have been performed using a commercial formulation (Kenalog™) as a comparator with the invention. No ocular toxicity was seen with TAC–PF. The inventors have an IND in place and have positive results in the treatment of diabetic macular edema with a single dose of TAC–PF. The targeted indications for the present novel TAC formulation include diabetic retinopathy and macular edema, uveitis and age-related macular degeneration. Additionally, this formulation, which benefits from an improved safety profile, could possibly be used in other indications where steroid injections are used to control inflammation.

This formulation is available for licensing and claims are directed to a pharmaceutical composition free of classical preservatives and comprising a glucocorticoid or angiostatic steroid. Claims are also directed to methods of making and treating a variety of ocular conditions and other inflammatory conditions including pain by a variety of routes of administration, including intravitreally, intrathecally, etc.

In addition to licensing, this technology is available for further development through collaborative research with the inventors.

Dated: February 17, 2005.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 05–3832 Filed 2–25–05; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, January 25, 2005, 1 p.m. to January 25, 2005, 4 p.m. National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852 which was published in the **Federal Register** on January 12, 2005, 70 FR 2178.

The meeting will be held on March 8, 2005, at the Neuroscience Center, Rockville, MD, from 1 p.m. to 5 p.m. as a telephone conference call. The meeting is closed to the public.

Dated: February 22, 2005.

**Laverne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05–3881 Filed 2–28–05; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Second Request for Data on Chemicals Evaluated by In Vitro or In Vivo Ocular Irritancy Test Methods

**Summary**

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM are collaborating with the European Center for the Validation of Alternative Methods (ECVAM) to evaluate the validation status of in vitro methods for assessing ocular irritation/corrosion. Data was previously requested (**Federal Register**, Vol. 69, No. 57, pp. 13859–13861, March 24, 2004, available at *http://iccvam.niehs.nih.gov/*) and used to prepare draft Background Review Documents (BRD) for four methods [(1) The Bovine Corneal Opacity and Permeability (BCOP) test; (2) the Isolated Rabbit Eye (IRE) test or the Rabbit Enucleated Eye Test (REET); (3) the Isolated Chicken Eye (ICE) test or the Chicken Enucleated Eye Test (CEET); and (4) the Hen's Egg Test—Chorion Allantoic Membrane (HET–CAM)], and to compile a database of *in vivo* data. ICCVAM and NICEATM are now finalizing these BRDs and want to ensure the inclusion of all available data. NICEATM is therefore issuing this second request for data generated using standardized *in vitro* and *in vivo* test methods used to identify severe, moderate, mild, or non-irritating substances. Test methods for identifying severe (irreversible) ocular irritation/corrosion for which data are sought include, but are not limited to: (1) The BCOP test; (2) the IRE test; (3) the ICE test; and (4) the HET–CAM. In addition, high quality data from standardized ocular irritancy test methods using rabbits (*e.g.*, EPA 1998; UN 2003) and *in vivo* data generated from procedures/protocols that might alleviate or reduce pain and suffering (*e.g.*, topical and systemic analgesic) in test animals are requested. These data will be used to evaluate the validation status of existing in vitro test methods for ocular irritancy/corrosion and to develop a list of substances with high quality *in vivo* data that can be considered as reference chemicals for future validation studies. Data from other *in vitro* methods used to assess reversible ocular irritation effects or non-irritation are also requested.

**Submission of Chemical and Protocol Information and Test Data**

Data and other information submitted in response to this notice should be sent to NICEATM [Dr. William S. Stokes, Director, NICEATM, NIEHS, 79 T. W. Alexander Drive, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, *iccvam@niehs.nih.gov*] and received by March 30, 2005. Data and other information received by this date will be compiled and added to the database maintained by NICEATM and utilized where appropriate for the final BRDs on the four methods listed above. Data received after this date will also be considered and used where applicable for future evaluation activities. All information submitted in response to this notice will be made publicly available upon request to NICEATM.

When submitting data or information on protocols, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable). NICEATM prefers data to be submitted as copies of pages from study notebooks and/or study reports, if available. Each submission for a chemical should preferably include the following information, as appropriate:

- Common and trade name
- Chemical Abstracts Service Registry Number (CASRN)
- Chemical and/or product class
- Commercial source
- *In vitro* test protocol used
- Rabbit eye test protocol used
- Human eye test protocol used
- Individual animal/human or *in vitro* responses at each observation time (*i.e.*, raw data).
- The extent to which the study complies with national/international Good Laboratory Practice (GLP) guidelines
- Date and testing organization

Those persons submitting data on chemicals tested for ocular irritancy in rabbits are referred to the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov/methods/eyeirrit.htm*) for an example of the type of experimental animal study information and data requested in this notice.