**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes a weight-of-evidence approach to determining whether additional immunotoxicity testing for nonbiological pharmaceuticals is appropriate when the findings from standard toxicity studies indicate signs of immunotoxicity. The draft guidance is intended to provide recommendations on nonclinical testing to identify compounds that have the potential to be immunosuppressive and guidance on a weight-of-evidence decision making approach for immunotoxicity testing.

**DATES:** Submit written or electronic comments on the draft guidance by April 11, 2005. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5922.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

**SUPPLEMENTARY INFORMATION:**

## I. Background

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, CDER and CBER (FDA), and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations.

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization (WHO), Health Canada, and the European Free Trade Area.

In November 2004, the ICH Steering Committee agreed that a draft guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals'' should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Safety Expert Working Group.

The draft guidance describes a weight-of-evidence approach to determining whether additional immunotoxicity testing for nonbiological pharmaceuticals is appropriate when the findings from standard toxicity studies indicate signs of immunotoxicity. The draft guidance provides the following: (1) Recommendations on nonclinical testing approaches to identify compounds which have the potential to be immunosuppressive and (2) guidance on a weight-of-evidence decision making approach for immunotoxicity testing. The primary data are from routine nonclinical toxicology studies conducted during drug development. Additional causes for concern that can affect the decision for additional immunotoxicity testing include the pharmacology of the drug, intended patient population, known drug class effects, and retention of the drug in cells of the immune system.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: February 1, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–2418 Filed 2–7–05; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Program Exclusions: January 2005

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of January 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under

