''Cosmetic Product Ingredient Statement,'' and on Form FDA 2512a, a continuation form. Amendments to product formulations (§ 720.6) also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, we request that the firm file Form FDA 2514, ''Notice of Discontinuance of Commercial Distribution of Cosmetic Product Formulation'' (§§ 720.3 and 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA's online filing system is available on FDA's VCRP Web site at *http://www.fda.gov/Cosmetics/RegistrationProgram/OnlineRegistration/ucm100241.htm.* The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512.

We place cosmetic product filing information in a computer database and use the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, voluntary filings provide us with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists our scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. We also use the information in defining and planning analytical and toxicological studies pertaining to cosmetics.

Information from the database is releasable to the public under our compliance with the Freedom of Information Act. We share nonconfidential information from our files on cosmetics with consumers, medical professionals, and industry.

In the **Federal Register** of February 6, 2014 (79 FR 7196), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section or Part	Form no.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Part 710 (registrations)	FDA 2511 [2]	81	1	81	0.2	16
720.1 through 720.4 (ingredient statements for new submissions).	FDA 2512 [3]	4,877	1	4,877	0.33	1,609
720.6 (amendments)	FDA 2512	1,042	1	1,042	0.17	177
720.6 (notices of discontinuance).	FDA 2512	1,826	1	1,826	0.1	183
720.8 (requests for confidentiality).		1	1	1	2.0	2.0
Total						1,987

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] The term ''Form FDA 2511'' refers to both the paper Form FDA 2511 and electronic Form FDA 2511 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at *http://www.fda.gov/Cosmetics/RegistrationProgram/OnlineRegistration/ucm090947.htm.*

[3] The term ''Form FDA 2512'' refers to the paper Forms FDA 2512, 2512a, and 2514 and electronic Form FDA 2512 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at *http://www.fda.gov/Cosmetics/RegistrationProgram/OnlineRegistration/ucm100241.htm.*

We base our estimate of the total annual responses on paper and electronic submissions received during calendar years 2011, 2012 and 2013. We base our estimate of the hours per response upon information from cosmetic industry personnel and our experience entering data submitted on paper Forms 2511, 2512, 2512a, and 2514 into the electronic system.

We estimate that, annually, 81 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 81 annual responses. Each submission is estimated to take 0.2 hour per response for a total of 16.2 hours, rounded to 16. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 4,877 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.33 hour per response for a total of 1,609.41 hours, rounded to 1,609. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 1,042 amendments to product formulations on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.17 hour per response for a total of 177.14 hours, rounded to 177. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 1,826 notices of discontinuance on Form FDA 2514. Each submission is estimated to take 0.1 hour per response for a total of 182.6 hours, rounded to 183. We estimate that, annually, one firm will file one request for confidentiality. Each such request is estimated to take 2 hours to prepare for a total of 2.0 hours. Thus, the total estimated hour burden for this information collection is 1,987 hours.

Dated: April 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09692 Filed 4–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Pediatric Clinical Investigator Training Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics (OPT) and the Center for Drug Evaluation and Research are announcing a 1-day public

workshop entitled ''Pediatric Clinical Investigator Training.'' The purpose of this workshop is to provide investigators with training and expertise in designing and conducting clinical trials in pediatric patients that will lead to appropriate labeling. The training course is intended to provide investigators with a clear understanding of some of the challenges of studying products in the pediatric population when the data are intended to be used to support product labeling, an overview of extrapolation as it relates to the pediatric population, a familiarity with FDA processes and timelines that are specific to pediatric product development, and an overview of ethically appropriate methods related to the design of clinical trials in the pediatric population.

DATES: The public workshop will be held on September 22, 2014, from 8 a.m. to 5:30 p.m.

ADDRESSES: The public workshop will be held at the Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. The hotel's telephone number is 301–897–9400.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8646, FAX: 301–847–8640, email: *terrie.crescenzi@fda.hhs.gov;* or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8659, FAX: 301–847–8640, *elizabeth.sanford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) made permanent the pediatric initiatives, Best Pharmaceuticals for Children Act and Pediatric Research Equity Act, which have stimulated pediatric research over the past 15 years. Though much progress has been made, pediatric trials for the purpose of developing product use parameters and information are still performed much less frequently than adult trials. As such, current standards for trials are much more oriented to adult scientific, ethical, and clinical processes. This situation is due, in part, to the fact that pediatric trials have a number of unique attributes and requirements, which must be met if the data are to be accepted or used by FDA.

The development of safe and effective products in the pediatric population presents many challenges. These challenges include trial design, appropriate endpoints, extrapolation of data from adults, and ethical issues. It is extremely important that pediatric researchers recognize and understand the challenges and differences between the standards for adult trials and pediatric trials. Researchers are responsible for ensuring the safe and ethical treatment of pediatric patients and obtaining adequate and reliable data to support regulatory decisions. There is a critical need for further pediatric research on medical products to obtain additional data, which will help ensure that these products are safe and effective in the pediatric population. We are able to obtain data and information in older children; however, the challenge of obtaining data from non-verbal children and neonates is much more difficult. This need reinforces our responsibility to educate clinical investigators to assure that children are only enrolled in research that is scientifically necessary, ethically sound, and designed to meet the challenges of review by FDA.

II. Participation in the Public Workshop

A. Registration

There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online by sending an email to *OPT@fda.hhs.gov* before September 8, 2014, and include the following information: Name, title, affiliation, email address, and telephone number. For those without Internet access, please contact Terrie L. Crescenzi or Betsy Sanford (see **FOR FURTHER INFORMATION CONTACT**) to register. In the event that a minimum number of participants have not registered, the workshop will be postponed. Registered participants will be notified of any change. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

Registration information, the agenda and additional background materials can be found at *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm.*

If you need special accommodations due to a disability, please contact Betsy Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

B. Videotaping

The workshop will be videotaped and available on the Internet at *http://wcms.fda.gov/FDAgov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm?ssSourceSiteId=null&SSContributor=true,* approximately 30 days after the workshop.

Dated: April 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09695 Filed 4–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Opportunity Number: HHS–2014–IHS–INMED–0001; CFDA Number: 93.970]

Funding Opportunity: American Indians Into Medicine

Announcement Type: New and Competing Continuation.

Key Dates

Application Deadline: June 13, 2014.
Review Date: June 25, 2014.
Earliest Anticipated Start Date: September 1, 2014.
Proof of Non-Profit Status Due Date: June 13, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive grant applications for the Indians into Medicine Program (INMED). This program is authorized under the authority of 25 U.S.C. 1616g, Indian Health Care Improvement Act, Public Law 94–437, as amended (IHCIA). This program is described in the Catalog of Federal Domestic Assistance under 93.970.

Background

The IHS, an agency within the Department of Health and Human Services (HHS), is responsible for providing Federal health services to American Indians and Alaska Natives (AI/AN). The mission of the IHS is to raise the physical, mental, social, and spiritual health of AI/AN. The IHCIA authorizes the IHS to administer programs that are designed to attract and recruit qualified individuals into health professions needed at IHS facilities. The programs administered are designed to encourage AI/AN to enter health professions and to ensure the availability of health professionals to serve AI/AN populations.