

2004) and associated foreign rights from PCT/US04/05881 (filed February 27, 2004) (HHS references E-093-2003/0,1,2)

to MedImmune, LLC, having a place of business in Gaithersburg, Maryland, USA. The patent rights in these inventions have been assigned to the United States of America.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before November 7, 2008 will be considered.

**ADDRESSES:** Requests for a copy of the patents and patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; e-mail: [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov); Telephone: (301) 435-5019; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** 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 sixty (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.

The above referenced technologies describe development of live, attenuated virus vaccines for respiratory syncytial virus (RSV), subgroups A and B, human parainfluenza, types 1, 2,3 (HPIV1, HPIV2, and HPIV3), and human metapneumovirus (hMPV).

The field of use in which NIH contemplates granting an exclusive license may be limited to the following and excludes fields employing any vectored vaccines and any human-bovine chimeras for RSV A, RSV B, HPIV3, HPIV2, HPIV1, and hMPV:

Live attenuated virus vaccines for intranasal administration to humans against RSV subgroups A and B, HPIV1, HPIV2, HPIV3, and hMPV based on the following viruses (in bold) and their corresponding attenuating mutations (in bulleted *italics*):

Human RSV subgroups A or B or A/B chimeras:

- *rcp248/404/1030ΔSH, including the stabilized version of this virus;*
- *ΔNS1;*
- *ΔM2-2.*

#### HPIV3

- *rcp45*

#### HPIV2

- *Mutations in C and L imported from other viruses, e.g., HRSV, BPIV3, and HPIV3, with or without stabilization by codon substitution or deletion;*
- *L(Δ1724);*
- *Viruses with P and V genes separated*

#### HPIV1

- *Mutations in C and L imported from other viruses, e.g., HRSV, BPIV3, and HPIV3, with or without stabilization by codon substitution or deletion;*
- *C(170);*
- *C(R84G) mutation;*
- *L(942stabilized);*
- *Viruses with P and C genes separated.*

#### hMPV

- *ΔG, alone or in combination with ΔSH;*
  - *ΔM2-2;*
  - *Avian-human chimera with avian P ORF placed in hMPV backbone.*
- 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.

Dated: August 26, 2008.

**Richard U. Rodriguez,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Toxicology Program (NTP); Report on Carcinogens (RoC); Request for Public Comments on the RoC Expert Panel's Recommendation on Listing Status for Styrene in the 12th RoC and the Scientific Justification for the Recommendation

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

**ACTION:** Request for comments.

**SUMMARY:** The RoC Office invites public comment on the recommendation from an expert panel on the listing status for styrene in the 12th RoC and the

scientific justification for the recommendation. The recommendation and scientific justification for styrene is available electronically in Part B of the Expert Panel Report (<http://ntp.niehs.nih.gov/go/29682>, see Expert Panel Report Part B) or in printed text from the RoC Office (see **FOR FURTHER INFORMATION CONTACT** below). The RoC Office convened an eleven-member expert panel of scientists from the public and private sectors on July 21-22, 2008. The panel was asked (1) to apply the RoC listing criteria to the relevant scientific evidence and make a recommendation regarding listing status (i.e., known to be a human carcinogen, reasonably anticipated to be a human carcinogen, or not to list) for styrene in the 12th RoC and (2) to provide the scientific justification for the recommendation.

**DATES:** The Expert Panel Report (Part B) for styrene will be available for public comment by September 3, 2008. Written comments should be submitted by October 23, 2008.

**ADDRESSES:** Comments should be sent to Dr. Ruth Lunn, Director, RoC Office [NIEHS, P.O. Box 12233, MD EC-14, Research Triangle Park, NC 27709, Fax: 919-541-0144, or [lunn@niehs.nih.gov](mailto:lunn@niehs.nih.gov). Courier address: Report on Carcinogens, 79 T.W. Alexander Drive, Building 4401, Room 3118, Research Triangle Park, NC 27709].

**FOR FURTHER INFORMATION CONTACT:** Dr. Ruth Lunn, RoC Office, 919-316-4637 [lunn@niehs.nih.gov](mailto:lunn@niehs.nih.gov).

