DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Immunotoxicity Studies for the National Toxicology Program.

Date: August 2, 2012.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: RoseAnne M McGee, Associate Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30 Research Triangle Park, NC 27709, (919) 541–0752, mcgee1@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: June 28, 2012.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of the Citrus Flavanones Hesperetin, Hesperidin, and Naringenin in Nutrition for Endothelial Function, Vascular Health, Diabetes, and Insulin Resistance

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 204(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 BioActor B.V., a company having a place of business in Maastricht, Netherlands, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/369,229, filed July 30, 2010 (HHS Ref. No. E–148–2010/0–US–01) and PCT Patent Application No. PCT/US2011/045898, filed July 29, 2011 (HHS Ref. No. E–148–2010/0–PCT–02), both entitled “Treatment of Metabolic Syndrome and Insulin Resistance with Citrus Flavanones.” The patent rights in these inventions have been assigned to the United States of America. The prospective exclusive license territory may be “worldwide”, and the field of use may be limited to “hesperidin, naringenin, and any derivatives thereof for use in nutrition relating to endothelial function, vascular health, diabetes, and insulin resistance, wherein the Licensed Products are marketed under an approved Health Claim or GRAS designation from the FDA, under an approved Health Claim or Novel Food designation from the EFSA, or a foreign regulatory equivalent of the above.”

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 6, 2012 will be considered.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the patent application(s), inquiries, and comments relating to the contemplated exclusive license should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4426; Facsimile: (301) 402–0220; Email: tarak@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Hesperidin is a flavonoid compound found in citrus fruits. Large epidemiological studies have linked increased consumption of flavonoid-rich foods, such as citrus, with reduced cardiovascular morbidity and mortality. Investigators from the National Center for Complementary and Alternative Medicine have demonstrated that administration of oral hesperidin to patients with metabolic syndrome attenuates biomarkers of inflammation and improves blood vessel relaxation, lipid cholesterol profiles, and insulin sensitivity when compared to controls. Thus, hesperidin and its active aglycone form, hesperetin, may be effective agents for the treatment of diabetes, obesity, metabolic syndrome, dyslipidemias, and their cardiovascular complications including hypertension, atherosclerosis, coronary heart disease, and stroke. This technology discloses methods for using a hesperetin or hesperidin composition to treat metabolic syndrome and insulin resistance. Also described is the use of the related citrus polyphenols, naringenin.

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 thirty (30) 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.

Only applications for a license in the field of use set forth in this notice and filed in response to this notice will be treated as objections to the grant of the
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Treatment Episode Data Set (TEDS)—New

The Treatment Episode Data Set (TEDS) is a compilation of client-level substance abuse treatment admission and discharge data submitted by States on clients treated in facilities that receive State funds. TEDS is related to SAMHSA’s Drug and Alcohol Services Information System (DASIS) (now the Behavioral Health Services Information System (BHSIS)), and was previously approved as part of the DASIS data collection (OMB No. 0930–0106). SAMHSA is now requesting OMB approval for TEDS separately from the other DASIS/BHSIS activities.

The BHSIS data collections involve primarily facility-level data systems, including the Inventory of Behavioral Health Services (I–BHS), which is an inventory of substance abuse and mental health treatment facilities, the National Survey of Substance Abuse Treatment Services (N–SSATS), and the National Mental Health Services Survey (NMHSS, OMB No. 0930–0119). The N–SSATS and NMHSS are census surveys of treatment facilities. In contrast, TEDS is a client-level data system that collects admission and discharge records from state substance abuse agencies. Therefore, SAMHSA is requesting OMB approval for the TEDS client-level data collection separately from the BHSIS facility-related activities.

TEDS data are collected to obtain information on the number of admissions and discharges at publicly-funded substance abuse treatment facilities and on the characteristics of clients receiving services at those facilities. TEDS also monitors trends in the demographic and substance use characteristics of treatment admissions. In addition, several of the data elements used to calculate performance measures for the Substance Abuse Prevention and Treatment (SAPT) Block Grant are collected in TEDS.

This request for OMB approval includes a request to continue the collection of TEDS client-level admissions and discharge data. Most states collect the TEDS data elements from their treatment providers for their own administrative purposes and are able to submit a crossed-walked extract of their data to TEDS. No significant changes are expected in the TEDS collection (other than recording the TEDS burden hours separately from the DASIS/BHSIS burden hours).

Estimated annual burden for the TEDS activities is shown below:

<table>
<thead>
<tr>
<th>Type of respondent and activity</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEDS Admission Data</td>
<td>52</td>
<td>4</td>
<td>6.25</td>
<td>1,300</td>
</tr>
<tr>
<td>TEDS Discharge Data</td>
<td>52</td>
<td>4</td>
<td>8.25</td>
<td>1,716</td>
</tr>
<tr>
<td>TEDS Crosswalks</td>
<td>5</td>
<td>5</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>52</td>
<td></td>
<td></td>
<td>3,066</td>
</tr>
</tbody>
</table>

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email a copy to summer.king@samhsa.hhs.gov. Written comments must be received before 60 days after the date of the publication in the Federal Register.

Cathy J. Friedman, Public Health Analyst.