

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pre-test of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 15,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.016 hours), for a total of 125 hours. Fifty-four hundred (5,400) respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 2,700 hours. The total estimated burden is 2,970 hours.

Dated: February 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-3320 Filed 2-19-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC): Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Committee to the Director, Centers for Disease Control and Prevention of the Department of Health and Human Services, has been renewed for a 2-year period extending through February 1, 2012.

Contact Person for More Information: Anne C. Haddix, PhD, Designated Federal Officer, ACD, CDC, 1600 Clifton Road, NE., M/S D14, Atlanta, Georgia 30333. Telephone 404-639-0663.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 11, 2010.

Andre Tyler,

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

[FR Doc. 2010-3148 Filed 2-19-10; 8:45 am]

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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): Healthy Passages Longitudinal Study of Youth, Funding Opportunity Announcement (FOA) DP 10-007, Initial Review.

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 the aforementioned meeting:

Time and Date: 1 p.m.-3 p.m., April 20, 2010 (Closed).

Place: Teleconference.

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 initial review, discussion, and evaluation of applications received in response to "Healthy Passages Longitudinal Study of Youth, FOA DP 10-007."

Contact Person for More Information: Michael Dalmat, DRPH., Scientific Review Officer, National Center for Chronic Disease and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-6423, E-mail: MED1@cdc.gov.

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 10, 2010.

Elaine L. Baker,

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

[FR Doc. 2010-3146 Filed 2-19-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1996-N-0006] (formerly Docket No. 1996N-0277)

Safety and Efficacy Review for Additional Ingredients in Over-the-Counter Drug Products for Human Use; Request for Environmental Impact Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for data and information.

SUMMARY: We (Food and Drug Administration (FDA)) are requesting data and information regarding the potential environmental impact of amending over-the-counter (OTC) drug monographs to include certain active ingredients not previously marketed in the United States or marketed in the United States under approved applications after the OTC drug review began in 1972. Thirteen active ingredients have been found eligible for potential inclusion in OTC drug monographs based on time and extent applications (TEAs). We are currently evaluating the safety and effectiveness of these ingredients.

DATES: Submit data, information, and general comments by May 24, 2010.

ADDRESSES: Submit electronic or written data, information, and general comments in response to this document. Submit electronic comments to <http://regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993-0002, 301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Ingredients Affected by This Notice

We are currently evaluating the safety and effectiveness of 13 active ingredients found eligible for possible addition to an OTC drug monograph via the TEA process described in 21 CFR 330.14. The ingredients under review are shown in table 1 of this document:

TABLE 1.—LIST OF ACTIVE INGREDIENTS FOUND ELIGIBLE FOR POSSIBLE ADDITION TO AN OTC DRUG MONOGRAPH

Active Ingredient	Monograph	Docket No.	Eligibility
Amiloxate	Sunscreen	FDA-2003-N-0196	July 11, 2003, 68 FR 41386
Bemotrizinol	Sunscreen	FDA-2005-N-0453	December 5, 2005, 70 FR 72449
Bisocotrizole	Sunscreen	FDA-2005-N-0453	December 5, 2005, 70 FR 72449
Climbazole	Dandruff	FDA-2005-N-0021	December 5, 2005, 70 FR 72448
Diethylhexyl butamido triazone	Sunscreen	FDA-2006-O-0314	July 26, 2006, 71 FR 42405
Ecamsule ¹	Sunscreen	FDA-2008-N-0474	September 12, 2008, 73 FR 53029
Enzacamene	Sunscreen	FDA-2003-N-0196	July 11, 2003, 68 FR 41386
Octyl triazone	Sunscreen	FDA-2003-N-0196	July 11, 2003, 68 FR 41386
Piroctone olamine	Dandruff	FDA-2004-N-0037	February 18, 2004, 69 FR 7652
Sodium picosulfate	Laxative	FDA-2006-O-0057	June 22, 2006, 71 FR 35917
Sodium shale oil sulfonate	Dandruff	FDA-2009-N-0146	April 7, 2009, 74 FR 15741
Triclosan	Acne	FDA-2005-N-0454	December 5, 2005, 70 FR 72447
Triclosan ¹	Antigingivitis/Antiplaque	FDA-1981-N-0015	July 6, 2004, 69 FR 40640

¹ These ingredients are marketed under approved new drug applications (NDAs).

