License Application Instructions for Biological Materials

Responses may be submitted on Form AD-761 or on letter size plain paper attached to Form AD-761. Please be sure to identify your responses by item number. Whether you use the form or separate sheets for your responses, the license application must be signed and dated by an authorized company representative. Responses should be concise and should include the applicant's business analysis used to make the decision to invest in the development and marketing of this invention.

Applying for a license from USDA is not a bidding process. Instead, USDA seeks commercial partners with the facilities, personnel and expertise to develop and market USDA inventions. License applicants must demonstrate a willingness to expend reasonable efforts and resources to commercialize the inventions to be licensed. The first license application received for a particular USDA invention is evaluated on its own merits. License fees and royalties are negotiated on a case by case basis and depend upon several factors, including the scope of the rights granted, the size of the potential market, and the time and financial investments required by the licensee to bring a product or service to market. Biological Materials Licenses are only offered on a nonexclusive basis.

Licenses are negotiated pursuant to the policy and objectives set forth in 35 U.S.C. 207-209 and 37 CFR 404. Pursuant to 35 U.S.C. 209, information submitted by a license applicant shall be treated as privileged and confidential and is not subject to disclosure under 5 U.S.C. 552 (Freedom of Information Act).

PLEASE READ THESE INSTRUCTIONS BEFORE COMPLETING THE LICENSE APPLICATION FORM. SUBMISSION OF AN INCOMPLETE APPLICATION MAY RESULT IN A DELAY IN THE LICENSE APPLICATION PROCESS. PLEASE BE AWARE THAT USDA CANNOT ASSURE THE CONFIDENTIALITY OF INFORMATION SUBMITTED ELECTRONICALLY.

Items 1 - This item is for the purpose of identifying the federally owned invention that is the subject of the license application. If you do not have this information, you can rely on the description provided under item 6 below.

Items 2, 3 and 4 - Not applicable for biological materials.

Item 5 – This box is pre-set as "Nonexclusive". Biological materials cannot be exclusively licensed.

Item 6 – Identify and describe the biological material to be licensed. Please include all identifying information available to you, including cell line, clone or isolate numbers, as appropriate, as well as any identifying characteristics.

Item 7 - Identify the individual, publication or other source of information concerning the availability for licensing of the identified invention. In many cases, the appropriate response will be “ARS, Office of Technology Transfer.”

Item 8 - Provide the complete name and address of the business or individual applying for a license.

Item 9 - If different from the response to Item 8, provide the complete name and address of the appropriate contact person for all license discussions.

Item 10 - Provide the state of incorporation for a business applicant or the state of citizenship for an individual applicant.

Item 11 - Provide a telephone number, a fax number, and an email address for the contact person identified under item 9.

Item 12 - Provide a brief description of the applicant’s current business, including the types of products manufactured and sold and the geographic area of product distribution. The description should also include basic business information concerning the applicant; e.g. the length of time the applicant has been in business, the size and location of business operations, etc. IN ALL CASES, please submit supporting documentation with your application; e.g., annual report, product catalogs, price lists, advertisements, etc. If such documents are available online, you may provide appropriate web sites or Internet addresses instead of paper documents.

Item 13 - Provide the number of employees employed by the applicant.

Item 14 - Indicate whether the applicant is a small business.

Item 15 - List fields of use in which applicant intends to practice the invention.

Item 16 – The box is pre-set with “NO” because it is not applicable to Biological Materials Licenses.

Item 17 - Indicate any special license terms or conditions desired by applicant. It is not necessary to respond to this item if it is not applicable.

Item 18 - Indicate applicant’s best knowledge of any current use of the invention by industry or government for research or commercial purposes.

Item 19 - List the countries where applicant intends to practice the invention.

Item 20 - THIS IS THE MOST CRITICAL ITEM ON THE APPLICATION FORM. Provide the applicant’s plan for commercializing the invention. The submitted plan should include:

a. A brief description of all commercial products expected to result from the license and how these products fit into applicant's current product line. You may also include any anticipated competitive advantages of these products and any possible product line extensions.

b. An approximate timeline, with relevant milestones, from the date the license agreement is signed until products are offered for sale. Itemize any factors that may arise during product development and scale-up that may affect the ultimate decision to offer products for sale.

c. Applicant's best current estimates of potential market size, market growth potential and any other market information available to applicant. A profitability analysis and any other financial projections available to applicant may also be included. These data will be used to help determine fair and reasonable license fees and royalties.

d. A concise description of the manufacturing, marketing, financial and technical resources needed to carry out applicant's commercialization plan, and how these resources will be provided and/or obtained by the applicant (e.g., applicant's existing facilities, in-house technical expertise, contract manufacturing, partnering with other entities, marketing through distributors, source(s) of financing, etc.).

e. Documentation of applicant's capability to provide and/or obtain the financial resources necessary to carry out the submitted plan. Such documentation might include the most recent annual report, the most recent SEC submission, accounting statements, bank statements, written commitments from third party investors, or any other documented source of financing sufficient to cover the anticipated financial investment required to carry out the submitted plan.

Item 21 - Provide any additional information that applicant would like to submit in support of the license application. It is not necessary to respond to this item if it is not applicable.

Item 22 - The license application must be signed and dated by an authorized company representative. The biological material license application may be submitted via e-mail, courier, and U.S. mail.

a. For e-mail, please convert the signed and dated original license application to a Portable Document Format (PDF) and send the PDF to license@usda.gov. Please address the e-mail to the attention of Business Licensing Officer.

b. For courier and U.S. mail, please submit the signed and dated original license application to:

Business Licensing Officer
U.S. Department of Agriculture

Agricultural Research Service
5601 Sunnyside Avenue, Rm 4-1159
Beltsville, Maryland 20705-5131
(301) 504-5989

Terms of License Agreements Granted by USDA

Licenses granted by USDA are royalty bearing and may include other fees and payments. **License fees and royalty rates are negotiable.** Information submitted by the applicant, including estimates of potential market size, market share and profitability, is used to help determine fair and reasonable terms. The financial and resource investments required for commercialization are also considered.

USDA license agreements include other terms required by law and regulation. (Please refer to 37 CFR 404.5). Licensees are required to submit periodic progress reports detailing the progress being made to commercialize the licensed materials. After the first sale of royalty bearing products, licensees are required to submit royalty reports, setting forth the amount of products made, used and sold and the amount of royalties due to USDA. Pursuant to 35 USC 209, all such reports are treated as privileged and confidential and are not subject to disclosure under 5 U.S.C. 552 (Freedom of Information Act).

Agency Disclosure of Estimated Burden (Rev. 09/04)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0518-0003. The time required to complete this information collection is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Applicants with suggestions for reducing this burden may contact: Business Licensing Officer, 5601 Sunnyside Avenue, Beltsville, MD 20705-5131.