

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.

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 August 1998.

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.

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.

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.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently.

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 report more often than quarterly does not apply to this process.

- requiring respondents to prepare written response in fewer than 30 days of receipt.

A written response in fewer than 30 days of receipt is not required from respondents.

- requiring respondents to submit more than an original and two copies of documents.

It is not required that respondents submit more than one original and two copies of documents for this process.

- requiring respondents to retain records for more than three years.

We do not require respondents to retain records for more than three years.

- in connection with a statistical survey.

There are no circumstances that require a statistical survey at this time.

- requiring the use of statistical data classification.

There are no requirements for the use of statistical data classification.

- that include a pledge of confidentiality that is not supported by authority established in statute or regulation.

A circumstance including a pledge of confidentiality that is not supported by authority established in statute or regulation does not apply.

- requiring respondents to submit proprietary trade secret or other confidential information.

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.

8. Provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice required by 5 CFR 1320.8 (d). 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, reporting format, etc.

Notice of Intent to Request an Extension of a Currently Approved Information Collection was published in the Federal Register on 4-27-07 on page number 81, Vol. No.72. A copy of the Notice is attached. No responses to the notice, either in writing or by phone, were received either before or since the closing of the comment period on 6-29-07.

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.

No payments or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for such assurance.

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.

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

12. Provide estimates of the hour burden of the collection of information. Provide estimates of annualized costs to respondents.

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 \$51 per hour, for a total of \$153 per application submitted. The estimated annual cost is approximately \$11,475.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from collection of information.

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.

The estimated cost of processing and filing each patent license application includes one hour review and approval by a Patent License Specialist at \$30 per hour and one hour of clerical support at \$10 per hour, for a total of \$40 per application. The total annualized cost to the Federal government for processing 75 applications is \$3,000.

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. Explain the reasons that display of the OMB approval expiration date 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 of OMB Form 83-I.

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