polypeptide capsule of poly-γ-D-glutamic acid (γDPGA). γDPGA is poorly immunogenic and has antiphagocytic properties. The bacterial capsule is essential for virulence. Antibodies to the capsule have been shown to enhance phagocytosis and killing of encapsulated bacilli. These antibodies in combination with antibodies that neutralize the toxins of *B. anthracis* could provide enhanced protection by their dual antibacterial and antitoxic activities. Such antibodies would be especially useful for antibiotic-resistant strains.

In order to obtain therapeutically useful anti-γ DPGA monoclonal antibodies (MAbs), the inventors immunized chimpanzees with conjugates of 15-mer glutamic acid polymers to immunogenic protein carriers (recombinant protective antigen (PA) of *B. anthracis*). After several immunizations, chimpanzees developed strong immune responses to γDPGA. A combinatorial Fab library of mRNA derived from the chimpanzee's bone marrow was prepared and eight (8) distinct Fabs reactive with native γDPGA were recovered. Two (2) of the Fabs were converted into full-length IgG with human γ1 heavy chain constant regions. These two (2) MAbs showed strong opsonophagocytic killing of bacilli in an *in vitro* assay. These two (2) MAbs were also tested for protection of mice challenged with virulent anthrax spores and results showed that both MAbs provided full or nearly full protection at a dose of 0.3 mg, the lowest dose tested, which is much more potent than previously reported murine anti-PGA MAbs. Since chimpanzee immunoglobulins are virtually identical to human immunoglobulins, these chimpanzee anticapsule MAbs may have clinically useful applications.

This application claims the antibody compositions described above. Also claimed are methods of treating or preventing *B. anthracis* infection in a mammalian host and isolated polynucleotides comprising a nucleotide sequence encoding the antibodies of the technology.

Applications: Development of anthrax vaccines, therapeutics and diagnostics.

Advantages: Strongly neutralizing antibodies, known regulatory pathway, potential for use as both a prophylaxis and therapy.

Development Status: Preclinical studies have been performed utilizing the monoclonal antibodies of this technology.

Inventors: Zhaochun Chen (NIAID), Robert H. Purcell (NIAID), Joanna Kubler-Kielb (NICHD), Lily Zhongdong Dai (NICHD), Rachel Schneerson (NICHD).

Patent Status: U.S. Provisional Application No. 61/116,222 filed 19 Nov 2008 (HHS Reference No. E–125–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize MAbs neutralizing anthrax toxins and capsule for comprehensive protection against anthrax. Please contact Bill Ronnenberg, NIAID Office of Technology Development, at 301–451–3522 for more information.

Dated: August 28, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–21482 Filed 9–3–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels A–M), RFA–DP09–101SUPP09, Initial Review

Cancellation: The notice was originally published in the **Federal Register** on July 14, 2009 (Volume 74, Number 133) [page 34026]. The following panels are cancelled: D, F, K, L and M.

Contact Person for More Information: Brenda Colley-Gilbert, PhD, Director, Extramural Research Program Office, CCCH, 4770 Buford Highway, MS K–92, Atlanta, GA 30341, Telephone (770) 488–6295.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 26, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–21379 Filed 9–3–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0233]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon, by holders of approved drug and biological products. This is the agency's report on the status of the studies and clinical trials that applicants have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT:

Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6464, Silver Spring, MD 20993–0002, 301–796–0700; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the act (21 U.S.C. 356(b)). Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to or has agreed to conduct by requiring the applicant to submit a report annually