will be collected in 6 community mental health sites. This project will collect data from clients using a brief survey administered on a voluntary basis. Collection of data will provide information on client demographics; current behaviors that may facilitate HIV transmission, including sexual and drug-use behaviors; current psychiatric symptoms, determined using brief rating scales; access and barriers to HIV testing, prevention, and treatment services; and adherence to psychiatric and medical treatment regimens.

CDC estimates the response rate will be approximately 90%. Of the 644 persons approached who agree to be surveyed, it is estimated that 95% of persons will meet the eligibility criteria and 98% will be able to provide informed consent. Therefore, the goal will be to approach 716 persons annually for participation in the study. The structured interview will take approximately 20 minutes to complete. Participation is voluntary. Data collection will provide important insights into the relationship between HIV/STI risk behaviors and psychiatric illness.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Approached Individual	Eligibility Screener	644	1	1/60	11
Eligible participant	Consent Questionnaire	612	1	10/60	102
Consented participant	Core Questionnaire	600	1	20/60	200
Total					313

Marilyn S. Radke,

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

[FR Doc. E8–17775 Filed 8–1–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Public Comment on Tribal Consultation Session To Be Held on September 11, 2008, in Phoenix, AZ

AGENCY: Office of Head Start (OHS).

ACTION: Notice of Public Comment on Tribal Consultation Session to be held on September 11, 2008, in Phoenix, Arizona.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of a one-day Tribal Consultation Session to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal governments operating Head Start (including Early Head Start) programs. The purpose of the Consultation Session is to discuss ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

Date & Location: The Consultation Session will be held on September 11, 2008, at the Hyatt Regency Phoenix in Phoenix, Arizona.

FOR FURTHER INFORMATION CONTACT: Renée Perthuis, Acting Regional Program Manager, American Indian/Alaska Native Program Branch, Office of Head Start, e-mail *reneeaian@acf.hhs.gov* or (202) 260–1721. Register to attend the Consultation Session online at *www.hsnrc.org.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services would like to invite leaders of Tribal governments operating Head Start (including Early Head Start) programs to participate in a formal Consultation Session with OHS leadership. The Consultation Session will take place on Thursday, September 11, 2008, at the Hyatt Regency Phoenix in Phoenix, Arizona.

The purpose of the Consultation Session is to solicit input on ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Specific topics will include policy, research, Head Start/Early Head Start conversion, program quality, and monitoring.

Tribal leaders and designated representatives interested in submitting written testimony or topics for the Consultation Session agenda should contact Renée Perthuis at *reneeaian@acf.hhs.gov.* The proposal agenda topics should include a brief description of the topic area along with the name and contact information of the suggested presenter.

The Consultation Session will be conducted with elected or appointed leaders of Tribal governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)]. Representatives from Tribal organizations and Native non-profit organizations are welcome to attend as observers. Those wishing to participate in the discussions must have a copy of a letter signed by an elected or appointed official or their designee, which authorizes them to serve as a representative of the Tribe. This should be submitted not less than three days in advance of the Consultation Session to Renée Perthuis at 202–205–9721 (fax).

A detailed report of the Consultation Session will be prepared and made available within 90 days of the consultation to all Tribal governments receiving funds for Head Start (including Early Head Start) programs.

Dated: July 29, 2008.

Patricia Brown,

Acting Director, Office of Head Start.

[FR Doc. E8–17774 Filed 8–1–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0387]

Draft Guidance for Industry on Labeling OTC Skin Protectant Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Skin Protectant Drug Products.'' This guidance provides recommendations on how to label over-the-counter (OTC) skin protectant drug products. An OTC skin protectant active ingredient can be combined with another OTC skin protectant active ingredient or OTC external analgesic, first aid antiseptic, or sunscreen active ingredients. Each of these combinations has specific labeling requirements, and therefore labeling of OTC skin protectant drug products is complex. This guidance is designed to clarify the permitted combinations of active ingredients along with the corresponding required labeling.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 3, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5424, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Skin Protectant Drug Products.'' In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA published a final rule establishing conditions under which OTC skin protectant drug products are generally recognized as safe and effective and not misbranded. In developing this final rule, FDA acknowledged the complex task that manufacturers of these products would face in meeting all the pertinent labeling requirements. This draft guidance provides recommendations on how to meet current labeling requirements according to OTC skin protectant active ingredient.

Because OTC skin protectant active ingredients can be combined with active ingredients from other OTC drug product categories, this draft guidance is based upon the following rulemakings: (1) Final rule for OTC skin protectant drug products (68 FR 33362, June 4, 2003); (2) final rule for format and content of labeling of OTC drugs (64 FR 13254, March 17, 1999); (3) proposed rule for OTC sunscreen drug products (72 FR 49070, August 27, 2007); (4) proposed rule for OTC external analgesic drug products (48 FR 5852, February 8, 1983); and (5) proposed rule for OTC first aid antiseptic drug products (56 FR 33644, July 22, 1991).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on labeling OTC skin protectant drug products. 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 regarding this document. 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 numbers 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: July 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17835 Filed 8–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review: Comment Request; Revision of OMB No. 0925–0002/exp. 10/31/08, Individual Ruth L. Kirschstein National Research Service Award Applications and Related Forms

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 12, 2008, Volume 73, No. 49, page 13242 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Individual Ruth L. Kirschstein National Research Service Award Applications and Related Forms; *Type of Information Collection Request:* Revision, OMB 0925–0002, Expiration Date 10/31/08. Form Numbers: PHS 416–1, 416–9, 416–5, 416–7, 6031, 6031–1.

Need and Use of Information Collection: The 416–1 and 416–9 are used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The other related forms (PHS 416–5, 416–7, 6031, 6031–1) are used by these individuals to activate, terminate, and provide for payback of a National Research Service Award.