], U.S. Patent Application 09/064,413 entitled "Use of Immunotoxins to Induce Immune Tolerance to Pancreatic Islet Transplantation" [HHS Ref. E-059-1998/0-US-01], U.S. Patent Application 09/291,712 entitled "Methods Related to the Combined Use of Immunotoxins and Agents that Inhibit Dendritic Cell Maturation" [HHS Ref. E-168-1999/0-US-01], and all continuing applications and foreign counterparts, to CK Life Sciences International, Inc., which has offices in Hong Kong. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to: The production and use of the immunotoxins covered by the licensed patent rights for the treatment of T-cell mediated diseases, including but not limited to T-cell lymphoma and autoimmune diseases.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 5, 2008 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: lambertson@od.nih.gov.

SUPPLEMENTARY INFORMATION: The invention concerns immunotoxins and methods of using the immunotoxins for the treatment of autoimmune diseases and T cell malignancies. A specific immunotoxin covered by this

technology is A-dmDT390-bisFV (UCHT1). The immunotoxins are targeted via an antibody that is specific to T cells, allowing the specific ablation of both malignant T cells and resting T cells. The transient ablation of resting T cells can "reset" the immune system by accentuating tolerating responses to autoimmune diseases like Lupus. Additionally, the immunotoxins can be used to treat T cell related cancers such as non-Hodgkins' lymphomas, including cutaneous T cell lymphoma (CTCL).

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, the 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.

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 exclusive license. 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: February 27, 2008.

Bonny Harbinger,

Deputy Director, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal**

Register on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://www.workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840/800-877-7016, (Formerly: Bayshore Clinical Laboratory).

- ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264.
- Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150.
- Aegis Sciences Corporation, 345 Hill Ave., Nashville, TN 37210, 615-255-2400, (Formerly: Aegis Analytical Laboratories, Inc.).
- Baptist Medical Center-Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).
- Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917.
- Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239-561-8200/800-735-5416.
- Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229-671-2281.
- DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310.
- Dynacare Kasper Medical Laboratories,* 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702/800-661-9876.
- ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609.
- Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630.
- Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823, (Formerly: Laboratory Specialists, Inc.).
- Kroll Laboratory Specialists, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130, (Formerly: Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).
- Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387.
- Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986, (Formerly: Roche Biomedical Laboratories, Inc.).
- Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).
- Laboratory Corporation of America Holdings, 13112 Evening Creek Drive, Suite 100, San Diego, CA 92128, 858-668-3710/800-882-7272, (Formerly: Poisonlab, Inc.).
- Laboratory Corporation of America Holdings, 550 17th Ave., Suite 300, Seattle, WA 98122, 206-923-7020/800-898-0180, (Formerly: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC; Laboratory of Pathology of Seattle, Inc.; DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).
- Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).
- LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).
- MAXXAM Analytics Inc.,* 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905-817-5700, (Formerly: NOVAMANN (Ontario), Inc.).
- MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244.
- MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295.
- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088.
- National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515.
- One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888-747-3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).
- Oregon Medical Laboratories, 123 International Way, Springfield, OR 97477, 541-341-8092.
- Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory).
- Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891x7.
- Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858-643-5555.
- Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770-452-1590/800-729-6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
- Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
- Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 866-370-6699/818-989-2521, (Formerly: SmithKline Beecham Clinical Laboratories).
- S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505-727-6300/800-999-5227.
- South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574-234-4176 x276.
- Southwest Laboratories, 4645 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602-438-8507/800-279-0027.
- Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517-364-7400, (Formerly: St. Lawrence Hospital & Healthcare System).
- St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405-272-7052.
- Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573-882-1273.
- Toxicology Testing Service, Inc., 5426 NW. 79th Ave., Miami, FL 33166, 305-593-2260.
- US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Elaine Parry,

Acting Director, Office of Program Services, SAMHSA.

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Published Privacy Impact Assessments on the Web

AGENCY: Privacy Office, Office of the Secretary, Department of Homeland Security.

ACTION: Notice of Publication of Privacy Impact Assessments.

SUMMARY: The Privacy Office of the Department of Homeland Security is making available nine (9) Privacy Impact Assessments on various programs and systems in the Department. These assessments were approved and published on the Privacy Office's Web site between July 1, 2007 and September 30, 2007.

DATES: The Privacy Impact Assessments will be available on the DHS Web site until May 5, 2008, after which they may be obtained by contacting the DHS Privacy Office (contact information below).

