DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, September 26, 2000, 12:30 p.m. to September 26, 2000 2:30 p.m., NIH, Rockledge 2, Bethesda, MD 20892 which was published in the Federal Register on September 21, 2000, 65 FR 57201–57202.

The meeting will be held October 24, 2000, from 11 a.m. to 12:30 p.m. The location remains the same. The meeting is closed to the public.

Dated: October 6, 2000.
LaVerne Y. Stringfield, Director, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROSPECTIVE GRANT OF EXCLUSIVE LICENSE

Prospective Grant of Exclusive License: Insulin Producing Cells Differentiated from Non-Insulin Producing Cells by GLP–1 and Exendin–4 and Use Thereof

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: PCT Patent Application Serial Number PCT/US99/180899 (PHS Ref. E–151–97/1) entitled “Insulin Producing Cells Differentiated from Non-Insulin Producing Cells by GLP–1 and Exendin–4 and Use Thereof” filed on August 18, 1999, claiming priority of August 10, 1998, to Amylin Pharmaceuticals, Inc., having a place of business in San Diego, CA. The patent rights in this invention have been assigned to the United States America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before December 18, 2000 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: John Rambosek, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: jr312d@nih.gov; Telephone: (301) 496–7056, ext. 270; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The patent application relates to a population of insulin producing cells differentiated from non-insulin producing cells by contacting the non-insulin producing cells with Glucagon-like peptide–1 (GLP–1), Exendin–4, or related peptides. The application also relates to the methods for obtaining the insulin producing cells and therapeutic uses in the treatment of diabetes mellitus.

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 limited to the field of use for development of products and methods for treatment of diabetes.

The field for use would include development, use, manufacture, distribution, import, export, marketing and sale of the licensed invention, throughout the world. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, 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.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Jack Spiegel, Director, Division of Technology Development and Transfer, Office of Technology Transfer.

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; National Toxicology Program (NTP) Board of Scientific Counselors’ Meeting; Review of Nominations for Listing in the 10th Report on Carcinogens

Pursuant to Public Law 92–463, notice is hereby given of the next meeting of the NTP Board of Scientific Counselors’ Report on Carcinogens (RoC) Subcommittee to be held on December 13, 14, and 15, 2000, at the Wyndham City Center, 1143 New Hampshire Ave., Washington, DC 20037. On December 13, registration will begin at 9 a.m. and the meeting will begin at 9:30 a.m. On December 14 and 15, the meeting will begin at 8:30 a.m. Pre-registration is not required; however, persons requesting time to make oral, public comments are asked to notify Dr. Mary S. Wolfe, Executive Secretary, prior to the meeting (contact information given below). The agenda covers the peer review of agents, substances, mixtures, or exposure circumstances nominated for listing in the 10th Report on Carcinogens, and includes an opportunity for public input.

Background

The Department of Health and Human Services (DHHS) Report on Carcinogens...
(RoC) is a public information document prepared for the U.S. Congress by the National Toxicology Program (NTP) in response to Section 301(b)(4) of the Public Health Service Act, as amended. The intent of the document is to provide a listing of those agents, substances, mixtures or exposure circumstances that are either “known” or “reasonably anticipated” to cause cancer in humans and to which a significant number of people in the United States are exposed. The process for preparation of the RoC has three levels of scientific peer review. Central to the evaluation of the review groups is the use of criteria for inclusion in or removal of listings from the Report. The current criteria for listing in or delisting from the Report were approved by the Secretary, DHHS, in September 1996. The major change in the RoC, which occurred as a result of the criteria revision, was to include consideration of all relevant information, including mechanistic data, in the decision to list in or delist from future editions. The review process for listing in or delisting from the RoC begins with initial scientific review by the National Institute of Environmental Health Sciences (NIEHS)/NTP Report on Carcinogens Review Committee (RG1), which is comprised of NIEHS/NTP staff scientists. The second scientific review group (RG2) is comprised of representatives from the Federal health research and regulatory agencies that are members of the NTP Executive Committee. The third is external public peer review by the NTP Board of Scientific Counselors (BSC) RoC Subcommittee. Following completions of these reviews and solicitation of public comments through announcements in the Federal Register and other media, the independent recommendations of the three scientific peer review groups and all public comments are presented to the NTP Executive Committee for review and comment. All recommendations and public comments are submitted to the Director, NTP, who reviews them and makes a final recommendation to the Secretary, DHHS, concerning the listing or delisting of chemicals or exposure circumstances in the RoC. The Secretary has final review and approval for the Tenth Report.

