

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### NIH Consensus Development Conference on Inhaled Nitric Oxide Therapy for Premature Infants

##### Notice

Notice is hereby given of the National Institutes of Health (NIH) "NIH Consensus Development Conference on Inhaled Nitric Oxide Therapy for Premature Infants" to be held October 27–29, 2010, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on October 27 and 28, and at 9 a.m. on October 29, and will be open to the public.

Infants born before the 37th week of pregnancy are said to be "premature" or "preterm" and face increased risk for a variety of complications. Babies born before the 28th week of pregnancy—more than 30,000 per year in the United States—are particularly vulnerable to breathing problems such as respiratory distress syndrome and respiratory failure due to their underdeveloped lungs. These infants often need respiratory support in the first days and weeks after birth. Those premature infants who still require supplemental oxygen 36 weeks after conception are diagnosed with bronchopulmonary dysplasia, which places them at greater risk for death or problems with long-term lung health, brain development, and brain function.

Nitric oxide is a chemical compound in gas form that is sometimes used to treat infants with severe breathing problems. Inhaled nitric oxide therapy was approved by the U.S. Food and Drug Administration in 2000 to treat term and near-term infants (born after the 33rd week of pregnancy) with respiratory failure. Inhaled nitric oxide therapy is typically administered in the neonatal intensive care unit using a device that delivers the drug in constant concentrations. It acts as a pulmonary vasodilator, widening the opening of blood vessels in the lungs. In term and near-term infants, use of this therapy may shorten the length of time respiratory support is required, thereby reducing progression to bronchopulmonary dysplasia and improving long-term lung health and brain development and function.

Since its approval, researchers have examined expanding the use of inhaled nitric oxide therapy to treat premature babies born at less than 34 weeks' gestation. Studies to evaluate its safety

and efficacy for these infants have had mixed results in terms of key outcomes. Thus, the potential benefits and harms of its use for premature infants with varying degrees of respiratory illness are not completely understood.

To advance understanding of these important issues, the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Office of Medical Applications of Research of the NIH will convene a Consensus Development Conference from October 27–29, 2010. The conference will address the following key questions:

- Does inhaled nitric oxide therapy increase survival and/or reduce the occurrence or severity of bronchopulmonary dysplasia among premature infants who receive respiratory support?
- Are there short-term risks of inhaled nitric oxide therapy among premature infants who receive respiratory support?
- Are there effects of inhaled nitric oxide therapy on long-term pulmonary and/or neurodevelopmental outcomes among premature infants who receive respiratory support?
- Does the effect of inhaled nitric oxide therapy on bronchopulmonary dysplasia and/or death or neurodevelopmental impairment vary across subpopulations of premature infants?
- Does the effect of inhaled nitric oxide therapy on bronchopulmonary dysplasia and/or death or neurodevelopmental impairment vary by timing of initiation, mode of delivery, dose and duration, or concurrent therapies?
- What are the future research directions needed to better understand the risks, benefits, and alternatives to nitric oxide therapy for premature infants who receive respiratory support?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On Friday, October 29, the panel will present a statement of its collective assessment of the evidence to answer each of the questions above. The panel will also hold a press telebriefing to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later. The primary sponsors of this meeting

are the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH Office of Medical Applications of Research.

Advance information about the conference and conference registration materials may be obtained from the NIH Consensus Development Program Information Center by calling 888–644–2667 or by sending e-mail to [consensus@mail.nih.gov](mailto:consensus@mail.nih.gov). The Information Center's mailing address is P.O. Box 2577, Kensington, Maryland 20891. Registration information is also available on the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

**Please Note:** The NIH has instituted security measures to ensure the safety of NIH employees and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the security measures at NIH, please visit the Web site at <http://www.nih.gov/about/visitorsecurity.htm>.

Dated: July 19, 2010.

**Francis S. Collins,**

*Director, National Institutes of Health.*

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form N–644, Revision of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day notice of information collection under review: Form N–644, Application for Posthumous Citizenship; OMB Control No. 1615–0059.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. This information collection was previously published in the **Federal Register** on April 22, 2010, at 75 FR 21013, allowing for a 60-day public comment period. The 60-day notice mentioned that during the 60-day comment period USCIS would be evaluating whether to revise the Form

N-644. On July 15, 2010, USCIS published a 30-day notice in the **Federal Register** at 75 FR 41216 extending the use of Form N-644. However, USCIS should have published a 30-day notice announcing a revision to the Form N-644, not an extension. Accordingly, this 30-day notice is published to let the public know that USCIS is revising Form N-644.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until August 25, 2010. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, 111 Massachusetts Avenue, Washington, DC 20529-2210. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at [rfs.regs@dhs.gov](mailto:rfs.regs@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via e-mail at [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). When submitting comments by e-mail please make sure to add OMB Control Number 1615-0059 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more 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, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies 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 collection of information on those who are to respond, including through 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.

### Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Application for Posthumous Citizenship.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N-644; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or Households.* This information collection will be used by USCIS to verify eligibility and review the request for awarding posthumous citizenship.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 50 responses at 1 hour and 50 minutes (1.83 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 92 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: <http://www.regulations.gov>.

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529-2210; Telephone 202-272-8377.

Dated: July 20, 2010.

#### Sunday Aigbe,

Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Agency Information Collection Activities: Permit To Transfer Containers to a Container Station

**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: 1651-0049.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork

Reduction Act: Permit to Transfer Containers to a Container Station. 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** (75 FR 26268) on May 11, 2010, 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 August 25, 2010.

**ADDRESSES:** Interested persons are invited to submit written comments on this 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) 395-5806.

**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 techniques or other forms of information.

*Title:* Permit to Transfer Containers to a Container Station.

*OMB Number:* 1651-0049.

*Form Number:* None.