SUPPORTING STATEMENT
Patent License Application. Form AD-761

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

   Public Law 96-517, HR 209 (Technology Transfer Commercialization Act of 2000), and 37 CFR Part 404 require Federal agencies to use the patent system to promote the utilization of inventions arising from federally supported research and provide the authority to grant patent licenses. 37 CFR 404.8 specifies the information which must be submitted by a patent license applicant to the Federal agency having custody of a patent. Form AD-761 collects the information specified under 37 CFR 404.8. The appropriate section of the cited regulations mandating the collection of this information is attached.

2. Indicate how, by whom and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

   USDA collects the information required by Federal Regulations to be submitted by all applicants for licenses to Government-owned inventions. The exact information to be collected is itemized in 37 CFR 404.8, as follows:

   § 404.8 Application for a license.
   An application for a license should be addressed to the Federal agency having custody of the invention and shall normally include:(a) Identification of the invention for which the license is desired including the patent application serial number or patent number, title, and date, if known;(b) Identification of the type of license for which the application is submitted;(c) Name and address of the person, company, or organization applying for the license and the citizenship or place of incorporation of the applicant;(d) Name, address, and telephone number of the representative of the applicant to whom correspondence should be sent;(e) Nature and type of applicant's business, identifying products or services which the applicant has successfully commercialized, and approximate number of applicant's employees;(f) Source of information concerning the availability of a license on the invention;(g) A statement indicating whether the applicant is a small business firm as defined in § 404.3(c)(h) A detailed description of applicant's plan for development or marketing of the invention, or both, which should include:(1) A statement of the time, nature and amount of anticipated investment of capital and other resources which applicant believes will be required to bring the invention to practical application;(2) A statement as to applicant's capability and intention to fulfill the plan, including information regarding manufacturing, marketing, financial, and technical resources;(3) A statement of the fields of use for which applicant intends to practice the invention; and (4) A statement of the geographic areas in which applicant intends to manufacture any products embodying the invention and geographic areas where applicant intends to use or sell the invention, or both; (i) Identification of licenses previously granted to applicant under federally owned

inventions;(j) A statement containing applicant's best knowledge of the extent to which the invention is being practiced by private industry or Government, or both, or is otherwise available commercially; and(k) Any other information which applicant believes will support a determination to grant the license to applicant.

Federal agencies are required by statute (35 USC 209) and regulation (37 CFR 404) to collect this information prior to granting patent licenses.

The collected information is used by the Office of Technology Transfer (OTT) to evaluate a patent license applicant's ability to bring an invention to practical application, as defined in 37 CFR 404.3. Pursuant to 37 CFR 404.14, the information collected may be treated by the collecting agency as privileged and confidential. Under the regulations, a license may be granted only if the applicant has supplied the Federal agency with a satisfactory plan for development or marketing of the invention, or both, and only if the applicant has provided supporting documentation and evidence of sufficient manufacturing, marketing, financial and technical resources to carry out the submitted plan. More than 75 patent licenses have been granted since the previous OMB approval date in March 2007.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

Form AD-761, and instructions for completing the form, are currently available on the USDA, ARS, Partnering Section (http://www.ars.usda.gov) under the heading "Licensing Information." Pursuant to 37 CFR 404.14, business plans submitted as required by 37 CFR 404.8(h) are treated by USDA, ARS as privileged and confidential and are not subject to disclosure under section 552 of Title 5 of the U.S. Code (Freedom of Information Act). Because ARS does not currently have any procedures in place to protect the confidentiality of business information and trade secrets submitted via the Internet, license applications cannot be submitted electronically. In addition, each completed license application must include a verifiable signature by an authorized company representative. ARS does not currently have the technical capability to verify electronic signatures. It is likely that, even if applicants were given the option to submit applications electronically, most applicants would prefer not to submit sensitive business information via the Internet.

4. Describe effort to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

No information is requested other than that which is required by regulation. There are no duplicate forms in use within the Department of Agriculture or approved for use by OMB. Information about a patent license applicant's confidential business plans for the

development and marketing of a specific government owned invention is not available from any source other than the applicant.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

   Pursuant to 37 CFR Part 404, the information collected is the same for both small and large businesses.

   Of the estimated 65 business respondents, approximately 25 are small businesses.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

   Information is collected only from those individuals or businesses who wish to obtain a patent license. The decision concerning when to submit the information resides entirely with the patent license applicant. No information is requested other than that which is required by regulation.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

   requiring respondents to report more often than quarterly;

   requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;.

   requiring respondents to submit more than an original and two copies of any document;

   requiring respondents to retain records, other than health, medical, government contact, grant-in-aid, or tax records for more than three years;

   in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

   requiring the use of statistical data classification that has not been reviewed and approved by OMB;

   that include a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

requiring respondents to submit proprietary trade secret or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

This information collection is conducted in a consistent manner with the guidelines of CFR 1320.5.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported.

Notice of Intent to Request an Extension of a Currently Approved Information Collection was published in the Federal Register on 6-30-10 on page number 125, Vol. No. 75. No responses to the notice, either in writing or by phone, were received. Also, no outside consults were used for this collection.

Every patent license application received by OTT is discussed in detail with the license applicant prior to the granting of a patent license. Feedback concerning the license application process is solicited from license applicants on an ongoing basis to ensure "user friendliness." Form AD-761 has been in use since 1981. No complaints have been received concerning the form during this time period.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for such assurance in statute, regulation, or agency policy.

Pursuant to 37 CFR 404.14, any plan submitted pursuant to 37 CFR 404.8(h) and any report required by 37 CFR 404.5(b)(6) may be treated by the Federal agency as privileged and confidential and not subject to disclosure under section 552 of Title 5 of the U.S. Code.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the

questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No justification for any questions of a sensitive nature have applied.

12. Provide estimates of the hour burden of the collection of information. The statement should:

Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

Since each respondent generally submits only one application per year, the annual burden for each respondent is 3 hours and the total annual burden is estimated at 225 hours. The estimate of burden was determined through informal consultation with patent license applicants. The estimated hour burden has been included in the Patent License Application Package since 1992 and no negative feedback has been received from applicants. The cost to each respondent for each patent license application is estimated to be 3 hours at $66 per hour, for a total of $198 per application submitted. The estimated annual cost is approximately $14,850.00. (see copy of worksheet)

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from collection of information, (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components:
(a) a total capital and start-up cost component annualized over its expected useful life;
(b) a total operation and maintenance and purchase of services component.

There are no capital or startup costs, nor are there any, operation, maintenance or purchase of services costs.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information

The estimated cost of processing and filing each patent license application includes one hour review and approval by a Patent License Specialist at $50.00 per hour and one hour of clerical support at $18.00 per hour, for a total of $68.00 per application. The total annualized cost to the Federal government for processing 75 applications is $5,100.00.

15. Explain the reasons for any program changes or adjustments reported on item 13 of the OMB Form 83-I.

    There are no program changes or adjustments reported on item 13.

16. For collections of information whose results will be published, outline plans for tabulation and publication.

    No collections of information should result in a publication.

17. I seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

    This form is not subject to change, therefore, in order to save on printing costs, the Agency requests not to display the expiration date on this form.

18. Explain each exception to the certification statement identified in Item 19 “Certification for Paperwork Reduction Act.”

    There are no exceptions to the certification statement identified in Item 19 of the OMB Form 83-I.