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.

In Vitro Ocular Irritancy Chemical Tests: BCOP, HET–CAM, ICE, and IRE

NICEATM is especially interested in data from four *in vitro* test methods used to identify severe (irreversible) ocular irritation/corrosion: BCOP, HET–CAM, ICE, and IRE. Because test methods for identifying severe eye irritants/corrosives are of high priority, NICEATM especially requests data on chemicals identified by these four methods as severe irritants, although data on mildly irritating and non-irritating substances are also welcome.

Other *In Vitro* Ocular Irritancy Methods

NICEATM also requests the submission of data and information for standardized *in vitro* ocular irritancy methods, other than the four identified above, and methods that might be used to identify non-irritating and mild to moderate irritants. Detailed test method protocols and other related information for these potential test methods should be submitted along with the data.

In Vivo Test Methods for Ocular Irritancy

NICEATM requests the submission of high quality *in vivo* data that might be used to identify appropriate reference chemicals for future validation studies of *in vitro* ocular irritancy test methods. Data are sought from studies conducted to comply with federal or other national/international testing requirements, but may not be publicly available because: (1) The data were submitted to regulatory authorities, but are proprietary and cannot be released to the public by regulatory authorities, or (2) there is no requirement to submit the data to regulatory authorities. In addition to data from studies in animals, NICEATM also welcomes the submission of data from human studies including any human post-marketing or occupational exposure/surveillance data that might be available.

Procedures for Reducing or Eliminating Pain and Suffering during *In Vivo* Ocular Irritancy Testing

NICEATM requests the submission of information and data from *in vivo* methods, procedures, and/or strategies that may reduce or eliminate the pain and suffering associated with current *in vivo* eye irritation methods, such as those using topical or systemic analgesics.

Background Information

In August 2003, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) unanimously recommended that NICEATM focus efforts on test methods for ocular irritancy and possibly hold a workshop and/or develop a background document on available methods. In October 2003, the U.S. Environmental Protection Agency nominated the following activities to ICCVAM: (1) Evaluate the validation status of the four *in vitro* ocular toxicity test methods (BCOP, IRE, ICE, and HET–CAM), (2) identify and develop *in vivo* ocular toxicity reference data to support the validation of *in vitro* test methods, (3) explore ways of alleviating pain and suffering from current *in vivo* ocular toxicity testing, and (4) review the state of the science and the availability of *in vitro* test methods for assessing mild or moderate ocular irritants. ICCVAM endorsed the review of these methods as a high priority and recommended that NICEATM develop Background Review Documents for BCOP, IRE, ICE, and HET–CAM. NICEATM convened an independent expert panel on January 11–12, 2005, to review the validation status of these four methods and develop conclusions and recommendations on standardized protocols and reference chemicals for future testing and validation studies. Availability of the expert panel's report will be announced in a future **Federal Register** notice.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from fifteen federal regulatory and research agencies that use or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability, and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (P.L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers and provides scientific support for the ICCVAM. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: *http://www.iccvam.niehs.nih.gov.*

References

EPA 1998. Health Effects Test Guidelines, OPPTS 870.2400, Acute Eye Irritation, EPA 712–C–98–195. Available: *http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-2400.pdf.*

UN 2003. Globally Harmonized System of Classification and Labelling of Chemicals (GHS). [ST/SG/AC.10/30]. United Nations, New York and Geneva. Available: *http://www.unece.org/trans/danger/publi/ghs/officialtext.html.*

Dated: February 17, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05–3831 Filed 2–25–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Testing Advisory Board to be held in March 2005.

The Drug Testing Advisory Board meeting will be open and will include a Department of Health and Human Services drug testing program update, a Department of Transportation drug testing program update, and a Nuclear Regulatory Commission drug testing program update. Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to arrange special accommodations for persons with disabilities.

The Board will also meet to develop the analytical and administrative policies for the final Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program that were published as proposed revisions in the **Federal Register** on April 13, 2004 (69 FR 19673). The submissions from 285 commentors have been made available to the public on the Web site *http://workplace.samhsa.gov*. This meeting will be conducted in closed session since discussing such public comments in open session and then developing the policies will significantly frustrate the Department's ability to develop the Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The HHS Office of General