When our initial assessment of safety and effectiveness data for any of these ingredients is complete, we will prepare a proposed rule describing our conclusions, which may include a proposal to add the ingredient to an OTC drug monograph. Such an action would be subject to the National Environmental Policy Act of 1969 (NEPA). In order to comply with NEPA, we need data and information regarding the potential environmental impact if these ingredients are included in an OTC drug monograph, especially if this results in their use in drug products marketed in the United States for the first time (see section II of this document). We did not previously request such data and information for these 13 active ingredients. Therefore, we are requesting such data at this time. We cannot publish proposed rules for any of these 13 active ingredients until we receive this data and information.

II. Data Being Requested

As stated in 21 CFR 25.1, FDA regulations must comply with NEPA. To comply with NEPA, an environmental assessment (EA) of agency actions is required unless we determine that a categorical exclusion is warranted. Many actions on OTC drug monographs have been categorically excluded from the NEPA requirement for an EA under § 25.31(a) (21 CFR 25.31(a)), because, for active ingredients already marketed in the United States, the actions generally have not resulted in increased use of

active ingredient. However, if we amend a monograph to include a new generally recognized as safe and effective (GRASE) active ingredient not previously marketed in the United States, this exclusion would not apply because our action would increase the use of the active ingredient. This situation may occur for active ingredients found eligible for inclusion in an OTC drug monograph under the TEA process on the basis of foreign marketing experience.

Active ingredients found eligible for potential inclusion in an OTC drug monograph under the TEA process might qualify for the categorical exclusions provided under § 25.31(b) or (c). These exclusions allow for active ingredients that will not exceed 1 part per billion (ppb) (1 microgram per liter) in the aquatic environment or active ingredients that naturally occur in the environment and do not alter significantly the concentration or distribution of the ingredient, its metabolites, or degradation products in the environment.

In order to determine whether any of the active ingredients found eligible for potential inclusion in an OTC monograph meet the requirements for any categorical exclusion, including § 25.31(b) or (c), or to prepare an EA, we need additional data and information. To assist the agency, we are requesting any information that would support the application of any categorical exclusion,

or that would support the preparation of an EA, if necessary.

To estimate the expected introductory concentration of an ingredient or ingredients in the aquatic environment for purposes of § 25.31(b), please refer to section III of the CDER Guidance on Environmental Assessment of Human Drug and Biologic Applications (CDER EA Guidance Document). This guidance document can be viewed at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070561.pdf>.

To complete an EA, we need information similar to that specified in section IV of the CDER EA Guidance Document (pages 9–27). We request that a submitter segregate any data or information that the submitter believes is protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c). If such data or information is included in the submission, we request that the submitter summarize the information, to the extent possible, for public disclosure (see 21 CFR 25.50 and 25.51(a)).

III. Submission of Data

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic data, information, and general comments. Submit a single copy of electronic data, information, and general comments or two paper copies of any mailed data, information, and general comments, except that individuals may submit one paper copy. Data, information, and

general comments are to be identified with the docket number found in brackets in the heading of this document. Received data, information, and general comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-3319 Filed 2-19-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 391-404 dated January 5, 2010).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice establishes the Office of Policy Analysis (RA53) and the Office of Data Management and Research (RA54) within the Office of Planning, Analysis and Evaluation (RA5); renames the Division of Health Information Technology and Quality (RA52) as the Office of Health Information Technology and Quality (RA52); establishes the Division of Workforce Development (RB44) within the Office of Management (RB4); and renames the Division of Policy Review and Coordination as the Division of Policy and Information Coordination (RB41) within the Office of Management (RB4).