FOR FURTHER INFORMATION CONTACT:

Hugo Teufel III, Chief Privacy Officer, Department of Homeland Security, Mail Stop 0550, Washington, DC 20528, or e-mail: pia@dhs.gov.

SUPPLEMENTARY INFORMATION: July 1, 2007 and September 30, 2007, the Chief Privacy Officer of the Department of Homeland Security (DHS) approved and published nine (9) Privacy Impact Assessments (PIAs) on the DHS Privacy Office Web site, <http://www.dhs.gov/privacy>, under the link for "Privacy Impact Assessments." Below is a short summary of each of those systems, including the DHS component responsible for the system, the name of the system, and the date on which the PIA was approved. Additional information can be found on the Web site or by contacting the Privacy Office.

System: Secure Border Initiative-net.
Component: Customs and Border Protection.

Date of approval: July 20, 2007.

The Secure Border Initiative-net (SBInet) is a DHS Customs and Border Protection (CBP) system designed to detect, identify, apprehend, and remove illegal entrants to the U.S. on and between the Ports of Entry (POE). This PIA addresses Project 28, which is a concept demonstration prototype for the SBInet program. Project 28 focuses on a 28 mile border segment surrounding the Sasabe, Arizona POE. This PIA has been conducted because SBInet collects and processes personally identifiable information (PII).

System: Arrival and Departure Information System.

Component: U.S. VISIT.

Date of approval: August 1, 2007.

The PIA for the Arrival and Departure Information System (ADIS) describes changes to ADIS corresponding to the publication of a new ADIS System of Records Notice (SORN). As now proposed, ADIS will be a DHS-wide system to serve certain programs, including those of the intelligence community, that require information, in support of the DHS mission, on individuals who seek to enter or who have arrived in or departed from the United States. US-VISIT conducted this PIA update based on these proposed changes.

System: Automated Targeting System.

Component: Customs and Border Protection.

Date of approval: August 3, 2007.

CBP has developed the Automated Targeting System (ATS). ATS is one of the most advanced targeting systems in the world. Using a common approach for data management, analysis, rules-based risk management, and user interfaces, ATS supports all CBP mission areas and the data and rules specific to those areas. CBP updated and republished the PIA in conjunction with the SORN and the Notice of Proposed Rulemaking (NPRM) for Privacy Act exemptions that was published on August 6, 2007 in the **Federal Register**.

System: Advanced Passenger Information System Update for Final Rule.

Component: Customs and Border Protection.

Date of approval: August 9, 2007.

CBP issued a Final Rule to amend regulations governing the submission of Advanced Passenger Information System (APIS) data by commercial aircraft and vessels prior to departing for or from the United States and for crew member (and certain non crew-

member) data for commercial aircraft overflying the United States. CBP published a PIA and an associated SORN and NPRM for Privacy Act exemptions for APIS.

System: Secure Flight Program.

Component: Transportation Security Administration.

Date of approval: August 9, 2007.

The Secure Flight Program is intended to match identifying information of aviation passengers and certain non-travelers against the consolidated and integrated terrorist watch list maintained by the Federal Government in a consistent and accurate manner, while minimizing false matches and protecting personally identifiable information. The program, this PIA, the associated SORN, and the NPRM are expected to change in response to public comment. A revised PIA and if necessary a revised SORN will be issued in conjunction with the Final Rule for Secure Flight.

System: Western Hemisphere Travel Initiative (WHTI) Land and Sea Rule.

Component: Customs and Border Protection.

Date of approval: August 10, 2007.

CBP, in conjunction with the Bureau of Consular Affairs at the Department of State, published a notice of proposed rulemaking to notify the public of how they intend to implement the WHTI for sea and land ports of entry. The proposed rule, would remove the current regulatory exceptions to the passport requirement provided under sections 212(d)(4)(B) and 215(b) of the Immigration and Nationality Act (INA). The PIA discusses the privacy impact of the program.

System: Verification Information System Update.

Component: U.S. Citizenship and Immigration Services.

Date of approval: September 5, 2007.

United States Citizenship and Immigration Services (USCIS) provides immigration status verification services for benefit determinations and employment authorization through its Verification Division. Presently, two programs exist to implement this mandate: the Systematic Alien Verification for Entitlements (SAVE) program for government benefits and the Employment Eligibility Verification/Basic Pilot Program, recently renamed "E-Verify," for employment authorization for all newly hired employees. The Verification Information System (VIS) is a composite information system incorporating data from various Department of Homeland Security databases and functions as the underlying information technology that