the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

| Subject name | Address | Effective date |
|---|---|---|
| **PROGRAM-RELATED CONVICTIONS** | | |
| ABENDROTH, MICHAEL | FLORENCE, CO | 2/20/2005 |
| AKHIGBE, SAMUEL | JONESVILLE, VA | 2/20/2005 |
| ALLCUTT, JOSEPH | ALEXANDRIA, LA | 2/20/2005 |
| ALVARINO, MAGDA | MIAMI, FL | 2/20/2005 |
| ARMSTRONG, JONI | FORT SMITH, AR | 2/20/2005 |
| BALL, DARCY | AUBURN, WA | 2/20/2005 |
| BAQUERIZO, MARIA | MIAMI, FL | 2/20/2005 |
| BROOKS, GLORIA | RENTON, WA | 2/20/2005 |
| BROWN, HEATHER | OKLAHOMA CITY, OK | 2/20/2005 |
| CHAMBERS, DEANA | DAVISON, MI | 2/20/2005 |
| DADYAN, GEGAM | LONG BEACH, CA | 2/20/2005 |
| DE LA VEGA, HAYDEE | MIAMI, FL | 2/20/2005 |
| DENNIE, TONY | MCDONOUGH, GA | 2/20/2005 |
| DUNN, FREDERIC | GULFPORT, MS | 2/20/2005 |
| ETHERTON, JERAMEY | LEXINGTON, KY | 2/20/2005 |
| FALCON, CORINA | DOWNEY, CA | 2/20/2005 |
| FIELDS, JEFFREY | SAN ANTONIO, TX | 2/20/2005 |
| FLORES, JUAN | LOS ANGELES, CA | 2/20/2005 |
| GOODMAN, GARY | SHERIDAN, OR | 2/20/2005 |
| HARRIS, LINDA | ATLANTA, GA | 2/20/2005 |
| HICKS, CAROLYN | BENTONIA, MS | 2/20/2005 |
| JAMES, ALMA | VALRICO, FL | 2/20/2005 |
| JIMENEZ, ANAY | HIALEAH, FL | 2/20/2005 |
| JOHNSON, ROSEMARY | FRESNO, CA | 2/20/2005 |
| LEAHEY, ROBERT | BEAVER, WV | 2/20/2005 |
| LITTLETON, DARLENE | CHAMPAIGN, IL | 2/20/2005 |
| LOPEZ, LIZZETTE | MIAMI, FL | 2/20/2005 |
| MCKINNEY, MICHELLE | FAIRFIELD, OH | 2/20/2005 |
| MURPHY, MONICA | BAKERSFIELD, CA | 2/20/2005 |
| PARRISH, VIVIAN | PORT ORANGE, FL | 2/20/2005 |
| PEKERMAN, KONSTANTYN | FORT DIX, NJ | 2/20/2005 |
| PENA, OVIDA | MIAMI, FL | 2/20/2005 |
| PORBEN, MIRIAM | HIALEAH, FL | 2/20/2005 |
| PRIME CARE SERVICES, INC | BRADFORD, PA | 2/20/2005 |
| QUEVEDO, IDANYS | HIALEAH, FL | 2/20/2005 |
| RODRIGUEZ, ALEXIS | MIAMI, FL | 2/20/2005 |
| RODRIGUEZ, ALFONSO | MIAMI, FL | 2/20/2005 |
| SARMIENTO, DAISY | MIAMI, FL | 2/20/2005 |
| SCHMITT, DERIL | LONG BEACH, CA | 2/20/2005 |
| ST JOHN, SAMUEL | PHENIX, VA | 2/20/2005 |
| TEJEDA, MARIA | MIAMI, FL | 2/20/2005 |
| TYLER, JOLIE | LORIS, SC | 2/20/2005 |
| VELAZCO, REBECA | MIAMI, FL | 2/20/2005 |
| VIDA, ALAIN | 1410 WATERLOO, BELGIUM, | 2/20/2005 |
| VILLAR, SILVIA | MIAMI, FL | 2/20/2005 |
| YANES, REGLA | MIAMI, FL | 2/20/2005 |
| **FELONY CONVICTION FOR HEALTH CARE FRAUD** | | |
| BLEGGI, NICOLA | LIVONIA, MI | 2/20/2005 |
| CARDENAS, KIMBERLY | LA PORTE, TX | 2/20/2005 |
| COTA, PETER | MADISON, OH | 2/20/2005 |
| DIAMOND-RILEY, ANGELA | CHICAGO, IL | 2/20/2005 |
| ENGLER, KIMBERLY | ROBERTSVILLE, MO | 2/20/2005 |
| FERNANDEZ, JOSE | OAKLAND PARK, FL | 2/20/2005 |
| HOPKINS, WYCONDA | FRESNO, CA | 2/20/2005 |
| KLEIN, REBECCA | PERRYSBURG, OH | 2/20/2005 |
| LADD, ELLA | OVERLAND PARK, KS | 2/20/2005 |
| MANZE, PATRICK | CHATHAM, NJ | 2/20/2005 |
| MARTIN-FREDERICK, CHARMAINE | PALMDALE, CA | 2/20/2005 |
| MILLER, TONI | ST JOSEPH, MO | 2/20/2005 |
| OBEROI, TEJBIR | WHITEDEER, PA | 2/20/2005 |
| OYSTER, CHERYL | KIRTLAND, OH | 2/20/2005 |
| SMITH, LISA | WESTMINSTER, SC | 2/20/2005 |

