Plus – Own report—up to six files with >500 respondents and/or sub-accounts	$1,000.00
End-of-day financial institution reconcilement data file (per month)[77]	$150.00
Statement of account spreadsheet file (per month)[78]	$150.00
Intra-day download search file (with AMI) (per month)[79]	$150.00
ACTS Report – < 20 sub-accounts	**$500.00**
ACTS Report – 21-40 sub-accounts	**$1,000.00**
ACTS Report – 41-60 sub-accounts	**$1,500.00**
ACTS Report – >60 sub-accounts	**$2,000.00**

[77] End of Day Reconcilement File option is available to FedLine Web Plus and FedLine Advantage Plus packages.
[78] Statement of Account Spreadsheet File option is available to FedLine Web Plus and FedLine Advantage Plus packages.
[79] ACTS Report options are limited to FedLine Command Plus and FedLine Direct Plus and Premier packages.

By order of the Board of Governors of the Federal Reserve System, October 31, 2013.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2013–26560 Filed 11–5–13; 8:45 am]

BILLING CODE 6210–01–C

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0096; Docket No. 2013–0077; Sequence No. 10]

Federal Acquisition Regulation; Submission for OMB Review; Patents

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning patents.

DATES: Submit comments on or before December 6, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0096, Patents, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching for ''9000–0096; Patents''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0096, Patents''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0096, Patents'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), IC 9000–0096, 1800 F Street NW., 2nd Floor, Washington, DC 20405.

Instructions: Please submit comments only and cite Information Collection 9000–0096, Patents, in all correspondence related to this collection. Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Marissa Petrusek, Procurement Analyst, at 202–501–0136. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755.

SUPPLEMENTARY INFORMATION:

A. Purpose

The patent coverage in Federal Acquisition Regulation (FAR) subpart 27.2 requires the contractor to report each notice of a claim of patent or copyright infringement that came to the contractor's attention in connection with performing a Government contract (FAR 27.202–1 and 52.227–2).

The contractor is also required to report all royalties anticipated or paid in excess of $250 for the use of patented inventions by furnishing the name and address of licensor, date of license agreement, patent number, brief description of item or component, percentage or dollar rate of royalty per unit, unit price of contract item, and number of units (FAR 27.202–5, 52.227–6, and 52.227–9).

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

A notice was published in the **Federal Register** at 78 FR 30304, on May 22, 2013.

B. Analysis of Public Comments

Two respondents submitted comments on the extension of the previsouly approved information collection. The analysis of the public comment is summarized as follows:

A. Approval To Extend This Information Collection Requirement

Comment: One respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because the analysis significantly underestimates the paperwork burden imposed by this requirement and has therefore not provided sufficient justification for the requested extension. The respondent further stated that the agency and OMB

should assess the need to extend this information collection requirement in the context of assessing the total information collection burden. The respondent further commented that the ''collective burden of compliance'' required of the Government acquisition community annually totals over 30 million hours. According to the respondent, the collective burden greatly exceeds the agency's estimates and outweighs any potential utility of the extension.

Comment: A second respondent noted that this extension should not be granted unless it is a no cost extension to the government. The burden is small and understood prior to contract award.

Response: The criteria for extension of an information collection requirement must be based primarily on the need and use for the required information. It is essential for contractors to report responsibility requirements, regardless of the number of responses. If the agencies have determined that the information is essential to protect the interests of the Government, then the extension should be approved.

B. Accuracy of the Data Estimates

Comment: One respondent commented that the agency did not accurately estimate the public burden, challenging that the agency's methodology for calculating the burden is insufficient and inadequate and does not reflect the total burden. The respondent stated that—

- Thirty respondents responding just once annually is grossly understated. Under FAR 52.227–6, Royalty Information, any response to a solicitation containing costs or charges for royalties totaling more than $250 triggers this information collection.
- The Agencies estimate the hours per response of thirty minutes (.5 hours) is inadequate. Each information collection requirement effectively imposes three separate requirements on the public: (1) The need to monitor whether reporting is required; (2) the need to compile and collect the required information; and (3) the need to disclose that information to the Government.

Response: Based on data extrapolated from the Federal Business Operations Web site, and in consultation with subject matter experts, the Councils have increased the number of respondents and the burden hour estimates from 30 to 104 respondents and from .5 hours to 1 hour, and separated out the data. This re-evaluation resulted in slightly upward adjustment from the data previously published in the **Federal Register** at 78 FR 30304, on May 22, 2013.

C. Collective Burden of Compliance

Comment: One respondent objects to the overall collective burden imposed by the Government on all respondents.

Response: The Councils cannot effectively address the broad allegations with regard to the accuracy and utility of the entire collective burden imposed on all Federal acquisitions. The Councils can only effectively address each individual collection requirement that is under consideration for OMB approval. The Councils constantly review information collection requirements imposed by the FAR regulations for ways to reduce the burdens and still achieve the objectives of the regulations, whether based on policy or statute.

D. Agencies' Estimated Burden Should Be Increased

Comment: One respondent provided that the Agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate, as was done in FAR Case 2007–006.

