

2820, or e-mail your request, including your address, to: [[darwinw@od.nih.gov](mailto:darwinw@od.nih.gov)].

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: May 4, 2011.

**Wanda R. Darwin,**

*Human Resources Specialist, Office of Human Resources, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Solicitation of Written Comments on the Draft Report and Draft Recommendations of the Vaccine Safety Working Group for Consideration by the National Vaccine Advisory Committee on the Federal Vaccine Safety System

**AGENCY:** National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (Pub. L. 99-660) (Section 2105) (42 U.S. Code 300aa-5 (PDF—78 KB)). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services as the Director of the National Vaccine Program. The ASH has charged the NVAC “To review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.” On behalf of the NVAC, the Vaccine Safety Working Group (VSWG) has developed a draft report and draft recommendations for the consideration by the NVAC in developing the NVAC’s final recommendations to the ASH. The National Vaccine Program Office (NVPO) is soliciting public comment on the National Vaccine Advisory Committee (NVAC) Vaccine Safety

Working Group draft report and draft recommendations for the federal vaccine safety system to be considered by the NVAC. Individuals and organizations are encouraged to submit their comments on the draft report and draft recommendations. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented in mid to late 2011 to the NVAC for deliberation and decision on their final recommendations.

**DATES:** To receive consideration comments should be received no later than 5 p.m. EST on June 6, 2011.

**ADDRESSES:** 1. The draft report and draft recommendations are available on the Web at <http://www.hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html>.

2. Electronic responses are preferred and may be addressed to [vaccinesafetyRFI@hhs.gov](mailto:vaccinesafetyRFI@hhs.gov).

3. Written responses should be addressed to: National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Room 739G.5, Washington, DC 20201, *Attention:* Vaccine Safety c/o Kristin Goddard.

**FOR FURTHER INFORMATION CONTACT:** Kristin Goddard, National Vaccine Program Office, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 439G.5, Washington, DC 20201, *Attn:* NVAC Vaccine Safety Working Group, telephone (202) 205-5317; fax 202-260-1165; e-mail [vaccinesafetyRFI@hhs.gov](mailto:vaccinesafetyRFI@hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services and has the responsibility for coordinating and fostering collaborations among the many Federal agencies involved in vaccine and immunization activities. NVPO also has responsibility for the management of the National Vaccine Advisory Committee, a chartered federal advisory committee that reports to the Assistant Secretary for Health in his role as the Director of the National Vaccine Program (NVP).

Recognizing the importance of vaccine safety in the NVP, the ASH charged NVAC to “review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of

vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.” On behalf of the NVAC the Vaccine Safety Working Group (VSWG) has developed a draft report and draft recommendations for the consideration by the NVAC in developing the NVAC’s final recommendations to the ASH. The VSWG membership represents a broad range of expertise including pediatric and adult infectious diseases, genomics, immunology, epidemiology, public health, maternal and child health, pharmacoepidemiology, and biostatistics. Through review of previous recommendations on improvement to the vaccine safety system, input from an array of experts and stakeholders, and identification of gaps in the current federal vaccine safety system the VSWG developed draft recommendations for the consideration of the NVAC to achieve the charge as noted above.

The draft report describes relative benefits and risks of vaccines, current vaccine coverage levels, successes and challenges of the current system, methodology for VSWG recommendation development, and the conclusions of the VSWG from these findings. From these conclusions the VSWG has developed draft recommendations in eight categories: Leadership, Coordination, Research, Post Licensure Surveillance, Clinical Practice, Communications, Stakeholder and Public Engagement, and Assurance and Accountability.

Through this request for comment HHS is seeking comments from everyone, including stakeholders and the broad public, on the NVAC Vaccine Safety Working Group draft report and draft recommendations to be submitted to the NVAC for consideration in their final recommendations to the ASH. Comments received will be available for public viewing on the NVAC Vaccine Safety Working Group section of the NVPO Web site (<http://www.hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html>).

##### II. Request for Comment

NVPO, on behalf of the NVAC Vaccine Safety Working Group, requests input on the draft report and draft recommendations. (<http://www.hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html>). In addition to general comments, NVPO is seeking input on any additional gaps not addressed in the NVAC Vaccine Safety Working Group draft report, and/or prioritization criteria and its application

to the draft recommendations. Please limit comments to six pages.

**III. Potential Responders**

HHS invites input from a broad range of individuals and organizations that have interests in vaccines and vaccine safety. Some examples of these organizations include but are not limited to the following:

- General public;
- Advocacy groups and public interest organizations;
- State and local governments;
- State and local public health departments;
- Vaccine manufacturing industry, distributors and other businesses;
- Health care professional societies and organizations.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. All comments submitted will be made publicly available. Anonymous submissions will not be considered and will not have their comments posted.

Written comment submission should not exceed six pages. Any information you submit will be made public. Consequently, do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public.

Public Access: Comments on the draft report and draft recommendations will be available to the public on the NVAC Web site at <http://www.hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html>. You may access public comments received by going to the above Web site.

Dated: May 4, 2011.

**Wanda K. Jones,**

*Principal Deputy Assistant Secretary for Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* Request for Assistance for Child Victims of Human Trafficking.  
*OMB No.:* 0970-0362.

*Description:* The William Wilberforce Trafficking Victims Protection Reauthorization Act (TVPPRA) of 2008, Public Law 110-457, directs the U.S. Secretary of Health and Human Services (HHS), upon receipt of credible information that a non-U.S. citizen, non-Lawful Permanent Resident (alien) child may have been subjected to a severe form of trafficking in persons and is seeking Federal assistance available to victims of trafficking, to promptly determine if the child is eligible for interim assistance. The law further directs the Secretary of HHS to determine if a child receiving interim assistance is eligible for assistance as a victim of a severe form of trafficking in persons after consultation with the Attorney General, the Secretary of Homeland Security, and nongovernmental organizations with expertise on victims of severe forms of trafficking.

In developing procedures for collecting the necessary information from potential child victims of trafficking, their case managers, attorneys, or other representatives to allow HHS to grant interim eligibility, HHS devised a form. HHS has determined that the use of a standard form to collect information is the best way to ensure requestors are notified of their option to request assistance for child victims of trafficking and to make prompt and consistent determinations

about the child's eligibility for assistance.

Specifically, the form asks the requestor for his/her identifying information, for information on the child, information describing the type of trafficking and circumstances surrounding the situation, and the strengths and needs of the child. The form also asks the requestor to verify the information contained in the form because the information could be the basis for a determination of an alien child's eligibility for federally funded benefits. Finally, the form takes into consideration the need to compile information regarding a child's circumstances and experiences in a non-directive, child-friendly way, and assists the potential requestor in assessing whether the child may have been subjected to trafficking in persons.

The information provided through the completion of a Request for Assistance for Child Victims of Human Trafficking form will enable HHS to make prompt determinations regarding the eligibility of an alien child for interim assistance, inform HHS' determination regarding the child's eligibility for assistance as a victim of a severe form of trafficking in persons, facilitate the required consultation process, and enable HHS to assess and address potential child protection issues.

*Respondents:* Representatives of governmental and nongovernmental entities providing social, legal, or protective services to alien persons under the age of 18 (children) in the United States who may have been subjected to severe forms of trafficking in persons.

**ANNUAL BURDEN ESTIMATES**

| Instrument  | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Request for Assistance for Child Victims of Human Trafficking ..... | 200                   | 1                                  | 1                                 | 200                |

Estimated Total Annual Burden Hours: 200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and

comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) the quality, utility, and clarity of the information to be collected; and (d)