Agenda

The meeting of the NTP RoC Subcommittee is scheduled for December 13, 14 and 15, 2000. Tentatively scheduled to be peer reviewed are eight nominated chemicals or exposure circumstances. These nominations are listed alphabetically in the attached table, along with supporting information and a tentative order of presentation and review. Background summary documents for each of the nominations are available to the public and include a summary of the scientific data and information used to evaluate the nomination. A copy of the draft background summary document for each of these nominations is available electronically on the NTP web homepage at http://ntp-server.niehs.nih.gov/ and the Environmental Health Information Service website at http://ehis.niehs.nih.gov/ or can be obtained in hard copy, as available, from: Dr. C.W. Jameson, Report on Carcinogens, NIEHS, MD EC±14, 79 Alexander Drive, Building 4401, Room 3118, P.O. Box 12233, Research Triangle Park, NC 27709 (919/541±4096; FAX 919/541±2242; email jameson@niehs.nih.gov). The April 5, 2000 Federal Register Announcement (Volume 65, Number 66, Page 17889±17891) calling for public comments on the nominations to be reviewed in 2000 for listing in the 10th RoC, indicated the Human Papillomaviruses and Lead and Lead Compounds would be among the nominations to be reviewed. The initial review of these two nominations by NTP staff found an extensive published database for each nomination and there was insufficient time to prepare adequately a comprehensive summary background document on each for review in 2000. Therefore, the nominations of Human Papillomaviruses and Lead and Lead Compounds are deferred for review until 2001.

Solar Radiation and Exposure to Sunlamps and Sunbeds was nominated by a private individual for review and delisting from the RoC. In addition the Suntanning Association for Education also nominated Exposure to Sunlamps and Sunbeds for review and delisting from the RoC. As outlined in the published listing/delisting procedures for the RoC, the RG1 reviewed these nominations and the data provided by the nominators based on its review of the available information concerning the carcinogenicity of Solar Radiation and Exposure to Sunlamps and Sunbeds, the RG1 determined that no new information was provided by the nominators that was not already considered during the listing procedure and recommended that, due to the lack of any significant new data to support this delisting, the nomination to delist should not proceed any further through the review process. Therefore, the delisting of Solar Radiation and Exposure to Sunlamps and Sunbeds is not on the agenda for review at the December 13th±15th RoC Subcommittee meeting. The nominators have been notified of this action and invited to resubmit the nomination to delist Solar Radiation and Exposure to Sunlamps and Sunbeds from the RoC providing additional justification and relevant new data to support the nomination.

Solicitation of Public Comment

The NTP Board of Scientific Counselors RoC Subcommittee meeting is open to the public, and time will be provided for public comment on each of the nominations under review. In order to facilitate planning for the meeting, persons requesting time for an oral presentation regarding a particular nomination should notify the Executive Secretary, Dr. Mary S. Wolfe, P.O. Box 12233, A3±07, Research Triangle Park, NC 27709 (telephone 919/541±3971; FAX 919/541±0295; email wolfe@niehs.nih.gov) no later than December 1, 2000. Persons registering to make comments are asked to provide, if possible, a written copy of their statement by December 1st so copies can be made and distributed to Subcommittee members for their timely review prior to the meeting. Written statements can supplement and expand the oral presentation, and each speaker is asked to provide his/her name, affiliation, mailing address, phone, fax, e-mail and supporting organization (if any). At least seven minutes will be allotted to each speaker, and if time permits, can be extended to 10 minutes. Individuals who register to make oral presentations by December 1st will be notified about the time available for their presentation at least one week prior to the meeting. Registration for making public comments will also be available on-site. Time allowed for presentation by on-site registrants may be less than that for preregistered speakers and will be determined by the number who register at the meeting. If registering on-site to speak and reading oral comments from printed copy, the speaker is asked to bring 25 copies of the text. These copies will be distributed to the Chair and Subcommittee members and supplement the record.

