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

providing information on the status of the postmarketing study/clinical trial. This report must also include reasons, if any, for failure to complete the study/clinical trial. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product and therefore play a vital role in fully characterizing the product.

Under the Modernization Act, commitments to conduct postmarketing studies or clinical trials included both studies/clinical trials that applicants agreed to conduct as well as studies/clinical trials that applicants were required to conduct under FDA regulations.[1]

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the President signed Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901, in Title IX of FDAAA, created a new section 505(o) of the act authorizing FDA to require certain studies and clinical trials for human drug and biological products approved under section 505 of the act or section 351 of the Public Health Service Act. Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies and clinical trials to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a product. This new authority became effective on March 25, 2008. FDA may now take enforcement action against applicants who fail to conduct studies and clinical trials required under FDAAA, as well as studies and clinical trials required under FDA regulations (see sections 505(o)(1), 502(z), and 303(f) of the act; 21 U.S.C. 355(o)(1), 352(z), and 333(f)).

Although regulations implementing the Modernization Act postmarketing authorities use the term ''postmarketing commitment'' to refer to both required studies and studies applicants agree to conduct, in light of the new authorities enacted in FDAAA, FDA has decided it is important to distinguish between enforceable postmarketing requirements and unenforceable postmarketing commitments. Therefore, in this notice and report, FDA refers to studies/clinical trials that an applicant is required to conduct as ''postmarketing requirements'' (PMRs) and studies/clinical trials that an applicant agrees to but is not required to conduct as ''postmarketing commitments'' (PMCs). Both are addressed in this notice and report.

C. FDA's Implementing Regulations

On October 30, 2000 (65 FR 64607), FDA published a final rule implementing section 130 of the Modernization Act. This rule modified the annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). The rule described the content and format of the annual progress report, and clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The rule became effective on April 30, 2001. The regulations apply only to human drug and biological products that are approved under NDAs, ANDAs, and BLAs. They do not apply to animal drugs or to biological products regulated under the medical device authorities.

The reporting requirements under §§ 314.81(b)(2)(vii) and 601.70 apply to PMRs and PMCs made on or before the enactment of the Modernization Act (November 21, 1997), as well as those made after that date. Therefore, studies and clinical trials required under FDAAA are covered by the reporting requirements in these regulations.

Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study/clinical trial that is required by FDA or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies/clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii). Furthermore, section 505(o)(1)(E) of the act as amended by FDAAA requires that applicants report periodically on the status of each required study/clinical trial and each study/clinical trial ''otherwise undertaken * * * to investigate a safety issue * * * .''

According to the regulations, once a PMR has been required or a PMC has been agreed upon, an applicant must report on the progress of the PMR/PMC on the anniversary of the product's approval until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the PMR/PMC, a schedule for completing the PMR/PMC, and a characterization of the current status of the PMR/PMC. The report must also provide an explanation of the PMR/PMC status by describing briefly the progress of the PMR/PMC. A PMR/PMC schedule is expected to include the actual or projected dates for the following: (1) Submission of the final protocol to FDA, (2) completion of subject accrual or initiation of an animal study, (3) completion of the study/clinical trial, and (4) submission of the final report to FDA. The status of the PMR/PMC must be described in the annual report according to the following definitions:

- *Pending*: The study/clinical trial has not been initiated (i.e., no subjects have been enrolled or animals dosed), but does not meet the criteria for delayed (i.e., the original projected date for initiation of subject accrual or initiation of animal dosing has not passed);
- *Ongoing*: The study/clinical trial is proceeding according to or ahead of the original schedule;
- *Delayed*: The study/clinical trial is behind the original schedule;
- *Terminated*: The study/clinical trial was ended before completion, but a final report has not been submitted to FDA; or
- *Submitted*: The study/clinical trial has been completed or terminated, and a final report has been submitted to FDA.