| Subject name | Address | Effective date |
|---|---|---|
| WINER, CLARENCE | KANSAS CITY, MO | 2/20/2005 |
| **FELONY CONTROL SUBSTANCE CONVICTION** | | |
| BAKER, MICHAEL | OCALA, FL | 2/20/2005 |
| BERTUCCI, PAMELA | METAIRIE, LA | 2/20/2005 |
| CARROLL, BRIDGET | CHESTERFIELD, MO | 2/20/2005 |
| HOPWOOD, BECKY | DAYTON, WA | 2/20/2005 |
| JACKSON, TERI | AVINGER, TX | 2/20/2005 |
| JACOBS, TAMIE | WEST PALM BEACH, FL | 2/20/2005 |
| MODI, KAILAS | OAKWOOD, VA | 2/20/2005 |
| PEPPER, CHRISTI | CADIZ, KY | 2/20/2005 |
| PORTALATIN, MICHELE | FLORISSANT, MO | 2/20/2005 |
| **PATIENT ABUSE/NEGLECT CONVICTIONS** | | |
| BALL, SANDRA | BROOKHAVEN, MS | 2/20/2005 |
| BELLANTON, JUDITH | WOODSTOCK, GA | 2/20/2005 |
| BYNEM, SHAKESHA | GILBERT, SC | 2/20/2005 |
| CRAWFORD, PHILIP | VILLAGE OF PALMETTO BAY, FL | 2/20/2005 |
| EVANS, BRIAN | FONTANA, CA | 2/20/2005 |
| EVANS, THOMAS | RIENZI, MS | 2/20/2005 |
| GONZALEZ, ERNESTO | TORRINGTON, WY | 2/20/2005 |
| GREENE, MARY | SACRAMENTO, CA | 2/20/2005 |
| HUNTER, FRANK | BRIDGETON, NJ | 2/20/2005 |
| MANDOLESI, MICHAEL | LONDON, OH | 2/20/2005 |
| MCCRAY, RHONDA | SHREVEPORT, LA | 2/20/2005 |
| NEACE, DARLENE | CYNTHIANA, KY | 2/20/2005 |
| OWENS, BUDDY | SOMERSET, KY | 2/20/2005 |
| PADGETT, TAMEKIA | BATESBURG, SC | 2/20/2005 |
| PAVIA, DAILLYN | GRANITE CITY, IL | 2/20/2005 |
| SANDIFER, TERESA | GREENWOOD, MS | 2/20/2005 |
| SLAVNEY, KENNETH | FRESNO, CA | 2/20/2005 |
| THOMAS, TAMIKA | EAST CLEVELAND, OH | 2/20/2005 |
| WATTS, WARDELL | CINCINNATI, OH | 2/20/2005 |
| **LICENSE REVOCATION/SUSPENSION/SURRENDERED** | | |
| ADAMS, JO | VIRGIE, KY | 2/20/2005 |
| ALBRITTON, CYNTHIA | BOYNTON BEACH, FL | 2/20/2005 |
| AMES, DIANNE | BRYAN, TX | 2/20/2005 |
| ARNOLD, LISA | WEST PALM BEACH, FL | 2/20/2005 |
| ATENCIO, SALLY | HENDERSON, NV | 2/20/2005 |
| ATWOOD-ALDEN, DONNA | NEWBURYPORT, MA | 2/20/2005 |
| AUTHELET, JERILYN | WARREN, RI | 2/20/2005 |
| BAILEY, CHERYL | SPARKS, NV | 2/20/2005 |
| BAUKNIGHT, POLLA | BELLEVUE, WA | 2/20/2005 |
| BINGHAM, NATHANIEL | CHICAGO, IL | 2/20/2005 |
| BLANTON, EBONY | PALMDALE, CA | 2/20/2005 |
| BOUTROS, SAMIR | BRIARWOOD, NY | 2/20/2005 |
| BOWLING, SARAH | JACKSON, KY | 2/20/2005 |
| CALLERAME, WILLIAM | LARGO, FL | 2/20/2005 |
| CAMPBELL, CHRISTINE | EVERETT, WA | 2/20/2005 |
| CHANEY, CINDY | HAMILTON, OH | 2/20/2005 |
| CHEATHAM, DOUGLAS | PHOENIX, AZ | 2/20/2005 |
| COMBS, JOYCE | HAZARD, KY | 2/20/2005 |
| CORDELL, KIMBERLY | ARITON, AL | 2/20/2005 |
| COX, CASEY | BARDSTOWN, KY | 2/20/2005 |
| COX, HILDA | DORA, AL | 2/20/2005 |
| CRIST-LEGG, BARBARA | WESTERVILLE, OH | 2/20/2005 |
| CRUZ, VANIDY | NEW BEDFORD, MA | 2/20/2005 |
| DELACRUZ BROWN, JENNIFER | CENTRAL FALLS, RI | 2/20/2005 |
| DIAZ, MAGDALENA | HOUSTON, TX | 2/20/2005 |
| DORAN, MICHAEL | MOUNT VERNON, WA | 2/20/2005 |
| EDDINGS, JOLENE | SILVER SPRINGS, NV | 2/20/2005 |
| FERNANDES, SHARON | ARCADIA, FL | 2/20/2005 |
| FLANDERS, CHERYL | WILLOUGHBY HILLS, OH | 2/20/2005 |
| FORD, KAYLA | KILLEN, AL | 2/20/2005 |
| FREE, MICHAEL | LANSING, IL | 2/20/2005 |
| FULLMAN, LINDA | MIDFIELD, AL | 2/20/2005 |
| FUQUA, LYNN | TONEY, AL | 2/20/2005 |
| GABALDON, JENNIFER | FLAGSTAFF, AZ | 2/20/2005 |
| GALINDO, VIOLET | PEORIA, AZ | 2/20/2005 |
| GILLEY, VICKIE | VERBENA, AL | 2/20/2005 |

| Subject name | Address | Effective date |
|---|---|---|
| GINN, DAVID | COCKEYSVILLE, MD | 2/20/2005 |
| GLOYD, JASON | HEBRON, OH | 2/20/2005 |
| GLUSCHKE, REGINA | POMPANO BEACH, FL | 2/20/2005 |
| GOMEZ, ALVERA | LAKE HAVASU, AZ | 2/20/2005 |
| GREEN, KARMEN | HOLYOKE, MA | 2/20/2005 |
| GREEN, PRISCILLA | QUINCY, FL | 2/20/2005 |
| GREER, KAREN | GREENEVILLE, TN | 2/20/2005 |
| GUARA, ANTHONY | DENVER, CO | 2/20/2005 |
| HARDIN, SUSAN | LAWRENCEBURG, KY | 2/20/2005 |
| HARDY, JERI | PORTER, TX | 2/20/2005 |
| HARRIS, LINC | BASTROP, TX | 2/20/2005 |
| HAYES, WILEY | LOCKPORT, IL | 2/20/2005 |
| HEATH, RICHARD | ALAMEDA, CA | 2/20/2005 |
| HERNANDEZ, REBECCA | CRESTWOOD, KY | 2/20/2005 |
| HIGHTOWER, ANNIE | TUSKEGEE, AL | 2/20/2005 |
| HINDS, WILLIAM | SODDY DAISY, TN | 2/20/2005 |
| HINOJOSA, MARIA | TEMECULA, CA | 2/20/2005 |
| HOWARD, ANNA | PORT ARTHUR, TX | 2/20/2005 |
| JENRETTE, VICKY | SUMMERVILLE, SC | 2/20/2005 |
| JENSEN, TAMMER | RIVERSIDE, CA | 2/20/2005 |
| JONES, KRISTINE | HUNTSVILLE, AL | 2/20/2005 |
| KANATZAR, MONTI | NICHOLASVILLE, KY | 2/20/2005 |
| KERR, SHEILA | OLIVE BRANCH, MS | 2/20/2005 |
| KLEIN, GALE | OLALLA, WA | 2/20/2005 |
| KLIMAS, RICHARD | HUNTSVILLE, AL | 2/20/2005 |
| LANE, GREGORY | BAKERSFIELD, CA | 2/20/2005 |
| LAZARRE, SANDRA | FT LAUDERDALE, FL | 2/20/2005 |
| LEONARD, JUDITH | LONG BRANCH, NJ | 2/20/2005 |
| LIPSCHUTZ, HOWARD | WYNNEWOOD, PA | 2/20/2005 |
| LOMAX, AVERY | ONTARIO, CA | 2/20/2005 |
| LUCIANO, CHERYLANNE | ATLANTIC BEACH, FL | 2/20/2005 |
| LUNA, TRACY | SPOKANE, WA | 2/20/2005 |
| MCCORMICK, NATALIE | INDIANAPOLIS, IN | 2/20/2005 |
| MEYER, JAMES | LITTLE ROCK, AR | 2/20/2005 |
| MOLINAR, ARTHUR | GLENDALE, AZ | 2/20/2005 |
| MONTECINO, DOUGLAS | MARRERO, LA | 2/20/2005 |
| MOORE, JANICE | JACKSONVILLE, FL | 2/20/2005 |
| NAVARRETTE, MARY | EL PASO, TX | 2/20/2005 |
| NICOSIA, PATRICIA | BERWYN, IL | 2/20/2005 |
| PALMER, LATRICIA | SPRING CITY, TN | 2/20/2005 |
| PATZ, ERIC | ORLANDO, FL | 2/20/2005 |
| PERRI, JODIE | BENSALEM, PA | 2/20/2005 |
| PITTS, ROCHELLE | PENSACOLA, FL | 2/20/2005 |
| POMONIS, LILLIAN | MESA, AZ | 2/20/2005 |
| POTTER, NICOLE | W WARWICK, RI | 2/20/2005 |
| PRESTON, ROBERT | YOUNGTOWN, AZ | 2/20/2005 |
| PRINTZ, BRUCE | WESTFIELD, NJ | 2/20/2005 |
| RICE, TONI | CRESTVIEW, FL | 2/20/2005 |
| RILES, RACHEL | MOCKSVILLE, NC | 2/20/2005 |
| ROAN, RHONDA | MONROE, LA | 2/20/2005 |
| ROEDERSHEIMER, MARCY | ROCKPORT, TX | 2/20/2005 |
| RUIZ, MIREYA | TUCSON, AZ | 2/20/2005 |
| RYAN, MICHAEL | EL MIRAGE, AZ | 2/20/2005 |
| SAUCEDA, MICHELLE | ARLINGTON, TX | 2/20/2005 |
| SCOTT, JIMMY | CUMBERLAND, KY | 2/20/2005 |
| SEDGWICK, DONNA | SPOKANE, WA | 2/20/2005 |
| SHEPHERD, LORETTA | ABERDEEN, OH | 2/20/2005 |
| SMITH, ANGELINE | ORLANDO, FL | 2/20/2005 |
| SMITH, JANET | POLO, IL | 2/20/2005 |
| SMITH, LETICIA | SURPRISE, AZ | 2/20/2005 |
| SMITH, MEON | LANCASTER, CA | 2/20/2005 |
| SMOOT, MARY | PHILADELPHIA, PA | 2/20/2005 |
| STUBBLEFIELD, MARQUETTA | NICHOLASVILLE, KY | 2/20/2005 |
| SWARTZ, PAUL | LAFAYETTE, IN | 2/20/2005 |
| TANNER, PATTI | BARLOW, KY | 2/20/2005 |
| TREADWELL, DIANE | WARE, MA | 2/20/2005 |
| TRUJILLO, RAFAEL | SUNLAND, CA | 2/20/2005 |
| VELEZ, LABONNIA | CLOVIS, CA | 2/20/2005 |
| VERA, MIRIAM | PORT ST LUCIE, FL | 2/20/2005 |
| WALSH, PATRICIA | WALTHAM, MA | 2/20/2005 |
| WALTERS, PATRICIA | SUWANEE, GA | 2/20/2005 |
| WATSON, MARTHA | MAYSLICK, KY | 2/20/2005 |
| WEISSMAN, ARTHUR | BUFFALO, NY | 2/20/2005 |
| WELBORN, VELVET | FULTON, MS | 2/20/2005 |

