

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2014, THROUGH MARCH 31, 2014—Continued

PMA No., Docket No.	Applicant	Trade name	Date of action
P090031, FDA-2014-M-0254 .....	Anika Therapeutics, Inc .....	MONOVISC™ Intra-articular Device.	Approved February 25, 2014.
P130015, FDA-2013-M-0326 .....	Roche Diagnostics Operations, Inc.	Elecsys® HBeAg Immunoassay and Elecsys® PreciControl HBeAg.	Approved March 14, 2014.

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>.

Dated: September 19, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-22807 Filed 9-24-14; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NICHD)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 Thursday, July 3, 2014, Vol. 79, No. 128, page 38047-38049 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 *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), 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.

**DATES:** *Comment 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.

**ADDRESSES:** 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 directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sarah L. Glavin, Project Clearance Liaison, Office of Science Policy, Analysis and Communication, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496-1877 or Email your request, including your address to *glavins@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

#### SUPPLEMENTARY INFORMATION:

*Proposed Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NICHD), 0925-0643, Expiration Date 10/31/2014, EXTENSION, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

*Need and Use of Information Collection:* There are no changes being requested for this submission. The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide information about the NICHD's customer or stakeholder perceptions, experiences and expectations, provide an early

warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the NICHD and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the NICHD's services will be unavailable.

The NICHD will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections

will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic

mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,950.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Estimated annual reporting burden

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Conference/Training—Pre and Post Surveys .....	100	1	15/60	25
Usability Testing .....	100	1	30/60	50
Focus Groups .....	750	1	1	750
Customer Satisfaction Survey .....	13,500	1	15/60	3,375
In-depth Interviews or Small Discussion Group .....	750	1	1	750
<b>Total .....</b>	<b>15,200</b>	<b>.....</b>	<b>.....</b>	<b>4,950</b>

Dated: September 18, 2014.

**Sarah L. Glavin,**

*Project Clearance Liaison, Office of Science Policy, Analysis, and Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.*

[FR Doc. 2014-22867 Filed 9-24-14; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-day Comment Request; Office of Minority Health Research Coordination Research Training and Mentor Program Applications**

**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 Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted 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 to address 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,