Written comments, in lieu of making oral comments, are welcome. All comments must include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any) and should be received by December 1st for distribution to the Subcommittee. Written comments received after December 1st will not be considered by Subcommittee members in their reviews.
Solicitation of Additional Information

The NTP would welcome receiving information from completed human or experimental animal cancer studies or studies of mechanism of cancer formation, as well as current production data, human exposure information, and use patterns for any of the nominations listed in this announcement. Organizations or individuals that wish to provide information should contact Dr. C.W. Jameson at the address given above.

The agenda and a roster of Subcommittee members will be available prior to the meeting on the NTP web homepage at http://ntp_server.niehs.nih.gov/ and upon request from Dr. Wolfe. Summary minutes from the previous meeting are available on the NTP web homepage and upon request from Dr. Wolfe.

Dated: October 6, 2000.
Kenneth Olden,
Director, National Toxicology Program.

SUMMARY DATA FOR NOMINATIONS TENTATIVELY SCHEDULED FOR REVIEW AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS’ REPORT ON CARCINOGENS SUBCOMMITTEE DECEMBER 13, 14, & 15, 2000

<table>
<thead>
<tr>
<th>Nomination to be reviewed/ CAS number</th>
<th>Primary uses or exposures</th>
<th>To be reviewed for</th>
<th>Tentative review order</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad Spectrum UV Radiation and UVA, UVB and UVC</td>
<td>Solar and artificial sources of ultraviolet radiation. Used widely as an antibiotic since the 1950s. Estrogens are widely used in post-menopausal therapy and in oral contraceptives for women.</td>
<td>Listing in the 10th Report</td>
<td>1</td>
</tr>
<tr>
<td>Chloramphenicol/(56–75–7)</td>
<td>Occupational exposure occurs during mining, milling and processing. Non-asbestiform talc (i.e. talc not containing asbestiform fibers) occurs in various geological settings around the world.</td>
<td>Listing in the 10th Report</td>
<td>6</td>
</tr>
<tr>
<td>Estrogens, Steroidal</td>
<td>Occupational exposure occurs during mining, milling and processing.</td>
<td>Listing in the 10th Report</td>
<td>7</td>
</tr>
<tr>
<td>Metallic Nickel &amp; Nickel Alloys</td>
<td>Widely used in commercial applications for over 100 years.</td>
<td>Listing in the 10th Report</td>
<td>4</td>
</tr>
<tr>
<td>Methyleugenol/(93–15–2)</td>
<td>Flavoring agent used in jellies, baked goods, nonalcoholic beverages, chewing gum, candy, and ice cream. Also used as a fragrance for many perfumes, lotions, detergents and soaps.</td>
<td>Listing in the 10th Report</td>
<td>3</td>
</tr>
<tr>
<td>Talc/(14807–96–6) (Asbestiform and Non-Asbestiform)</td>
<td>Asbestiform talc (i.e. talc containing asbestiform fibers) occurs in various geological settings around the world. Occupational exposure occurs during mining, milling and processing. Non-asbestiform talc (i.e. talc not containing asbestiform fibers) occurs in various geological settings around the world.</td>
<td>Listing in the 10th Report</td>
<td>8</td>
</tr>
<tr>
<td>Trichloroethylene (TCE)/(79–01–6)</td>
<td>Trichloroethylene is widely used as a solvent with 80–90% used worldwide for degreasing metals.</td>
<td>Upgrade to Known</td>
<td>2</td>
</tr>
<tr>
<td>Wood Dust</td>
<td>It is estimated that at least two million people are routinely exposed occupationally to wood dust worldwide. Non-occupational exposure also occurs. The highest exposures have generally been reported in wood furniture and cabinet manufacture, especially during machine sanding and similar operations.</td>
<td>Listing in the 10th Report</td>
<td>5</td>
</tr>
</tbody>
</table>

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.


ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4238, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708–3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This Notice is soliciting comments from members of the public and affected...