Databases containing information on PMRs/PMCs are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

II. Summary of Information From Postmarketing Status Reports

This report, published to fulfill the annual reporting requirement under the Modernization Act, summarizes the status of PMRs and PMCs as of September 30, 2008. If a requirement or commitment did not have a schedule, or

[1] FDA could require postmarketing studies and clinical trials under the following circumstances: To verify and describe clinical benefit for a human drug approved in accordance with the accelerated approval provisions (21 U.S.C. 356(b)(2)(A); 21 CFR 314.510 and 601.41); for a drug approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 601.91(b)(1)); and for marketed drugs that are not adequately labeled for children (Pediatric Research Equity Act (21 U.S.C. 355B; Public Law 108–155)).

a postmarketing progress report was not received in the previous 12 months, the PMR/PMC is categorized according to the most recent information available to the agency.

Information in this report covers any PMR/PMC that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including PMRs required under FDAAA (section 505(o)(3) of the act), PMRs required under FDA regulations (e.g., PMRs required to demonstrate clinical benefit of a product following accelerated approval (see footnote 1 of this document)), and PMCs agreed to by the applicant.

Information summarized in this report includes the following: (1) The number of applicants with open (uncompleted) PMRs/PMCs, (2) the number of open PMRs/PMCs, (3) the status of open PMRs/PMCs as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports, (4) the status of concluded PMRs/PMCs as determined by FDA, and (5) the number of applications with open PMRs/PMCs for which applicants did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about PMRs/PMCs submitted by applicants to CDER and CBER is provided on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm*. Neither the Web site nor this notice include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. Numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site because this notice incorporates totals for all PMRs/PMCs in FDA databases, including PMRs/PMCs undergoing review for accuracy. In addition, the report in this notice will be updated annually while the Web site is updated quarterly (i.e., January, April, July, and October).

Many applicants have more than one approved product and for many products there is more than one PMR or PMC. Specifically, there were 158 unique applicants with 297 NDAs/ANDAs that had open PMRs/PMCs. There were 54 unique applicants with 94 BLAs that had open PMRs/PMCs.

Annual status reports are required to be submitted for each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application. In fiscal year (FY) 2008, 27 percent (59/215) of NDA/ANDA and 52 percent (43/83) of BLA annual status reports were reported late or were overdue at the close of the FY, September 30, 2008. Of the annual status reports due but not submitted within 60 days of the anniversary date of U.S. approval of the original application, 100 percent (59/59) of the NDA/ANDA and 42 percent (18/43) of the BLA reports were submitted before September 30, 2008.

Most PMRs are progressing on schedule (95 percent for NDAs/ANDAs; 89 percent for BLAs). Most PMCs are also progressing on schedule (96 percent for NDAs/ANDAs; 78 percent for BLAs). Most of the PMCs that are currently listed in the database were developed before the postmarketing requirements section of FDAAA took effect.[2]

III. What's New About This Report

This report now provides six separate tables instead of one summary table. The tables distinguish between PMRs and PMCs and between on-schedule and off-schedule PMRs and PMCs according to the original schedule milestones. On-schedule PMRs/PMCs are categorized as pending, ongoing, or submitted. Off-schedule PMRs/PMCs that have missed one of the original milestone dates are categorized as delayed or terminated. The tables include data as of September 30, 2008.

Table 1 of this document provides an overall summary of the data on all PMRs and PMCs. Tables 2 and 3 of this document provide detail on PMRs. Table 2 of this document provides additional detail on the status of on-schedule PMRs.

Table 1 of this document shows that most PMRs (95 percent for NDAs/ANDAs and 89 percent for BLAs) and most PMCs (96 percent for NDAs/ANDAs and 78 percent for BLAs) are on schedule. Overall, of the PMRs that are pending (i.e., have not been initiated), 73 percent were created within the past 3 years.

Table 2 of this document shows that most pending PMRs for both drug and biological products are in response to the Pediatric Research and Equity Act (PREA), under which FDA requires sponsors to study new drugs, when appropriate, for pediatric populations. Under section 505B(a)(3) of the act, the initiation of these studies generally is deferred until required safety information from other studies has first been submitted and reviewed. PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely. The next largest category of pending PMRs comprises those studies/clinical trials required by FDA under FDAAA, which became effective on March 25, 2008.

