

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Dated: January 21, 2005.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-1494 Filed 1-26-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### List of Drugs for Which Pediatric Studies Are Needed

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH) is providing notice of a "List of Drugs for Which Pediatric Studies Are Needed." The NIH developed the list in consultation with the Food and Drug Administration (FDA) and pediatric experts, as mandated by the Best Pharmaceuticals for Children Act. This list adds to the previously published lists prioritizing drugs most in need of study for use by children to ensure the safety and efficacy of their medication. The NIH will update the list at least annually until the Act expires on October 1, 2007.

**DATES:** The list is effective upon publication.

**FOR FURTHER INFORMATION CONTACT:** Dr. Tamar Lasky, National Institute of Child Health and Human Development (NICHD), 6100 Executive Boulevard, Suite 5C01G, Bethesda, MD 20892-7510, e-mail [BestPharmaceuticals@mail.nih.gov](mailto:BestPharmaceuticals@mail.nih.gov), telephone (301) 594-8670 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The NIH is providing notice of a "List of Drugs for Which Pediatric Studies Are Needed," as authorized under Section 3, Pub. L. 107-109 (42 U.S.C. 409I). On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that not later than one year after the date of enactment, the NIH in consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish an annual list of certain approved drugs for which pediatric studies are needed. For inclusion on the list, an approved drug must meet the following criteria: (1) There is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (2) there is a submitted application that could be approved under the criteria of

section 505(j) of the Federal Food, Drug, and Cosmetic Act; (3) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there is a referral for inclusion on the list under section 505A(d)(4)(c); and additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population. The BPCA further stipulates that in developing and prioritizing the list, the NIH shall consider for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in the pediatric population; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (4) whether reformulation of the drug is necessary. In developing this list, the NIH consulted with the FDA, the American Academy of Pediatrics, and other experts in pediatric research and practice. A preliminary list of drugs was drafted and categorized as a function of indication and use. The drugs were then prioritized based on frequency of use in the pediatric population, severity of the condition being treated, and potential for providing a health benefit in the pediatric population.

The following off-patent drugs were reviewed by expert consultants at an October 25 and 26, 2004, scientific meeting at NICHD and recommended for further study: Ivermectin for scabies; hydrocortisone valerate ointment and cream for dermatitis; hydrochlorothiazide for hypertension; ethambutol for tuberculosis; griseofulvin for tinea capitis; methadone for opiate addicted neonates; hydroxychloroquine for connective tissue disorders.

The following off-patent drugs were recommended for re-labeling based on evidence available in the literature: Acyclovir for herpetic infections.

The following off-patent drugs were recommended for systematic literature review and/or further consultation with scientific community to finalize scientific questions in need of study: Cyclosporine for heart transplant patients; clonidine for autism, attention deficit disorder; flecainide for life threatening ventricular arrhythmias.

The following on-patent drugs were referred to the NICHD by the Foundation for NIH, reviewed by expert consultants at the October 25 and 26, 2004, scientific meeting, and recommended for further study: Sevelamer for renal failure; morphine for analgesia.

The following on-patent drugs were recommended for systematic literature review and/or further consultation with the scientific community to finalize scientific questions in need of study: Bupropion for depression.

Dated: January 19, 2005.

**Elias A. Zerhouni,**

*Director, National Institutes of Health.*

[FR Doc. 05-1495 Filed 1-26-05; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Office for Civil Rights and Civil Liberties

[DHS-2005-0001]

#### Submission for New Information Collection, DHS Individual Complaint of Employment Discrimination Form (DHS 3090-1)

**AGENCY:** Office for Civil Rights and Civil Liberties, DHS.

**ACTION:** Notice; 30-day notice request for comments.

**SUMMARY:** The Department of Homeland Security, Office for Civil Rights and Civil Liberties has submitted 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. The information collection was previously published in the **Federal Register** on October 14, 2004 at 69 FR 61033-61034, allowing for a 60-day public comment period. No comments were received by DHS on this information collection. The purpose of this notice is to allow an additional 30 days for public comments.

**DATES:** Comments are encouraged and will be accepted until February 28, 2005. This process is conducted in accordance with 5 CFR 1320.10

**ADDRESSES:** *Submitting comments:* You may submit comments either electronically, or by mail or courier, or you may hand deliver in person. When submitting comments please only choose one of the methods listed below. It is not necessary to submit duplicate sets of comments by using more than one method of submission (*i.e.*, if you submit electronic comments then it is not necessary to submit comments by mail).

When submitting electronic comments you must include Docket No. DHS-2005-0001, and the Agency name, in the subject box.

When submitting comments by mail or courier, or hand delivery, you must

include the title of the notice and Docket No. DHS-2005-0001, at the beginning of the correspondence.

**Submitting electronic comments:** You may submit comments electronically by using one of the methods listed below. All comments received will be posted without change to <http://www.epa.gov/feddocket>, including any personal information provided.