#### SUPPLEMENTARY INFORMATION:

#### Background

Styrene is a flammable liquid used worldwide in the manufacture of polystyrene, which is used extensively in the manufacture of plastic packaging, thermal insulation in building construction and refrigeration equipment, and disposable cups and containers. Styrene also is used in other polymers and resins that are used to manufacture boats, shower stalls, tires, automotive parts, and many other products. The general population is exposed to styrene from inhalation of indoor air; and outdoor air, tobacco smoke, and ingestion of food. Occupational exposure occurs mainly in the reinforced plastics, styrene-butadiene rubber, and styrene monomer and polymer industries.

As part of the RoC review process (available at <http://ntp.niehs.nih.gov/go/15208>), the NTP announced the availability of the draft background document for styrene (**Federal Register**: May 20, 2008; Vol. 73, No. 98, pages 29139-29140), invited public comments

on the draft background document, and announced the styrene expert panel meeting. The RoC Office convened an eleven-member expert panel of scientists from the public and private sectors to evaluate styrene. The expert panel met on July 21–22, 2008, in a public forum at the Radisson Governors Inn, Research Triangle Park, North Carolina. The panel was charged to peer review the draft background document for styrene and then to make a recommendation on its listing status in the 12th RoC and to provide a scientific justification for that recommendation. Details about the meeting, including public comments received and the expert panel reports, are available on the RoC Web site (<http://ntp.niehs.nih.gov/go/29682>). The expert panel report for styrene contains two parts: Part A contains the peer-review comments on the draft background document and Part B is the recommendation on listing status and its scientific justification. The expert panel recommended that (1) styrene be listed in the 12th RoC as reasonably anticipated to be a human carcinogen. The panel's recommendation on listing status and its scientific justification are now being released for public comment.

#### Request for Comments

The RoC Office invites written public comments on the expert panel's recommendation on listing status for styrene and the scientific justification for the recommendation. All comments received will be posted on the RoC Web site. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Lunn (see **ADDRESSES** above). The deadline for submission of written comments is October 23, 2008.

#### Next Steps

The RoC Office is in the process of finalizing the background document for styrene based upon the expert panel's peer review comments and the public comments received (73 FR 29139). Persons can register free-of-charge with the NTP listserv (<http://ntp.niehs.nih.gov/go/231>) to receive notification when the final background document is posted on the RoC Web site (<http://ntp.niehs.nih.gov/go/10091>). As part of the RoC review process, two government groups will also conduct reviews of styrene; these meetings are not open to the public. Upon completion of these reviews, the NTP will (1) draft a substance profile for styrene, which contains its listing

recommendation for the 12th RoC and the scientific information supporting that recommendation; (2) solicit public comment on the draft substance profile; and (3) convene a meeting of the Board of Scientific Counselors to peer review the draft substance profile.

#### Background Information on the RoC

The RoC is a Congressionally mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as "substances") that may pose a hazard to human health by virtue of their carcinogenicity. The RoC follows a formal, multi-step process for review and evaluation of selected chemicals. Substances are listed in the report as either known or reasonably anticipated human carcinogens. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services. Information about the RoC and the review process is available on its Web site (<http://ntp.niehs.nih.gov/go/roc>) or by contacting Dr. Lunn (see **FOR FURTHER INFORMATION CONTACT** above).

Dated: August 29, 2008.

**Samuel H. Wilson,**

*Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.*

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**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Agency Information Collection Activities: Entry and Manifest of Merchandise Free of Duty

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments; extension of an existing information collection: 1651–0013.

**ACTION:** Proposed collection; comments requested.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Entry and Manifest of Merchandise Free of Duty. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This

document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (73 FR 36544) on June 27, 2008, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

**DATES:** Written comments should be received on or before October 8, 2008.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395–6974.

**SUPPLEMENTARY INFORMATION:** U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13).

Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Title:* Entry and Manifest of Merchandise Free of Duty.

*OMB Number:* 1651–0013.

*Form Number:* CBP Form–7523.

*Abstract:* CBP Form–7523 is used by carriers and importers as a manifest for the entry of merchandise free of duty under certain condition and by CBP to authorize the entry of such merchandise. It is also used by carriers to show that the articles being imported