| Subject name | Address | Effective date |
|---|---|---|
| WETTEROW, MELANIE | PHOENIX, AZ | 2/20/2005 |
| WHITE, SEAN | GLENDALE, AZ | 2/20/2005 |
| WHITTENTON, ANGELA | COATS, NC | 2/20/2005 |
| WILD, LISA | COLUMBIA, CT | 2/20/2005 |
| WILLIAMS, PATRICIA | ANNANDALE, VA | 2/20/2005 |
| WILLIAMS, WARREN | OAKLAND, CA | 2/20/2005 |
| WOOLLEY, TODD | OLYMPIA, WA | 2/20/2005 |
| ZIBA, GRACE | LOMA LINDA, CA | 2/20/2005 |
| **FRAUD/KICKBACKS/PROHIBITED ACTS/SETTLEMENT AGREEMENTS** | | |
| GLANZER, ELROY | IDAHO FALLS, ID | 2/18/2004 |
| **OWNED/CONTROLLED BY CONVICTED ENTITIES** | | |
| MONTECINO'S DRUGS, INC | MARRERO, LA | 2/20/2005 |
| VALLEY COUNTRY CARE | EDEN VALLEY, MN | 2/20/2005 |
| **DEFAULT ON HEAL LOAN** | | |
| BUKOWSKI, TODD | WASHINGTON, DC | 11/19/2004 |
| MANRIQUEZ, ANTONIO | COACHELLA, CA | 2/20/2005 |
| RICHARDS, JOHN | WASHINGTON, DC | 2/20/2005 |

