requests on the behalf of both collaborating agencies. Data for the study is collected from the following three major sources: Baseline forms, follow-up surveys (at 6, 12, and 30 months after study entry), and implementation research and site visits. Data collection for all but one STED site has been reviewed and approved by OMB (see OMB #0970–0413). This notice is specific to the request for approval of the contact information form and baseline information form for the new STED site. These forms will collect important demographic and other information from all study participants in this site prior to the point of random assignment. These data will be important for describing the study sample and for estimating program effects for particular groups of interest.

Respondents: Study participants in the treatment and control groups at one additional STED site.

ANNUAL BURDEN ESTIMATES—NEW INSTRUMENTS

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Participant contact information form	4,002	1,334	1	.08	107
Participant baseline information form	4,002	1,334	1	.25	334
Total					441

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Karl Koerper,

OPRE Reports Clearance Officer.

[FR Doc. 2015–16283 Filed 7–1–15; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee Data Submission System for Formula Funds Allocations.

OMB No.: 0970–0043.

Description: The Refugee Data Submission System for Allocation of Formula Funds is designed to satisfy the statutory requirements of the Immigration and Nationity Act (INA). Section 412(a)(3) of the Act requires that the Director of the Office of Refugee Resettlement (ORR) make a periodic assessment of the needs of refugees for assistance and services and the resources available to meet those needs. This assessment includes compiling and maintaining data on secondary migration of refugees within the United States after arrival. Further, INA 412(c)(1)(B) states that formula funds shall be allocated based on the total number of refugees in each State, taking into account secondary migration. In order to meet these statutory requirements, ORR requires each State to submit disaggregated individual records containing certain data elements for eligible populations. ORR uses the information collected through the Web site to determine secondary migration for the purposes of formula funds allocation to States. The submission of individual records via the Refugee Data Submission System for Allocation of Formula Funds is a reliable and secure process for collecting data for the purposes of tracking secondary migration and allocating formula funds. Data submitted by the States via the Web site are also compiled and analyzed for inclusion in ORR's Annual Report to Congress.

Respondents: States, Wilson/Fish Alternative Projects, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Data Submission for Formula Funds Allocations	50	1	20	1,000

Estimated Total Annual Burden Hours: 1,000.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be

identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–16285 Filed 7–1–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

New Methods To Predict the Immunogenicity of Therapeutic Coagulation Proteins; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''New Methods to Predict the Immunogenicity of Therapeutic Coagulation Proteins''. The purpose of the public workshop is to discuss recent scientific progress in identifying the genetic determinants for an unwanted immune response to therapeutic coagulation proteins (immunogenicity), and to identify and discuss potential new methods to predict such immunogenicity. Immunogenicity results in the development of antibodies that target the therapeutic protein and can affect the safety and efficacy of the biological product. The workshop has been planned in partnership with the National Heart, Lung and Blood Institute, National Institutes of Health (NIH), the National Hemophilia Foundation, and the Plasma Protein Therapeutics Association. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government Agencies.

Date and Time: The public workshop will be held on September 17, 2015, from 8:30 a.m. to 5 p.m. and on September 18, 2015, from 8:30 a.m. to 12 p.m.

Location: The public workshop will be held at the Ruth Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health Campus, 9000 Rockville Pike, Bethesda, MD 20892. The entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center located adjacent to the Medical Center Metro, where routine security check procedures will be performed. Please visit the following Web site for location, parking, security, and travel information: *http://www.nih.gov/about/visitor/index.htm.* Please visit the following Web site for information on the Natcher Conference Center: *http://www.genome.gov/11007522.*

Contact Person: Freddy Barnes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–6943, *William.Barnes@fda.hhs.gov.* For questions email: *CBERPublicEvents@fda.hhs.gov* (Subject line: FDA MPICPDT Workshop).

Registration: Please visit the following Web site to register for the workshop by August 27, 2015: *http://methodspredictimmunogenicity.eventbrite.com.* There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8:15 a.m.

If you need special accommodations due to a disability, please contact Freddy Barnes (see *Contact Person*) at least 7 days in advance.

Supplementary Information: The development of unwanted immune responses to therapeutic coagulation protein products may affect both product efficacy and patient safety. In the case of replacement coagulation protein therapies, the inhibitory anti-drug antibodies also interact with the endogenous protein and may result in serious adverse events in patients. Both product and patient specific factors may affect the immunogenicity of therapeutic coagulation protein products. There are currently several initiatives underway to assess the genetic basis for developing unwanted immune responses to coagulation protein products in individuals with hemophilia, which will result in the accumulation of large data sets over the next few years. The workshop aims to address what patients, healthcare professionals and regulators may do with this information to improve patient outcomes.

In addition, an unprecedented number of new engineered recombinant coagulation proteins are in development. This workshop will discuss the state-of-the art with respect to leveraging scientific progress to predict the immunogenicity of protein amino acid sequences that do not exist in nature, and whether there is a need for novel strategies in the design and conduct of clinical trials for these products.

The first day of the workshop will include presentations and panel discussions on the following topics: (1) Overview of the current understanding of genetic factors that affect immunogenicity of therapeutic coagulation proteins; (2) recent advances in immunology relevant to immunogenicity; (3) emerging computational, in vitro and ex vivo tools to predict the immunogenicity of therapeutic coagulation proteins and how these tools may be evaluated in a clinical setting; and (4) initiatives to determine the genetic factors that affect immunogenicity of coagulation protein products in individuals with hemophilia and strategies to optimize the outcome data.

The second day of the workshop will include presentations and panel discussions on the following topics: (1) Challenges related to the development of novel recombinant coagulation protein products; (2) a round-table discussion and question and answer session; and (3) workshop summary.

Transcripts: Please be advised that as soon as possible after a transcript of this public workshop will be available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm438035.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: June 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16365 Filed 7–1–15; 8:45 am]

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