

| Form title  | Number of respondents | Number of responses/ respondent | Average burden per response (in hrs.) |
|---|-----------------------|---------------------------------|---------------------------------------|
| Supplementary Data Collection, Craniotomy Patient Report .....    | 9                     | 58                              | 27/60                                 |
| Supplementary Data Collection, Spinal Fusion Patient Report ..... | 18                    | 60                              | 27/60                                 |
| Supplementary Data Collection, Ventricular Shunt Patient .....    | 10                    | 180                             | 27/60                                 |
| AUR Surveillance Monthly Report:                                  |                       |                                 |                                       |
| ICP .....   | 30                    | 12 (1×12)                       | 2                                     |
| Laboratory Technician .....                                       | 30                    | 60 (5×12)                       | 3                                     |
| Pharmacy Technician .....   | 30                    | 48 (4×12)                       | 2                                     |
| AUR Surveillance Contact Information .....                        | 40                    | 1                               | 10/60                                 |
| Antimicrobial Prescribing Practices .....                         | 30                    | 1                               | 15/60                                 |

Dated: November 3, 2004.

**B. Kathy Skipper,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04-24892 Filed 11-8-04; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60 Day-05AD]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-498-1210 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited 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) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Helping to End Lead Poisoning (HELP): A Questionnaire Study of Medicaid Providers' Beliefs, Barriers, Knowledge, and Cues to Action for Childhood Blood Lead Testing—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

According to the United States Department of Health and Human Services (DHHS), lead poisoning is one of the most serious environmental threats to children in the United States. Very high blood lead levels in children can cause encephalopathy, coma, and even death. At lower levels, lead poisoning is a silent attacker because most children who are lead poisoned do not show symptoms. Low levels of lead poisoning are often associated with reductions in IQ and attention span, and with learning disabilities, hyperactivity, and behavioral problems. Because of these subtle effects, the best way to determine if a child has lead poisoning is by giving the child a blood lead test. Children eligible for Medicaid are typically at highest risk for lead exposure. DHHS policies require blood

lead testing for all children participating in federal health care programs.

However, most children in or targeted by federal health care programs have not been tested. This study will help to provide some of the reasons why most children are not being tested.

Although blood lead testing is important, it is ineffective unless it is performed when the child is young enough to receive the full benefits of effective environmental interventions. Thus, it was determined by CDC that more information is needed to understand the barriers Medicaid providers face when it comes to blood lead testing.

HELP is a comparison study between two communities in Wisconsin. To determine why some areas in Wisconsin have high blood lead testing rates and others do not, Medicaid providers in two areas will be studied. Community 1 has high and Community 2 has low blood lead testing rates. Questionnaires will be mailed to all Medicaid providers in these two Wisconsin communities. The questionnaires will be mailed from the Wisconsin Childhood Lead Poisoning Prevention Program in Milwaukee, Wisconsin. CDC will analyze the data from the questionnaires. CDC and the Wisconsin Childhood Lead Poisoning Prevention Program staff will use this information to understand the barriers Medicaid providers face concerning blood lead testing and to develop effective strategies that promote blood lead testing among Medicaid providers. There are no costs to respondents except their time to participate.

ANNUALIZED BURDEN TABLE

| Respondents                                    | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden hours |
|--|-----------------------|------------------------------------|---------------------------------------|--------------------|
| Targeted Medicaid Providers in Wisconsin ..... | 500                   | 1                                  | 10/60                                 | 83                 |
| Total .....                                    | .....                 | .....                              | .....                                 | 83                 |

Dated: November 3, 2004.

**B. Kathy Skipper,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04-24893 Filed 11-8-04; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004N-0480]

**The Minor Use and Minor Species Animal Health Act; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a new Office of Minor Use and Minor Species (MUMS) Animal Drug Development and is requesting comments on the implementation of the newly enacted MUMS Animal Health Act. This notice is intended to provide the public with contact information for the new MUMS office as well as to provide a venue for public comment.

**DATES:** Submit written or electronic comments by January 10, 2005.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments).

**FOR FURTHER INFORMATION CONTACT:** Andrew Beaulieu, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301-827-2945, [abeaulie@cvm.fda.gov](mailto:abeaulie@cvm.fda.gov). Alternatively, you may contact Margaret Oeller, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301-827-3067, [moeller@cvm.fda.gov](mailto:moeller@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The MUMS Animal Health Act became law on August 2, 2004 (Public Law 108-282). Several elements of the law became immediately effective on that date. These include the provisions for designation of MUMS drugs under section 573 and for conditional approval of MUMS drugs under section 571. The indexing provisions under section 572

of the law will only become effective upon publication of final implementing regulations. As mandated by the MUMS law, FDA has established the new Office of MUMS Animal Drug Development in the Center for Veterinary Medicine (CVM). FDA is requesting comments on any aspect of implementation of the MUMS legislation (see section II of this document). Requests for further information should be directed to the Office of MUMS Animal Drug Development (see **FOR FURTHER INFORMATION CONTACT**).

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-24880 Filed 11-8-04; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004N-0458]

**Dietary Supplements; Strategy for the Further Implementation and Enforcement of the Dietary Supplement Health and Education Act of 1994; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of its strategy for the further implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA). The strategy sets forth a series of specific, integrated research and regulatory measures, including guidance, regulations, and science-based compliance and enforcement mechanisms. Through implementation of these measures, FDA hopes to improve the transparency, predictability, and consistency both of the agency's scientific evaluations of dietary supplement product and

ingredient safety, and of its regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. FDA expects that this improved transparency will help engage stakeholders in the development of further measures to implement DSHEA.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the strategy for the further implementation of DSHEA to Vickey Lutwak, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1775, FAX: 301-436-2636, e-mail: [Vickey.Lutwak@fda.gov](mailto:Vickey.Lutwak@fda.gov).

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:**

Vickey Lutwak, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1775, FAX: 301-436-2636, e-mail: [Vickey.Lutwak@fda.gov](mailto:Vickey.Lutwak@fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In January 2000, FDA's Center for Food Safety and Applied Nutrition (CFSAN) issued its "Dietary Supplement Strategy: Ten Year Plan" (the 10-year plan) (accessible at <http://www.cfsan.fda.gov/~dms/ds-strat.html>). The 10-year plan sets as a goal a science-based regulatory program that fully implements DSHEA and affords consumers a high level of confidence in the safety, composition, and labeling of dietary supplement products. The 10-year plan sets forth a series of critical initiatives: (1) Improving the safety of products through, for example, regulations on current good manufacturing practice requirements for dietary supplements, guidance on premarket safety notifications for new dietary ingredients, and better adverse event report monitoring; (2) improving the labeling of products by, for example, clarifying what data and information are needed to substantiate structure/function and related claims in the labeling of a product; (3) clarifying the boundaries between dietary supplements, conventional foods, and drugs; (4) taking enforcement action against unsafe products and products whose labels are inaccurate or