Chapter RA5—Office of Planning, Analysis and Evaluation

Section RA5-10, Organization

Delete in its entirety and replace with the following:

The Office of Planning, Analysis and Evaluation (RA5) is headed by the Director, Office of Planning, Analysis and Evaluation, within the Office of the Administrator, Health Resources and Services Administration, who reports directly to the Administrator. The Office of Planning, Analysis and Evaluation includes the following components:

(1) Immediate Office of the Director (RA5);

(2) Office of Planning and Evaluation (RA51);

(3) Office of Health Information Technology & Quality (RA52);

(4) Office of Policy Analysis (RA53); and

(5) Office of Data Management and Research (RA54).

Section RA5-20, Functions

(1) Delete the functional statement for the Office of Planning, Analysis and Evaluation (RA5) and replace in its entirety; (2) establish the Office Policy Analysis (RS53); (3) establish the Office of Data Management and Research (RA54); and renames the Division of Health Information Technology and Quality (RA52) as the Office of Health Information Technology and Quality (RA52).

Office of Planning, Analysis and Evaluation (RA5)

(1) Provides Agency-wide leadership for policy development, data collection and management, major analytic activities, research, and evaluation; (2) develops HRSA-wide policies; (3) coordinates the Agency's strategic planning process; (4) conducts and coordinates analyses, evaluation and research; (5) coordinates the Agency's intergovernmental activities; (6) maintains liaison between the Administrator, other OPDIVs, Office of the Secretary staff components, and other Departments on critical matters involving analysis of program policy undertaken in the Agency; (7) prepares policy analysis papers and planning documents as required; (8) analyzes budgetary data with regard to planning guidelines; (9) collaborates with the Office of Operations in the development of budgets, performance plans, and other administration reporting requirements; (10) conducts and/or guides the Agency's research and program evaluation; (11) provides leadership in the development of policies on health information technology and quality; and (12) provides support for the Department's Medical Claims Review Panel.

Office of Planning and Evaluation (RA51)

(1) Provides leadership in the development of the long-term Agency-wide strategic plan; (2) participates with HRSA organizations in developing strategic plans for their component; (3) conducts major program evaluation efforts; (4) provides advice and assistance to program-level HRSA components in the design and conduct of evaluations; (5) develops annual performance plans; (6) analyzes

budgetary data with regard to planning guidelines; (7) develops and produces performance reports required under the Government Performance and Accountability Report and OMB; (8) conducts the public use reports clearance function; and (9) conducts, guides, and/or participates in evaluations studies and prepares reports on HRSA program efficiencies.

Office of Health Information Technology & Quality (RA52)

(1) Provides support, policy direction, and leadership for HRSA's health quality efforts; (2) serves as the focal point for developing policy to promote the coordination and advancement of health information technology, including telehealth, to HRSA's programs, including the use of electronic health record systems; (3) develops an Agency-wide health information technology and telehealth strategy for HRSA; (4) assists HRSA components in program-level health information technology and health quality efforts; (5) ensures successful dissemination of appropriate information technology advances, such as electronic health records systems, to HRSA programs; (6) works collaboratively with States, foundations, national organizations, private sector providers, as well as departmental agencies and other Federal departments in order to promote the adoption of health information technology and health quality policy; (7) ensures the health information technology policy and activities of HRSA are coordinated with those of other HHS components; (8) assesses the impact of health information technology and quality initiatives in the community, especially for the uninsured, underserved, and special needs populations; (9) translates technological advances in health information technology to HRSA's programs; (10) provides guidance in using the results of the medical claims review process to HRSA programs to improve quality; and (11) provides support for the Department's Medical Claims Review Panel.

Office of Policy Analysis (RA53)

(1) Serves as the principal Agency resource for policy analysis; (2) analyzes issues arising from legislation, budget proposals, regulatory actions, and other program or policy actions; (3) serves as focal point within HRSA for analysis of healthcare payment systems and financing issues; (4) collaborates with HHS Agencies to examine the impact of Medicare, Medicaid, and Children's Health Insurance Program (CHIP) on HRSA grantees and safety net providers;