2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* May 14, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for GADAVIST (NDA 201–277) was initially submitted on May 14, 2010.

3. *The date the application was approved:* March 14, 2011. FDA has verified the applicant's claim that NDA 201–277 was approved on March 14, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,470 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by March 24, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 22, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, you must submit two copies of the written petition. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA 2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01307 Filed 1–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Customer and Other Partners Satisfaction Surveys

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health Clinical Center (CC) 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 November 6, 2013, pp. 66750–66751, 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 National Institutes of Health Clinical Center (CC), 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.

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.

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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact Dr. David K. Henderson, Deputy Director for Clinical Care, National Institutes of Health Clinical Center, Building 10, Room 6–1480, 10 Center Drive, Bethesda, Maryland 20892, or call non-toll free: 301–496–3515, or email your request or comments, including your address to: < *dkh@nih.gov* >. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Title: Generic Clearance for Surveys of Customers and Other Partners, 0925–0458, Expiration Date 12/31/2013, Type of Submission: REINSTATEMENT WITHOUT CHANGE, National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the perceptions of various Clinical Center customers and other partners of Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; (4) to evaluate the perceptions of various Clinical Center customers and other partners of implemented service modifications, and (5) for hospital accreditation. These surveys are voluntary and necessary for the proper performance of Clinical Center functions and will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected via the web or by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,900.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
FY 2014				
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138
FY 2015				
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138
FY 2016				
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138

Dated: January 14, 2014.

David K. Henderson,

Deputy Director for Clinical Care, CC, National Institutes of Health.

[FR Doc. 2014–01343 Filed 1–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Improved Therapeutic Immunotoxins

Description of Technology: Immunotoxins kill cancer cells while allowing healthy, essential cells to survive. As a result, patients receiving immunotoxins are less likely to experience the deleterious side-effects associated with non-discriminate therapies, such as chemotherapy or radiation therapy. Unfortunately, the continued administration of immunotoxins often leads to a reduced patient response due to the formation of neutralizing antibodies against immunogenic epitopes contained within the toxin. One such toxin is Pseudomonas exotoxin A (PE). To improve the therapeutic effectiveness of PE-based immunotoxins through multiple rounds of drug administration, NIH inventors previously reduced the immunogenicity of PE through the removal of B-cell and T-cell epitopes by mutation or deletion. Although this resulted in immunotoxins with improved therapeutic activity, the modifications to reduce immunogenicity decreased the activity of PE. Through further specific modification, the inventors have now created a PE that has reduced immunogenicity with limited loss of activity. The resulting PE-based immunotoxins have increased resistance to the formation of neutralizing antibodies, while retaining greater activity, and are expected to have improved therapeutic efficacy.

Potential Commercial Applications:

- Essential payload component of immunotoxins
- Treatment of any disease associated with increased or preferential expression of a specific cell surface receptor
- Specific diseases include hematological cancers, lung cancer, ovarian cancer, breast cancer, and head and neck cancers

Competitive Advantages: