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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Skin Protectant Drug Products.''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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 3, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Skin Protectant Drug Products.''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.

Frequency of response: Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed. *Affected Public:* Individuals or Households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* Adult scientific trainees and professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:* 34,454; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 4.1; and *Estimated Total Annual Burden Hours Requested:* 142,301. The annualized cost to respondents is estimated at: $4,980,535.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be sent via e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie, Project Clearance Branch, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Suite 350, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number (301) 435–0941, or e-mail your request, including your address to: *curriem@od.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: July 24, 2008.

Pam Gilden,

Division of Grants Policy, Office of Policy for Extramural Research Administration, Office of Extramural Research, National Institutes of Health.

[FR Doc. E8–17727 Filed 8–1–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Antibodies and Antisera Recognizing Members of the ArfGap Family of Proteins

Description of Technology

The technology involves antibodies and antisera that recognize members of the ArfGap protein family, including the following proteins:

- ACAP1, which is related to ASAP1, a putative oncogene that regulates cancer cell invasion into normal tissues. ACAP1 regulates integrins, which are critical for cell movement associated with cancer cell invasion and is a target of the oncogene Akt.
- ACAP2, which is related to ASAP1, a putative oncogene that regulates cancer cell invasion into normal tissues.
- AGAP2 (also known as PIKE–A), ASAP1 (also called AMAP1 and DDEFl), and ASAP3 all exhibit elevated expression levels in cancer cells compared to non-transformed cells and as putative oncogenes have been implicated as regulators of cancer cell invasion into normal tissues and contributors to brain, eye and breast, and liver cancers, respectively.
- ARAP1 (also called Centaurin Delta 2), which has been implicated as a regulator of epidermal growth factor receptor, which plays important roles in several malignancies.
- ARAP2 (also called Centaurin Delta 1), GIT1 and GIT2; all three of which have been implicated as regulators of cell migration required for cancer cell invasion into normal tissues and metastasis.
- ARAP3, a target of the Src oncogene, has been implicated as a regulator of cell movement and signaling.
- ArfGAP1, which is critical to cell function, including protein trafficking.
- ASAP2 (also known as PAG3 or as Pap in the 1999 Molecular and Cellular Biology publication), is highly related to ASAP1, which has been implicated as a regulator of cancer cell invasion into normal tissues.

The table below summarizes the antibodies and antisera available against different ArfGap proteins. Each material has been raised or generated to the peptide sequence listed.

ANTIBODIES AND ANTISERA RECOGNIZING ARFGAP PROTEINS

ArfGap member	Antibody/serum ID (Alt. Name)	Antibody source	Peptide sequence (ID)	HHS Ref. No.
ACAP1	1241 (Arf6-specific GAP)	Rabbit	RPRGQPPVPPKPSIR(556)	E–244–2008/0
ACAP2	1288	Rabbit	REKGDESEKLDKKSS(365)	E–242–2008/0
AGAP2	4569, 4571	Rabbit	ERVDDPELQDSI and PLSREPPPSPMVKKQ (483)	E–222–2008/0
ARAP1	1153	Rabbit	SLIPLRGSENEMRRSV	E–220–2008/0