Response: The Council takes serious consideration, during the open comment period, to all comments received and will adjust the paperwork burden estimate based on reasonable considerations provided by the respondents. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from 3 to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government. In this particular instance, the burden was prepared using the burden hours method taking into consideration the time, effort and financial resources put on the entity submitting the information. This includes reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated hours must also be viewed as an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, it must be noted that the burden includes estimated hours only for those actions which a company would not undertake in the normal course of business. In this instances, the total burden hours were revised slightly upwards.

C. Annual Reporting Burden

This information collection reflects a slight adjustment from what was published in the **Federal Register** at 78 FR 30304, on May 22, 2013, for the number of respondents required to comply with FAR 52.227–2, 52.227–6 and 52.227–9. This change is primarily due to a re-evaluation based on consultations with subject matter experts and updated data retrieved from the Federal Business Opportunities Web site.

For FAR 52.227–2, data extrapolated from the Federal Business Opportunties Web site indicates that there were a total of 18 solicitations. The Government estimates that there are an additional 18 solicitations which were not accounted for in Federal Business Opportunties. It is further estimated that each solicitation would result in approximately two contract awards, or 72 (36 * 2) unique vendors. Of the 72 unique vendors, it is estimated that approximately 30 percent or 20 unique vendors would have claims of patent (or copyright) infringement made against them as a result of their contract work requiring government notification. It is estimated that there is an average of one response per contract, resulting in approximately 20 responses per year. Two burden hours are estimated per response to monitor claims of patent or copyright infringement and prepare, review, and submit the required notification. It is estimated that this work would be completed by a mid-level program manager and an attorney.

For FAR 52.227–6, data extrapolated from the Federal Business Opportunties Web site indicates that there were a total of eight solicitations. The Government estimates that there are an additional 12 solicitations which were not accounted for in Federal Business Opportunties, totaling 20. It is further estimated that each solicitation would result in approximately two contract awards, or 40 (20 * 2) unique vendors, required to submit royalty information with their proposal. Of the 40 unique vendors, it is estimated that approximately 10 percent or four unique vendors would be required to submit additional information prior to contract award. It is estimated that there is an average of one response per solicitation, resulting in approximately 44 responses per year. One burden hours is estimated per response to disclose the requested information in the proposal including such items as the amount of royalty paid, the patent numbers and a brief description of the component on which the royalty is paid, and to submit the required notification. It is estimated that

one hour is needed to provide a copy of the current license agreement and redact any proprietary data, and to submit it to the government. It is estimated that this work would be completed by a mid-level program manager.

For FAR 52.227–9, data extrapolated from Federal Business Opportunties Web site indicates that there was a total of one solicitation. The Government estimates that there are an additional nine solicitations which were not accounted for in Federal Business Opportunties, totaling 10. It is further estimated that each solicitation would result in approximately one contract award, or 10 unique vendors. It is also estimated that each contract will have three subcontractors, for a total of 30 unique subcontractor vendors. Of the 40 (10 + 30) unique vendors, it is estimated that approximately 100 percent or 40 unique vendors would be required to submit a statement of royalties paid. It is estimated that there is an average of one response per solicitation, resulting in approximately 40 responses per year. 0.5 burden hours are estimated per response to submit a statement of royalties paid or required to be paid by the contract.

a. FAR 52.227–2:
Number of Respondents: 20.
Responses per Respondent: 1.
Total Responses: 20.
Average Burden Hours per Response: 2.
Total Burden Hours: 40.
b. FAR 52.227–6:
Number of Respondents: 44.
Responses per Respondent: 1.
Total Responses: 44.
Average Burden Hours per Response: 1.
Total Burden Hours: 44.
c. FAR 52.227–9:
Number of Respondents: 40.
Responses per Respondent: 1.
Total Responses: 40.
Average Burden Hours per Response: .5.
Total Burden Hours: 20.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0096, Patents, in all correspondence.

Dated: October 31, 2013.

Karlos Morgan, Sr.,

Acting Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2013–26578 Filed 11–5–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0631]

Determination That MOBAN (Molindone Hydrochloride) Tablets (5 Milligrams, 10 Milligrams, 25 Milligrams, 50 Milligrams, and 100 Milligrams) and Capsules (5 Milligrams, 10 Milligrams, and 25 Milligrams) Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that MOBAN (molindone hydrochloride (HCl)) tablets (5 milligrams (mg), 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 301–796–3381.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) are the subject of NDA 017111, held by Endo Pharmaceuticals, and initially approved on January 18, 1974. MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) are indicated for the management of schizophrenia. MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

CorePharma, LLC, submitted a citizen petition dated May 22, 2013 (Docket No. FDA–2013–P–0631), under 21 CFR 10.30, requesting that the Agency determine whether MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address MOBAN (molindone HCl) capsules (5 mg, 10 mg, and 25 mg), that dosage form has also been discontinued, and on our own initiative, we have also determined that MOBAN (molindone HCl) capsules (5 mg, 10 mg, and 25 mg) were not withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules