- Quality Metrics Beyond Compliance To Drive Strategic Value
- Risk Categorization of Your Company
- Challenges That Lie Outside U.S. Borders
- Global Supply Chain Risk Management Case Studies
- FDA Investigator Insights

The conference includes:

- Networking by topic
- Case studies
- Small group discussions
- Action plans
- Keynote dinner at the Newport Aquarium

The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the ongoing health and safety of patients. These challenges include designing products with the patient in mind, building quality into the product from the onset, selecting the right suppliers, and considering total product lifecycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job right the first time. FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices.

The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: January 21, 2015.

Leslie Kux,

Associate Comissioner for Policy.

[FR Doc. 2015–01418 Filed 1–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Discretionary Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: February 12, 2015, 8:30 a.m. to 5:00 p.m.; February 13, 2015, 9:00 a.m. to 4:00 p.m.

Place: Webinar and In-Person, National Institutes of Health, 5635 Fishers Lane, Rockville, Maryland 20857.

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webinar. Whether attending in-person or via webinar, all participants must register for the meeting. The registration link will be made available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/.* The registration deadline is Friday, January 30, 2015, 11:59 p.m. Eastern Time.

Purpose: The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act (PHS), 42 U.S.C. 217a: Advisory councils or committees, was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) A final report on the Mucopolysaccharidosis 1 (MPS 1) Condition Nomination for inclusion on the Recommended Uniform Screening Panel (RUSP), (2) a final report on the Laboratory Procedures and Standards Subcommittee's Timely Newborn Screening Project, (3) a presentation from the U.S. Preventive Services Task Force on the transfer of newborn screening topics (sickle cell disease, phenylketonuira, congenital hypothyroidism) to the Committee, (4) update on the condition review of Adrenoleukodystrophy (ALD), (5) update from the Pilot Study Workgroup and discussion on the different mechanisms and challenges for implementing pilot studies, (6) presentation on analyzing costs when implementing screening for a new condition, (7) presentation by the Newborn Screening Translational Research Network Long-term Follow-up Project, and (8) updates on priority projects from the Committee's subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training.

The Committee is expected to vote on whether or not to recommend to the Secretary the addition of MPS 1 to the RUSP. Tentatively, the Committee is expected to review and/or vote on the final recommendations on timely newborn screening. Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Registration information will be on the Committee Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.* The registration deadline is Friday, January 30, 2015, 11:59 p.m. Eastern Time. Written comments must be received by the deadline in order to be included in the February meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.,* parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single

representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: *lvasquez@hrsa.gov.*

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: *dsarkar@hrsa.gov.*

More information on the Advisory Committee is available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2015–01351 Filed 1–26–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 Day Comment Request; Evaluation of the NHLBI Proteomics Centers Program: Qualitative Interviews (NHLBI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Pothur Srinivas, Ph.D., Project Officer/ICD Contact, Two Rockledge Center, 6701 Rockledge Drive, Room 10188, MSC 10193, Bethesda, MD 20892, or call non-toll-free number (301) 435–0550, or Email your request to: *srinivap@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Evaluation of the NHLBI Proteomics Centers Program: Qualitative Interviews 0925–New, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: The Proteomics Centers Program was established in 2010 with the goal of applying proteomic approaches to gain a better mechanistic understanding of the physiologic pathways underlying defined clinical conditions related to heart, lung, and blood diseases. The primary goal of the program is to help facilitate a better understanding of the underlying mechanisms in heart, lung, and blood diseases which could contribute to more effective diagnoses, risk stratification, intervention, and prevention. Given the rapid developments in proteomic technologies and approaches in the last five years, it is important to determine the extent to which the efforts of the centers have matured, leading to discovery of new targets for intervention and clinically actionable tool sets. An eighteen-month outcome evaluation will coincide with the completion of funding for the program. This information collection request is being made for one component of this evaluation: Semi-structured interviews with key informants across four targeted groups, internal and external to the program. The results of the evaluation will help determine the extent to which these desired outcomes were achieved as well as to inform future of proteomics research funding and commitments by the NHLBI. The key informant interviews are necessary to understand the perspectives of internal and external program stakeholders as it relates to the success, limitations, and opportunities that can shape future research funding.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 48.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Principal investigators and key personnel	27	1	50/60	23
External Proteomics investigators	9	1	50/60	8
Trainees and junior investigators	20	1	50/60	17

Dated: January 14, 2015.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–01421 Filed 1–26–15; 8:45 am]

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