SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance describes a weight-of-evidence approach to determining whether additional immunotoxicity testing for nonbiological pharmaceuticals is appropriate when the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 The draft guidance is intended to provide recommendations on nonclinical testing to identify compounds that have the potential to be immunosuppressive and guidance on a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DATES: Submit written or electronic comments on the draft guidance by April 11, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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

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).