

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**

Study to Examine Web-Based Administration of the Youth Risk Behavior Survey—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Youth Risk Behavior Survey (YRBS) has been conducted biennially since 1991 using paper-and-pencil

questionnaires in schools. Because of technological improvements in survey research methods, CDC is considering changing to Web-based administration of the YRBS. Because YRBS is the only national source of data for at least 10 national health objectives in Healthy People 2010, it is critical to understand (1) whether it is feasible to change to web-based administration, and (2) how a change to web-based administration, both with and without the use of skip patterns in the questionnaire, might affect prevalence estimates of the priority health risk behaviors reported in the YRBS.

CDC is proposing two studies to address these issues. The first study is a survey of U.S. high school principals, using a questionnaire designed to assess the feasibility and burden of web-based administration in schools. The second

study is a survey of approximately 6000 9th- and 10th-grade students attending schools in the United States, using the YRBS questionnaire. In the second study, students will be assigned randomly to one of the following conditions: (1) Paper-and-pencil group administration without skip patterns, (2) web-based group administration without skip patterns, (3) web-based group administration with skip patterns, and (4) web-based individual administration without skip patterns. An additional 1500 9th- and 10th-grade students assigned to condition #4 will participate in a sub-study to assess how incentives affect participation rates.

There are no costs to respondents except their time to participate in the survey and, in the case of school administrators, to assist in school recruitment.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hours)
High school students .....	7500	1	45/60	5625
High school principals .....	600	1	25/60	250
School administrators .....	210	1	30/60	105
Total .....				5980

Dated: February 28, 2007.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): The Small Business Innovation Research (SBIR) 020, "New Laboratory Tests for Tuberculosis and Detection of Drug Resistance" and SRIB 021, "Development of Novel Information System for Remote Tuberculosis Control and Prevention"**

*Correction:* This notice was published in the **Federal Register** on February 23, 2007, Volume 72, Number 36, page 8166. The reference to the acronym SRIB 021 in the SEP title is corrected to read SBIR 021.

*For Further Information Contact:* Felix Rogers, PhD, M.P.H., Scientific

Review Administrator, Coordinating Center for Infectious Diseases, National Center for Immunization and Respiratory Diseases, Office of the Director, CDC, 1600 Clifton Road NE., Mailstop E05, Atlanta, GA 30333, Telephone 404.639.6101.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 28, 2007.

**Elaine L. Baker,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Agricultural Center Review, Program Announcement (PAR) 06-057**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces a meeting of the aforementioned Special Emphasis Panel.

*Times and Dates:* 8 a.m.–5 p.m., April 10, 2007 (Closed). 8 a.m.–12 p.m., April 11, 2007 (Closed).

*Place:* Renaissance Hotel, 107 6th Street, Pittsburgh, PA 15222, telephone (412) 562-1200.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of research grant applications in

response to PAR 06-057, "Agricultural Center Review."

*For Further Information Contact:* Stephen Olenchock, Scientific Review Administrator, 1095 Willowdale Road, Morgantown, WV 26506, telephone (304) 285-6271.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

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

[FR Doc. E7-3852 Filed 3-5-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001D-0432]

#### Guidance for Industry on Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children." This guidance provides recommendations regarding the design, conduct, and evaluation of clinical trials to assess the effects of orally inhaled and intranasal corticosteroids on growth in children. For this class of drug products, measurement of growth is considered a sensitive surrogate of, and an important sentinel for, the potential to cause systemic effects. Growth studies designed and carried out following the recommendations in this guidance can provide adequate and well-controlled data that are consistent among drug products and can be included in product labeling. This guidance finalizes the draft guidance published on November 6, 2001.

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

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Peter Starke, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3300, Silver Spring, MD 20993-0002, 301-796-2300.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children." This guidance provides recommendations for the design, conduct, and evaluation of clinical studies to assess the effects of orally inhaled and intranasal corticosteroids on linear growth ("growth study"). The guidance was developed by the Division of Pulmonary and Allergy Products in consultation with the Division of Metabolism and Endocrinology Products and the Office of Biostatistics to encourage the collection of evidence that can consistently and accurately describe the effects of intranasal and orally inhaled corticosteroids on growth velocity in children.

In July 1998, the Pulmonary and Allergy Drugs Advisory Committee and the Metabolic and Endocrine Drugs Advisory Committee were jointly convened to discuss the implications of findings in previous clinical studies that indicated that inhaled corticosteroids can, as a class of drug products, affect linear growth in pediatric patients. The joint committee concluded that data were sufficient to justify inclusion of a precautionary statement in the labeling for this class of drug products, but the data were inadequate to precisely determine the decrement in growth velocity resulting from the use of these drug products. Members of the joint committee recommended that companies filing new drug applications for all newly approved corticosteroid products conduct further studies, as post-approval phase 4 commitments, to assess the effects of nasally and orally inhaled corticosteroids on growth velocity in prepubertal children. On November 6, 2001 (66 FR 56109), FDA

published for comment in the **Federal Register** a draft of this guidance.

Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration in finalizing this guidance. Changes are based on thorough review of all comments received, growth studies submitted since publication of the draft guidance, and previously submitted growth data. Changes or updates were made to all sections of the guidance, and are briefly summarized here.

A new overview section and updated background and data analysis sections include a more thorough discussion of the objective of and the appropriate statistical comparisons for a growth study. These changes will affect future labeling for such studies. Recommendations for sample size calculations and primary and secondary "sensitivity" analyses have been reviewed and modified based on review of growth studies submitted since publication of the draft guidance as well as previously submitted data. The general study recommendations and protocol design sections include a discussion of the appropriate patient populations to be studied and modifications to recommendations for the inclusion and exclusion criteria, assessments of adherence, and spacer use.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the evaluation of the effects of orally inhaled and intranasal corticosteroids on growth in children. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.