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.

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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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