ANNUALIZED SUMMARY TABLE—Continued

Respondents	Number of respondents	Responses/ respondent	Total responses	Total annualized hour burden
Campus Staff	152	7	152	206
Total	132,060	49	133,890	26,444

Written comments and recommendations concerning the proposed information collection should be sent by July 2, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: May 25, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–13146 Filed 6–1–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: Screening, Brief Intervention, Brief Treatment and Referral to Treatment (SBIRT) Cross-Site Evaluation—New

SAMHSA is conducting a cross-site external evaluation of the impact of programs of screening, brief intervention (BI), brief treatment (BT) and referral to treatment on patients presenting at various health care delivery units with a continuum of severity of substance use. SAMHSA's SBIRT program is a cooperative agreement grant program designed to help States and Tribal Councils expand the continuum of care available for substance misuse and use disorders. The program includes screening, brief intervention, brief treatment and referrals to treatment for persons at risk for dependence on alcohol or drugs. The cross-site evaluation will provide a comprehensive assessment of the effects of SBIRT on patient outcomes, performance site practices, and treatment systems. This information will allow SAMHSA to determine the extent to which SBIRT has met its objectives of implementing a comprehensive system of identification and care to meet the needs of individuals at all points along the substance use continuum.

A paper and pencil survey will be administered to practitioners in sites where SBIRT services are being delivered. The practitioner survey is designed to evaluate the implementation of proposed SBIRT models by measuring their penetration and practitioners' willingness to adopt. Furthermore, the survey will document moderating factors related to practitioner and health care delivery unit characteristics.

The 93 question practitioner survey includes collection of demographic information as well as questions that attempt to assess barriers to implementation encountered by the practitioners and to gauge the effectiveness of the training they received. These measures were developed and used by Babor *et al.* (2005) in their comparable study comparing different implementation strategies for primary care screening and brief intervention programs for hazardous and harmful drinkers. The practitioner survey also includes an instrument developed by Panzano and Roth (2006) to measures an organization's willingness to adopt new innovative practices.

TOTAL BURDEN HOURS FOR THE CROSS-SITE PATIENT SURVEY

Instrument/Activity	Number of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage	Total respondent cost [a]
Practitioner Survey	1,075	1	.30	322.5	$32	$10,320

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 25, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–13145 Filed 6–1–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–N–0196] (formerly Docket No. 2003N–0233)

Drometrizole Trisiloxane Eligibility for Potential Inclusion in Sunscreen Monograph; Over-the-Counter Sunscreen Drug Products for Human Use; Request for Safety, Effectiveness, and Environmental Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: As part of our ongoing review of over-the-counter (OTC) drug products, we (Food and Drug Administration, FDA) are announcing a call-for-data for safety, effectiveness, and environmental information for drometrizole trisiloxane, in concentrations up to 15 percent, as a sunscreen single active ingredient and in combination with generally recognized as safe and effective (GRASE) sunscreen active ingredients found in the sunscreen monograph. We reviewed a time and extent application (TEA) for drometrizole trisiloxane and determined that it is eligible to be considered for inclusion in our OTC drug monograph system. We will evaluate the submitted safety and effectiveness data and information to determine whether drometrizole trisiloxane can be GRASE for its proposed OTC use. We also request data and information to assess the projected environmental effects of a potential GRASE determination in order to assist us in complying with the requirements of the National Environmental Policy Act of 1969 (NEPA).

DATES: Submit data, information, and general comments by August 31, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2003–N–0196, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Anita Kumar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5445, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Eligibility of Drometrizole Trisiloxane

In January 2009, we received a TEA (Ref. 1) requesting that drometrizole trisiloxane be found eligible for review and potential inclusion in our OTC sunscreen drug monograph (part 352 (21 CFR part 352)). After reviewing the TEA, we believe that it includes adequate data demonstrating that drometrizole trisiloxane has been marketed for the prevention of sunburn for a material time and to a material extent as required by § 330.14 (21 CFR 330.14) (Ref. 2). Drometrizole trisiloxane-containing sunscreen products indicated for the prevention of sunburn have been marketed directly to consumers for over 5 continuous years in 40 countries, with over 177 million dosage units marketed in 54 countries. Therefore, we conclude that drometrizole trisiloxane, in concentrations up to 15 percent, is eligible to be considered for potential inclusion in the OTC sunscreen drug monograph as a single active ingredient and in combination with GRASE sunscreen active ingredients found in § 352.10.

II. Request for Data and Information

We invite all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of drometrizole trisiloxane for use as an active ingredient in OTC sunscreen products. The data should be sufficient so that we can determine whether the ingredient can be GRASE and not misbranded under recommended conditions of OTC use. Interested parties may refer to 21 CFR 330.10(a)(4) regarding the evidence necessary for establishing general recognition of safety and effectiveness.

Because the TEA that we reviewed did not include an official or proposed United States Pharmacopeia-National Formulary (USP–NF) drug monograph for drometrizole trisiloxane, we are asking interested parties to provide such a monograph to us. An active ingredient must be recognized in an official USP–NF drug monograph that sets forth its standards of identity, strength, quality, and purity in order to be included in a final OTC monograph (§ 330.14(i)).

In addition, 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. Therefore, we also invite all interested persons to either submit data and information that would support a determination that the potential inclusion of drometrizole trisiloxane in the OTC monograph for sunscreen meets the requirements for any categorical exclusion found in 21 CFR 25.31, or to prepare an EA, if necessary. For additional information on the types of information that would support our environmental assessment, please refer to section IV (pages 9 through 27) of the Center for Drug Evaluation and Research Guidance on Environmental Assessment of Human Drug and Biologic Applications. The guidance document can be viewed at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070561.pdf*.

For all data and information submitted, we request that a submitter segregate any data or information that the submitter believes is protected from disclosure by 5 U.S.C. 552(b), 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 confidential information, to the extent possible, so that the summary can be publicly disclosed (see 21 CFR 25.50 and 25.51(a); § 330.14(f)).