

#### VI. Other Qualified Persons (as required by section 319F-3(i)(8)(B) of the Act)

With regard to the administration or use of a Covered Countermeasure, section 319F-3(i)(8)(A) of the Act defines the term "qualified person" as a licensed individual who is authorized to prescribe, administer, or dispense the Covered Countermeasure under the law of the State in which such covered countermeasure was prescribed, administered or dispensed.

Additional persons who are qualified persons pursuant to section 319F-3(i)(8)(B) are the following: (1) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency, and (2) Any person authorized to prescribe, administer, or dispense Covered Countermeasures or who is otherwise authorized under an Emergency Use Authorization.

#### VII. Additional Time Periods of Coverage After Expiration of Declaration (as required by section 319F-3(b)(3)(B) of the Act)

I have determined that, upon expiration of the time period specified in Section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition and covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F-3(a) of the Act shall extend for that period.

#### VIII. Amendments

This Declaration has not previously been amended. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-3(b)(4) of the Act.

#### IX. Definitions

For the purpose of this declaration, including any claim for loss brought in accordance with section 319F-3 of the PHS Act against any covered persons defined in the Act or this declaration, the following definitions will be used:

**Administration of a Covered Countermeasure:** as used in Section 319F-3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures

to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

**Authority Having Jurisdiction:** means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, State, or Federal boundary lines) or functional (e.g. law enforcement, public health) range or sphere of authority.

**Covered Persons:** as defined at section 319F-3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms "manufacturer," "distributor," "program planner," and "qualified person" are further defined at sections 319F-3(i)(3), (4), (6), and (8) of the Act.

**Declaration of Emergency:** a declaration by any authorized local, regional, State, or federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

**Pandemic Influenza Diagnostics:** means diagnostics to identify avian or other animal influenza A viruses that pose a pandemic threat, or to otherwise aid in the diagnosis of pandemic influenza, when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR Part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.

**Pandemic Influenza Personal Respiratory Protection Devices:** means personal respiratory protection devices for use by the general public to reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as an influenza pandemic, when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR Part 312; or (6)

used under section 520(g) of the FDCA and 21 CFR part 812.

**Pandemic Influenza Respiratory Support Devices:** means devices to support respiratory function for patients infected with highly pathogenic influenza A H5N1 viruses or other influenza viruses that pose a pandemic threat when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR Part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.

Dated: December 17, 2008.

**Michael O. Leavitt,**  
*Secretary.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the NTP Board of Scientific Counselors

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

**ACTION:** Meeting announcement and request for comments.

**SUMMARY:** Pursuant to Public Law 92-463, notice is hereby given of a meeting of the NTP Board of Scientific Counselors (NTP BSC). The NTP BSC is a federally chartered, external advisory group composed of scientists from the public and private sectors that provides primary scientific oversight to the NTP and evaluates the scientific merit of the NTP's intramural and collaborative programs.

**DATES:** The NTP BSC meeting will be held on February 24, 2009. The deadline for submission of written comments is February 6, 2009, and for pre-registering to attend the meeting, including providing notice of intent to present oral comments, is February 17, 2009. Persons needing interpreting services in order to attend should contact 301-402-8180 (voice) or 301-435-1908 (TTY). For other accommodations, contact 919-541-2475 or e-mail [niehsoeeo@niehs.nih.gov](mailto:niehsoeeo@niehs.nih.gov). Requests should be made at least 7 days in advance of the event.

**ADDRESSES:** The NTP BSC meeting will be held in the Rodbell Auditorium, Rall Building at the NIEHS, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709. Public comments and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP BSC, NTP Office of Liaison, Policy and Review, NIEHS, P.O. Box 12233, MD A3-01, Research Triangle Park, NC 27709; telephone: 919-541-4253; fax: 919-541-0295; or e-mail: [shane@niehs.nih.gov](mailto:shane@niehs.nih.gov). Courier address: NIEHS, 111 T.W. Alexander Drive, Room K2138, Research Triangle Park, NC 27709.

**FOR FURTHER INFORMATION CONTACT:** Dr. Barbara Shane (telephone: 919-541-4253 or e-mail: [shane@niehs.nih.gov](mailto:shane@niehs.nih.gov)).

**SUPPLEMENTARY INFORMATION:**

**Preliminary Agenda and Availability of Meeting Materials**

The primary agenda topic is the peer review of draft substance profiles for some candidate substances under review for the 12th Report on Carcinogens (RoC). The draft substance profiles will be available by December 24, 2008, on the NTP BSC meeting Web site (<http://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the Executive Secretary for the NTP BSC (see **ADDRESSES** above). Other materials for the meeting will be posted on the Web site as available. Following the meeting, summary minutes will be prepared and made available on the meeting Web site.

**Attendance and Registration**

This meeting is scheduled for February 24, 2009, beginning at 8:30 a.m. and continuing until adjournment. It is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP BSC meeting Web site by February 17, 2009, to facilitate access to the NIEHS campus. The NTP is making plans to videocast the meeting through the Internet at <http://www.niehs.nih.gov/news/video/live>.

**Request for Comments**

Written comments are invited on the draft substances profiles and should be received by February 6, 2009. Persons submitting written comments should include their name, affiliation (if applicable), phone, e-mail, and sponsoring organization (if any) with the document. Comments submitted in response to this notice will be provided to the NTP BSC and NTP staff and posted on the meeting Web site. The submitter will be identified by name,

affiliation, and/or sponsoring organization, if applicable.

Time will be allotted during the meeting for the public to present oral comments to the NTP BSC on the draft substance profiles. Each organization is allowed one time slot per draft profile. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the NTP BSC chair. Registration for oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register on-site.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP BSC (see **ADDRESSES** above) by February 6, 2009, to enable review by the NTP BSC prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the NTP BSC and NTP staff and to supplement the record.

**Background Information on the Report on Carcinogens**

The RoC is a public information document prepared for the U.S. Congress by the 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 NTP is following a multi-step scientific review process with multiple opportunities for public input for preparation of the 12th RoC (<http://ntp.niehs.nih.gov/go/29353>) that was announced in the **Federal Register** on April 16, 2007 [72FR18999]. Information about the review of the candidate substance for the 12th RoC, including public comments and background documents, is available on the RoC Web site (<http://ntp.niehs.nih.gov/go/10091>).

**Background Information on the NTP Board of Scientific Counselors**

The NTP BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the overall program and its centers. Specifically, the NTP BSC advises the NTP on matters of scientific program

content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. NTP BSC meetings are held annually or biannually.

Dated: December 12, 2008.

**Samuel H. Wilson,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket Number NIOSH-141]

**Notice of Draft Document Available for Public Comment**

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of Draft Document Available for Public Comment.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document available for public comment entitled "Preventing Deaths and Injuries of Fire Fighters When Fighting Fires in Unoccupied Structures." The draft document and instructions for submitting comments can be found at <http://www.cdc.gov/niosh/review/public/141/>. Comments may be provided to the NIOSH Docket Number above.

**PUBLIC COMMENT PERIOD:** January 5, 2009 to March 9, 2009.

**Status:** Written comments may be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, Mailstop C34, Cincinnati, Ohio 45226, telephone (513)