



Your Life Sciences Company May Qualify for Small Business Programs

In fulfilling its needs for goods and services, the U.S. Government sets an annual goal of allocating 23% of its spending on goods and services provided by small businesses. As part of the annual \$200 billion Federal market, there are small business set-aside programs administered by the Small Business Administration (SBA), such as the Historically Underutilized Business Zone (HUBZone) Empowerment Contracting Program and the Woman-Owned Small Business Program.

For biotech and life sciences firms, there are also small business programs focused on research and technology. Under the Small Business Innovation Research (SBIR) Program, agencies with annual research and development budgets greater than \$100 million set aside 2.5% of their budgets for awards to small high-technology companies. The Small Business Technology Transfer (STTR) Program provides that agencies with annual research and development budgets greater than \$1 billion set aside 1.5% of their budgets for awards to small high-technology companies that collaborate with non-profit research institutions.

In addition, qualifying biotech and life sciences firms may be able to take advantage of the favorable treatment granted to small businesses under other Federal procurement programs, financial assistance programs, and patent fee discount programs.

IS YOUR COMPANY A SMALL BUSINESS?

Basic Requirements

The Small Business Act defines a small business as a business that:

1. is independently owned and operated;
2. is not dominant in its field of operation; and
3. meets the SBA size standard established for its industry according to the North American Industry Classification System (NAICS).

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While there is a good deal of guidance on size standards in the SBA regulations, neither the Small Business Act nor SBA regulations elaborate on the requirement that a business be “independently owned and operated.” However, this term has been interpreted to mean that a business may not be owned or controlled by a large business, or a business that would not qualify as a small business under applicable SBA size standards.

Size Standards

The SBA assigns size standards to each industry type in the NAICS. These standards are based on the average annual receipts or the average number of employees of a firm.

The receipts of a business are its total income plus cost of goods sold. The SBA calculates receipts by combining a business concern’s average annual receipts with the average annual receipts of all its affiliates.

Where an industry size standard is based on the average number of employees, SBA counts all individuals employed on a full-time, part-time, or other basis, including temporary employment. Again, the calculation combines the average number of employees of a business concern with the average number of employees of all its affiliates.

For businesses engaged in research and development in the life sciences, the size standard is 500 employees. A complete list of size standards is available through the SBA website at <http://www.sba.gov/size/sizetable2002.html>.

Affiliation

In determining whether a business qualifies for small business status, the SBA will consider the business and all of its affiliates. It therefore is important to consider what constitutes an “affiliate” under SBA regulations. Affiliation exists where one entity controls or has the power to control another entity, or a third party controls or has the power to control both entities. Control may be positive (the ability to direct corporate action) or negative (the ability to prevent corporate action). Affiliation may be based on any of the following factors:

- Stock Ownership — it is not necessary for an entity to own 50% or more of a company’s voting stock to be deemed an affiliate. If an entity owns a block of voting stock that is large compared to other blocks of voting stock, that is sufficient for a finding of affiliation.
- Stock Options, Convertible Securities, and Agreements to Merge — these are considered to have a present effect; in determining the size of a

business, the SBA treats stock options, convertible securities and agreements to merge as if the rights granted thereby have been exercised.

- Common Management
- Identity of Interest — examples are family members, individuals or firms with common investments, or firms that are economically dependent based on contractual or other relationships.
- Newly Organized Concern Rule — affiliation exists where former officers, directors, principal stockholders, managing members or key employees of one business organize a new business in the same or related industry and serve as officers, directors, principal stockholders, managing members or key employees of the new business, and one business is furnishing the other with contracts, facilities, financial assistance or technical assistance.
- Joint Ventures
- Franchise and License Agreements — affiliation may be based on common ownership, common management or excessive restrictions on the sale of the franchise, but not on standardized quality, advertising, accounting format or other similar provisions in a franchise or license situation.

In determining affiliation, the SBA considers the totality of the circumstances, and may find affiliation in cases where no single factor is sufficient to support a finding of affiliation.

Self-Certification

A business seeking small business treatment in government procurements must self-certify that it is a small business. The government contracting officer may accept such certification as true unless any interested party protests such certification or there exists other credible information on the basis of which the contracting officer may question the certification. Knowing misrepresentation of size status may result in severe criminal penalties as provided under the Small Business Act.

SMALL BUSINESS STATUS IS NOT ONE-SIZE-FITS-ALL

Meeting the applicable SBA size standard qualifies a business as a small business for most government programs. However, for certain procurement programs, a business must meet the size standard established by the procuring agency's contracting officer based on the industry classification of the goods or services covered by the particular contract. This may not always be the same industry classification as the business's classification under the NAICS. Also, certain programs have their own specific size standards.

Therefore, it is important to confirm size standard requirements on a case-by-case basis.

There are also special requirements for the SBIR Program. Under the SBIR Program, a business is a small business if, together with any affiliates, it has 500 or fewer employees and:

1. it is at least 51% owned and controlled by one or more individuals who are U.S. citizens or permanent resident aliens;
2. it is at least 51% owned and controlled by another business that is itself at least 51% owned and controlled by one or more individuals who are U.S. citizens or permanent resident aliens; or
3. it is a joint venture in which each entity to the venture meets either of the above requirements.

It is important to understand that in this context, the term "individuals" is limited to natural persons, as opposed to entities. In the Size Appeal of CBR Laboratories, Inc. (SBA No. SIZ-4423 (2001)), Administrative Judge Blazsik held that CBR Laboratories did not satisfy the definition of small business for purposes of the SBIR Program because it was a wholly-owned subsidiary of a non-profit corporation. Furthermore, Judge Blazsik specifically excluded institutional investors, such as venture capital funds, from the definition of "individuals" in the Size Appeal of

Cognetix, Inc. (SBA No. SIZ-4560 (2003)).

More information on the SBIR and STTR Programs is available at <http://www.sba.gov/sbir/>.

Similarly, there are specific size standards applicable to businesses seeking eligibility for reduced patent fees. To qualify as a small business for this purpose and obtain a 50% discount on patent fees, a business and its affiliates must:

1. have 500 or fewer employees; and
2. not have assigned any rights in the invention to any inventor who is not an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business.

GETTING WITH THE PROGRAM

In order to take advantage of small business opportunities, consider taking the following steps:

- Register with the Central Contractor Register (CCR) at <http://www.ccr.gov/>, which agency contracting officers use to search prospective vendors.
- Search procurement opportunities in the FedBizOpps database at <http://www.fedbizopps.gov/>.
- Contact the Office of Small Disadvantaged Business Utilization (OSDBU) of the agency you are interested in. For

Health and Human Services, see <http://www.dhhs.gov/osdbu/>.

- Attend small business fairs held by agencies you are interested in.

The SBA website, <http://www.sba.gov/>, is also a great resource, providing applicable laws and regulations, as well as user friendly guidance and information on local SBA offices and training events.

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