Section 921 of FDAAA requires FDA to review the backlog of postmarketing safety commitments and report to Congress. CDER contracted with an external group to review the backlog of its PMRs/PMCs as well as PMR/PMC annual status reports.[3] The contractors's report was recently completed and can be found on the FDA Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm064436.htm*. As Exhibit 9 of the report shows, the external review has resulted in a decreased number of NDA PMRs/PMCs categorized as pending because their statuses have been updated to other categories (e.g., submitted). Some of this decrease is reflected in the NDA statistics reported in this notice, which shows the status of the PMRs/PMCs as of September 30, 2008, and additional status changes will be reflected in the statistics reported in the next annual notice showing the status of the PMRs/PMCs as of September 30, 2009.

[2] Although there are PMCs that might meet FDAAA standards for required safety studies/clinical trials under section 505(o)(3)(B) of the act (21 U.S.C. 355(o)(3)(B)) if they were first determined to be necessary today, they may be converted to PMRs only if FDA becomes aware of new safety information.

[3] The external backlog review covered PMRs/PMCs for NDAs and CDER-regulated BLAs. CBER conducted a separate backlog review of the CBER-regulated BLAs.

Table 3 of this document provides additional detail on the status of off-schedule PMRs. The majority of off-schedule PMRs (which account for only 5 percent of the total for NDAs/ANDAs and 11 percent for BLAs) are delayed according to the original schedule milestones (93 percent (13/14) for NDAs/ANDAs; 71 percent (5/7) for BLAs). However, after discussion between FDA and applicants, the original schedules may have been adjusted for unanticipated delays in the progress of the study/clinical trial (e.g., difficulties with subject enrollment in a trial for a marketed drug or need for additional time to analyze results). In this report, study status reflects the status in relation to the original study schedule regardless of whether adjustments to the schedule have been made.

Tables 4 and 5 of this document provide additional detail on the status of PMCs. Table 4 provides additional detail on the status of on-schedule PMCs. Pending PMCs comprise 56 percent (544/965) of the on-schedule NDA and ANDA PMCs and 40 percent (112/279) of the on-schedule BLA PMCs.

Table 5 of this document provides additional details on the status of off-schedule PMCs. The majority of off-schedule PMCs (which account for only 4 percent for NDAs/ANDAs and 22 percent for BLAs) are delayed according to the original schedule milestones (91 percent (39/43) for NDAs/ANDAs; 97 percent (76/78) for BLAs). However, after discussion between FDA and applicants, the original schedules may have been adjusted for unanticipated delays in the progress of the study/clinical trial (e.g., difficulties with subject enrollment in a trial for a marketed drug or need for additional time to analyze results).

Table 6 of this document provides details about PMRs and PMCs that were concluded in the previous year. Most concluded PMRs and PMCs were fulfilled (80 percent of NDA/ANDA PMRs and 70 percent of BLA PMRs; 86 percent of NDA/ANDA PMCs and 97 percent of BLA PMCs).

TABLE 1.—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2008)

	NDA/ANDA (% of Total PMR or % of Total PMC)	BLA (% of Total PMR or % of Total PMC)[1]
Number of open PMRs	306	65
On-schedule open PMRs (see table 2 of this document)	292 (95%)	58 (89%)
Off-schedule open PMRs (see table 3 of this document)	14 (5%)	7 (11%)
Number of open PMCs	1,008	357
On-schedule open PMCs (see table 4 of this document)	965 (96%)	279 (78%)
Off-schedule open PMCs (see table 5 of this document)	43 (4%)	78 (22%)

[1] On October 1, 2003, FDA completed a consolidation of certain therapeutic products formerly regulated by CBER into CDER. Consequently, CDER now reviews many BLAs. Fiscal year statistics for postmarketing requirements and commitments for BLAs reviewed by CDER are included in BLA totals in this table.