- **EPA Federal Partner EDOCKET Web site:** The Department of Homeland Security and its agencies (excluding the United States Coast Guard and Transportation Security Administration) will use the EPA Federal Partner EDOCKET system at <http://www.epa.gov/feddocket> for submitting electronic comments. Follow instructions on that Web site for submitting electronic comments.

- **Federal eRulemaking Portal:** You may also submit electronic comments at <http://www.regulations.gov>. Follow the instructions at that Web site for submitting electronic comments.

**Submitting comments by mail, hand delivery or courier:**

- **Mail:** When submitting comments by mail, please send the comments to Office of Management and Budget, Attn: Desk Officer for Homeland Security, Office of Management and Budget, Room 10235, Washington, DC 20503; telephone 202-395-7316. To ensure proper handling, please reference Docket No. DHS-2005-0001 on your correspondence. This mailing address may also be used for submitting comments on paper, disk, or CD-ROM.

- **Hand Delivery/Courier:** The address for submitting comments by hand delivery or courier is the same as that for submitting comments by mail.

For additional instructions on submitting comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

**Viewing comments:** You may view comments and background material at: <http://www.epa.gov/feddocket> or <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mary McGoldrick, (202) 772-9921 (this is not a toll free number).

#### **SUPPLEMENTARY INFORMATION:**

##### **Request for Comments**

The Office of Management and Budget is particularly interested in comments which:

- (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 agency's 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 submissions of responses.

#### **Analysis**

**Agency:** Department of Homeland Security, Office for Civil Rights and Civil Liberties.

**Title:** DHS Individual complaint of Employment Discrimination Form (DHS 3090-1).

**OMB No.:** 1610-NEW.

**Frequency:** On Occasion.

**Affected Public:** Federal Government and Individuals or households.

**Estimated Number of Respondents:** 1,200.

**Estimated Time Per Response:** 30 minutes per response.

**Total Burden Hours:** 600.

**Total Cost Burden:** None.

**Description:** This form will allow a complainant to submit required information used by the Department to process an employment discrimination complaint with the Department of Homeland Security. The information contained in this form will allow the Department to accept, investigate and further process, or to dismiss issues.

Dated: January 21, 2005.

**Steve Cooper,**

*Chief Information Officer.*

[FR Doc. 05-1519 Filed 1-26-05; 8:45 am]

**BILLING CODE 4410-10-P**

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## **DEPARTMENT OF HOMELAND SECURITY**

### **Coast Guard**

[CGD05-04-225]

#### **Implementation of Sector Baltimore**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of organizational change.

**SUMMARY:** The Coast Guard announces the stand-up of Sector Baltimore. The Sector Baltimore Commanding Officer has the authority, responsibility and missions of the prior Activities Commander, Captain of the Port (COTP), Officer in Charge, Marine Inspection (OCMI), Federal On Scene

Coordinator (FOSC), Federal Maritime Security Coordinator (FMSC), and Search and Rescue Mission Controller (SMC) Baltimore. The Coast Guard has established a continuity of operations whereby all previous practices and procedures will remain in effect until superseded by an authorized Coast Guard official and/or document.

**DATES:** This notice is effective January 27, 2005.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket CGD05-04-225 and are available for inspection or copying at Fifth District Marine Safety, 431 Crawford Street, Portsmouth, VA 23704 between 7:30 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Commander Brian Hall, Fifth District Marine Safety Division at (757) 398-6691.

#### **SUPPLEMENTARY INFORMATION:**

##### **Discussion of Notice**

Sector Baltimore is located at 2401 Hawkins Point Road, Bldg. 70, Baltimore, MD 21226-1791 and contains a single Command Center. Sector Baltimore is composed of a Response Department, Prevention Department, and Logistics Department. All existing missions and functions performed by Activities Baltimore have been realigned under this new organizational structure as of January 1, 2005. Activities Baltimore no longer exists as an organizational entity. Sector Baltimore is responsible for all Coast Guard missions in the following zone: "the boundary of Sector Baltimore Marine Inspection zone and Captain of the Port zone starts at a point at 75° 30.0' W. longitude on the Delaware-Maryland boundary and proceeds along the Delaware-Maryland boundary West and North to the Pennsylvania boundary; thence West along the Pennsylvania-Maryland boundary to the West Virginia boundary; thence Southerly and Easterly along the Maryland-West Virginia boundary to the intersection of the Maryland-Virginia-West Virginia boundaries; thence Southwestward along the Loudoun County, Virginia boundary to the intersection with Fauquier County, Virginia; thence Easterly along the Loudoun County, Virginia boundary to the intersection with the Prince William County, Virginia boundary; thence Southerly along the Prince William County boundary to the intersection with Stafford County, Virginia; thence Easterly along the Prince William County, Virginia Boundary to the