Dated: February 1, 2005.

**Katherine B. Petrowski,**

*Director, Exclusions Staff, Office of Inspector General.*

[FR Doc. 05–2369 Filed 2–7–05; 8:45 am]

**BILLING CODE 4150–04–P**

## 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 an agency 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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Methods for Treating Active Uveitis**

Robert Nussenblatt (NEI) and Thomas Waldmann (NCI), Zhuqing Li (NEI), Ronald Buggage (NEI).

U.S. Provisional Patent Application No. 60/616,760 filed 06 Oct 2004 (DHHS Reference No. E–328–2004/0–US–01).

*Licensing Contact:* Susan Carson; 301/435–5020; *carsonsu@mail.nih.gov.*

Intraocular inflammatory disease (uveitis) is characterized by pain and a decrease in vision that can lead to blindness if not treated appropriately. The incidence and prevalence of the disease are approximately 52/100,000 and 112/100,000, and this translates into an incidence of 151,000 per year and a prevalence of 322,000. The numbers are expected to increase as the population ages. Treatment of severe uveitis often focuses on the control of the inflammatory symptoms using high dose corticosteroids, cytotoxic drugs or other immunosuppressive agents and there is a need for therapies that reduce the major side effects associated with the prolonged use of systemic steroids (*e.g.* hyperglycemia, osteoporosis and loss of immunocompetence).

Daclizumab is a humanized anti-Tac (HAT) antibody that specifically binds to the alpha subunit (CD25 or Tac subunit) of the human high affinity interleukin-2 (IL–2) receptor expressed on the surface of activated lymphocytes. Dr. Nussenblatt and colleagues at the NEI have previously shown that daclizumab can be used to successfully treat quiescent uveitis. Long term daclizumab therapy at a dose of 1mg/kg can be used instead of standard immunosuppressive agents to treat severe uveitis for more than 4 years with no adverse effects attributable to the medication, and subcutaneously administered daclizumab also appeared to be clinically effective. However, subjects with active uveitis were less likely under this regimen to have their disease controlled (J. Autoimmunity (2003) 21, 283–293).

The present invention targets patients with refractory, active uveitis and consists of a high dose intravenous induction therapy using daclizumab at two different doses and times followed by a longer term maintenance therapy. Positive therapeutic effects have been seen with this protocol in a small group of patients within 4–6 weeks after the initiation of therapy. As previous work indicated that IL–2R receptors have a slow turnover rate on CD4 positive subpopulation of lymphocytes, a possible mechanism of action of this new protocol is saturation of CD25 (TAC) receptors on cells in sequestered sites.

Available for licensing are methods directed to this treatment of active uveitis using a high dose pulsatile induction protocol of an interleukin-2 (Il–2) receptor antagonist. Methods are also provided for the treatment of corneal transplant rejection, limbal stem cell rejection following transplantation, optic neuritis and dry eye.

**Novel Thermostable Y-Family DNA Polymerases**

Roger Woodgate (NICHD), John P. McDonald (NICHD), and Wei Yang (NIDDK).

U.S. Provisional Patent Application No. 60/573,684 filed 20 May 2004 (DHHS Ref No. E–166–2004/0–US–01); U.S. Provisional Patent Application No. 60/623, 490 filed 29 Oct 2004 (DHHS Ref No. E–166–2004/1–US–01).