TABLE 2.—SUMMARY OF ON-SCHEDULE POSTMARKETING REQUIREMENTS (NUMBERS AS OF SEPTEMBER 30, 2008)

On-Schedule Open PMRs	NDA/ANDA (% of Total PMR)	BLA (% of Total PMR)[1]
Pending by type		
Accelerated approval	15	3
PREA[2]	194	24
Animal efficacy[3]	2	0
FDAAA safety (since March 25, 2008)	30	12
Total	241 (79%)	39 (60%)
Ongoing		
Accelerated approval	17	3
PREA[2]	13	6
Animal efficacy[3]	0	0
FDAAA safety (since March 25, 2008)	0	4
Total	30 (10%)	13 (20%)
Submitted		
Accelerated approval	12	2
PREA[2]	9	4

TABLE 2.—SUMMARY OF ON-SCHEDULE POSTMARKETING REQUIREMENTS (NUMBERS AS OF SEPTEMBER 30, 2008)—Continued

On-Schedule Open PMRs	NDA/ANDA (% of Total PMR)	BLA (% of Total PMR)[1]
Animal efficacy[3]	0	0
FDAAA safety (since March 25, 2008)	0	0
Total	21 (12%)	6 (9%)
Combined Total	292 (95%)	58 (89%)

[1] See note 1 for table 1 of this document.
[2] Many PREA studies have a pending status. PREA studies are usually deferred because the product is ready for approval in adults. Initiation of these studies also may be deferred until additional safety information from other studies has first been submitted and reviewed.
[3] PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely.

TABLE 3.—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS (NUMBERS AS OF SEPTEMBER 30, 2008)

Off-Schedule Open PMRs	NDA/ANDA (% of Total PMR)	BLA (% of Total PMR)[1]
Delayed		
Accelerated approval	4	2
PREA	9	3
Animal efficacy	0	0
FDAAA safety (since March 25, 2008)	0	0
Total	13 (4%)	5 (8%)
Terminated	1 (0.3%)	2 (3%)
Combined total	14 (5%)	7 (11%)

[1] See note 1 for table 1 of this document.

TABLE 4.—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2008)

On-Schedule Open PMCs	NDA/ANDA (% of Total PMC)	BLA (% of Total PMC)[1]
Pending	544 (54%)	112 (31%)
Ongoing	166 (17%)	93 (26%)
Submitted	255 (25%)	74 (21%)
Combined total	965 (96%)	279 (78%)

[1] See note 1 for table 1 of this document.

TABLE 5.—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2008)

Off-Schedule Open PMCs	NDA/ANDA (% of Total PMC)	BLA (% of Total PMC)[1]
Delayed	39 (4%)	76 (21%)
Terminated	4 (0.4%)	2 (1%)
Combined total	43 (4%)	78 (22%)

[1] See note 1 for table 1 of this document.

TABLE 6.—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS (OCTOBER 1, 2007 TO OCTOBER 1, 2008)

	NDA/ANDA (% of Total)	BLA (% of Total)[1]
Concluded PMRs		
Requirement met (fulfilled)	12 (80%)	7 (70%)

TABLE 6.—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS (OCTOBER 1, 2007 TO OCTOBER 1, 2008)—Continued

	NDA/ANDA (% of Total)	BLA (% of Total)[1]
Requirement not met (released and new revised requirement issued)	1 (7%)	0
Requirement no longer feasible or product withdrawn (released)	2 (13%)	3 (30%)
Total	15	10
Concluded PMCs		
Commitment met (fulfilled)	94 (86%)	30 (97%)
Commitment not met (released and new revised requirement/commitment issued)	3 (3%)	0
Commitment no longer feasible or product withdrawn (released)	12 (11%)	1 (3%)
Total	109	31

[1] See note 1 for table 1 of this document.

Dated: August 31, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21302 Filed 9–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Application for Allowance in Duties

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information: 1651–0007.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Application for Allowance in Duties. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before November 3, 2009, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (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 estimates 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 including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or recordkeepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Application for Allowance in Duties.

OMB Number: 1651–0007.

Form Number: CBP Form 4315.

Abstract: Form 4315 is required by CBP in instances of claims of damaged or defective imported merchandise on which an allowance in duty is made in the liquidation of an entry. The information is used to substantiate an importer's claim for such duty allowances.

Current Actions: There are no changes to the information collection. This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 12,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Time per Respondent: 8 minutes.

Estimated Total Annual Burden Hours: 1,600.

Dated: September 1, 2009.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E9–21366 Filed 9–3–09; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5285–N–28]

Notice of Proposed Information Collection: Comment Request; Request for Approval of Advance of Escrow Funds

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.