

**OMB Supporting Statement
Patent License Application
Collection Number 0518-0003**

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.

(a) An application for a license should be addressed to the Federal agency having custody of the invention and shall normally include: (1) Identification of the invention for which the license is desired including the patent application serial number or patent number, title, and date, if known; (2) Identification of the type of license for which the application is submitted; (3) Name and address of the person, company, or organization applying for the license and the citizenship or place of incorporation of the applicant; (4) Name, address, and telephone number of the representative of the applicant to whom correspondence should be sent; (5) Nature and type of applicant's business, identifying products or services which the applicant has successfully commercialized, and approximate number of applicant's employees; (6) Source of information concerning the availability of a license on the invention; (7) A statement indicating whether the applicant is a small business firm as defined in § 404.3(c); (8) A detailed description of applicant's plan for development or marketing of the invention, or both, which should include: (i) 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; (ii) A statement as to applicant's capability and intention to fulfill the plan, including information regarding manufacturing, marketing, financial, and technical resources; (iii) A statement of the fields of use for which applicant intends to practice the invention; and (iv) 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; (9) Identification of licenses

previously granted to applicant under federally owned inventions; (10) 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 (11) Any other information which applicant believes will support a determination to grant the license to applicant.

(b) An executed CRADA which provides for the use for research and development purposes by the CRADA collaborator under that CRADA of a Federally owned invention in the Federal laboratory's custody (pursuant to 35 U.S.C. 209 and 15 U.S.C. 3710a(b)(1)), and which addresses the information in paragraph (a) of this section, may be treated by the Federal laboratory as an application for a license.

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.

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, Office of Technology Transfer, Licensing Section (<https://www.ars.usda.gov/ott/licenses-section-folder/licensing-process/>) website under the heading "Apply for a License." Applicants are given the option either to fill in the form or to submit their applications using a more convenient format, provided that all of the questions listed on the form are answered. Pursuant to 35 U.S.C. 209 (f) and 37 CFR 404.14, this information must be treated by USDA, ARS as privileged and confidential and not subject to disclosure under section 552 of Title 5 of the U.S. Code (Freedom of Information Act).

The Technology Licensing Program Office accepts signed and dated original license applications that are submitted via e-mail, courier and U.S. mail. The instruction forms on the ARS, OTT, Licensing Section website provide clear instructions for submitting applications via email, courier, and U.S. mail to the Business Licensing Officer. As a result of the pandemic, most license applicants have submitted license applications via email.

However, it is still important to allow license applicant's the opportunity to submit license applications in paper format if they are not comfortable sending the required information via email.

At this time, ARS does not intend to develop a secure website/portal and database to receive electronic license application submissions as it is not cost effective due to the high cost of developing such a system.

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. If this information is not collected, individuals or business cannot obtain a USDA patent license.

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.

A Federal Register notice was published on July 23, 2021 on page number 15673, Vol. No. 86. Two comments were received that has no bearing on 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."

The following consultants were used for this collection. The questions asked and the consultant's responses are listed below their name.

a. Kristina J. Hennessy, DVM, PhD., CEO, Hennessy Research Associates, LLC, 7940 Marshall Drive, Lenexa, KS 66214.

- (1) What is your opinion on the time it takes to fill out the license application?

Pretty easy – does not take much time or ask unimportant questions.

- (2) Was it too complicated?

Not a bit.

- (3) Do you have any suggestions?

I'm happy with the process. I had great communication with USDA personnel (Diana Halsey) on the process and understood the timing all the way through.

b. Karl Cameron Schiller, COO, Pheronym, Inc., 1100 Main St., Ste 300-PL, Woodland, CA 95695.

- (1) What is your opinion on the time it takes to fill out the license application?

It took approximately 6 hours between me and our PI counsel.

- (2) Was it too complicated?

No.

- (3) Do you have any suggestions?

No.

c. Amelia Gibson, PhD, MBA, Senior Director of Product Licensing, Kerafast Inc. and Absolute Antibody NA, 21 Drydock Ave., 7th Floor, Boston, MA 02210.

- (1) What is your opinion on the time it takes to fill out the license application?

The initial application was somewhat time consuming, namely Section 20 regarding the development and marketing plans.

- (2) Was it too complicated?

It is on par with applications required for other government agencies. Not complicated or confusing but can be time consuming.

- (3) Do you have any suggestions?

Perhaps an initial, complete application by company for the first license and then an abbreviated form for subsequent applications. Our marketing and development plan does not change. An online form would also be helpful.

d. Vik Sakhalkar, CEO, Faust Bio-Agricultural Service, Inc., 6080 Wigrich Road, Independence, OR 97351.

(1) What is your opinion on the time it takes to fill out the license application?

Application process is straightforward. Questions were simple and reasonable. It should not take more than a week to fill out the application.

(2) Was it too complicated?

I have only gone through one application process so far with ARS, so my experience is limited. The process has not been overly complicated in my opinion. Especially for a product that has not been fully patented yet. I was pleasantly surprised with a strong communication and engagement by various groups such as technical and regulatory on your interest to provide good solutions for me.

(3) Do you have any suggestions?

I understand the complexity that comes with releasing new and unproven technologies. I like to add that the timely help provided by Dr Dardick and Dr Vince Contreras to walk me through various steps was extremely valuable!

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.

The number of respondents for this collection is 75. 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 cost to each respondent for each patent license application is estimated to be 3 hours at \$107.96 per hour, for a total of \$323.88 per application submitted. The estimated annual cost is approximately \$24,291.00.

The wage rate of \$74.49 (Natural Sciences Managers) was based on data from the U.S. Department of Labor, Occupational Employment and Wages; For release 10:00 a.m. (ET) Wednesday, March 31, 2021 at <http://www.bls.gov/news.release/pdf/ocwage.pdf>. To account for fringe benefits, we used the Bureau of Labor Statistics' (BLS) *Occupational Employment Statistics (OES) (2020)*. Fringe markup is from the following BLS release: *Employer Costs for Employee Compensation* news release text; For release 10:00 a.m. (ET) Thursday, September 16, 2021 (<https://www.bls.gov/news.release/pdf/ecec.pdf>). BLS reported that for civilian workers, fringe benefits accounted for 31.0 percent of total compensation and wages accounted for the remaining 69.0 percent. To calculate the loaded hourly wage for each occupation, we divided the mean hourly wage by 69.0 percent. Accordingly, the loaded hourly wage rate is $\$74.49 / .690 = \107.96 .

- 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 $\$61 / .690 = \88.40 (loaded hourly wage rate) per hour and one hour of clerical support at $\$22 / .690 = \31.88 (loaded hourly wage

rate) per hour, for a total of \$120.28 application. The total annualized cost to the Federal government for processing 75 applications is \$9,021.00.

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 since the last approval.

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. In 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.