



Department of the Treasury
Internal Revenue Service
P.O. Box 2508
Cincinnati, OH 45201

Date:
June 25, 2015
Employer ID number:

Contact person/ID number:

Contact telephone number:

Form you must file:

Tax years:

UIL: 501.33-00, 501.35-00,
501.36-01

Number: **201538025**
Release Date: 9/18/2015

Dear _____ :

This letter is our final determination that you don't qualify for tax-exempt status under Section 501(c)(3) of the Internal Revenue Code (the Code). Recently, we sent you a proposed adverse determination in response to your application. The proposed adverse determination explained the facts, law, and basis for our conclusion, and it gave you 30 days to file a protest. Because we didn't receive a protest within the required 30 days, the proposed determination is now final.

Because you don't qualify as a tax-exempt organization under Section 501(c)(3) of the Code, donors can't deduct contributions to you under Section 170 of the Code. You must file federal income tax returns for the tax years listed at the top of this letter using the required form (also listed at the top of this letter) within 30 days of this letter unless you request an extension of time to file.

We'll make this final adverse determination letter and the proposed adverse determination letter available for public inspection (as required under Section 6110 of the Code) after deleting certain identifying information. Please read the enclosed Notice 437, *Notice of Intention to Disclose*, and review the two attached letters that show our proposed deletions. If you disagree with our proposed deletions, follow the instructions in the Notice 437 on how to notify us. If you agree with our deletions, you don't need to take any further action.

We'll also notify the appropriate state officials of our determination by sending them a copy of this final letter and the proposed determination letter (under Section 6104(c) of the Code). You should contact your state officials if you have questions about how this determination will affect your state responsibilities and requirements.

If you have questions about this letter, you can contact the person listed at the top of this letter. If you have questions about your federal income tax status and responsibilities, call our customer service number at 1-800-829-1040 (TTY 1-800-829-4933 for deaf or hard of hearing) or customer service for businesses at 1-800-829-4933.

Sincerely,

Director, Exempt Organizations

Enclosure:

Notice 437

Redacted Letter 4036, *Proposed Adverse Determination Under IRC Section 501(c)(3)*

Redacted Letter 4038, *Final Adverse Determination Under IRC Section 501(c)(3) - No Protest*



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Contact fax number:

Legend:

B = state
C = date
D = association

UIL:

501.33-00
501.35-00
501.36-01

We considered your application for recognition of exemption from federal income tax under Section 501(a) of the Internal Revenue Code (the Code). Based on the information provided, we determined that you don't qualify for exemption under Section 501(c)(3) of the Code. This letter explains the basis for our conclusion. Please keep it for your records.

Issues

Do you qualify for exemption under section 501(c)(3) of the Code? No, for reasons given below.

Facts

You were formed as a corporation in the state of B on C to promote the development of the medical device industry and medical devices for underserved patients in orphan markets.

You are a membership organization of qualified medical device professionals. Your Board of Directors consists of three to five members, together with your officers.

Your mission is to facilitate meaningful innovations that improve care and/or the cost of care for orphan markets that may otherwise be ignored or inappropriately resourced. You are open to the broad spectrum of the medical device industry, but you intend to focus on the needs of women and products used in rare diseases and conditions.

It is your belief that non-profit status will help you build the trust necessary to work with innovators, and you will be better perceived by non-traditional capital investors.

To achieve your purpose, you give free business counseling to medical product startup companies. You educate inventors and medical device innovators on how to get new products to market that would not have a chance under the majority of current distribution models. You go on to say you are targeting technologies that help small market innovation not being addressed in the current market.

You have counseled several inventors and start up medical device companies with a focus on “un-met” medical needs. The only relevant criterion in being able to receive free services is that the invention be related to health care or medical products.

The medical device market is highly regulated by the FDA. Because of the high cost of obtaining market approval from the FDA a lot of good products are not brought to the market. You have reviewed several technologies that would add safety to medical devices, but the distribution system would not support the new product because there were no disposable parts. The medical device industry relies on disposable parts so sales reps are in constant contact with hospitals/customers. You are challenging this model by supporting product development that really helps the end users and patients, not just the distributor. Specific examples of counseling including reaching out to the D to review and evaluate the inventions, give guidance on patent protections, and enter into license arrangements to the inventors could get a new technology to the market.

You also target technologies that help small markets that are not being addressed. You will provide a niche service that directs the financial, technical and market development for small market innovations. You leverage your corporate status and expertise, experience and relationships in the medical device industry. You were established as a non-profit to facilitate and encourage financial participation that will be used in providing professional education programs for innovators and interested parties in the healthcare industry. You also expect to receive revenue opportunities from products brought to market.

When you accept a project, you will take ownership and assume the risk for the technical, financial, reimbursement and market development efforts. Your approach to the resources required for technical development is through a “pay-it-forward” model. You assume there is typically some degree of excess capacity with contract R&D, contract manufacturing and main stream medical device companies. Your connections in the industry will enable you to identify vendors willing to invest time and resources on worthy projects with a mutually acceptable commitment for payment at a future date. A similar approach for the quality and regulatory requirements will be used.

A strategy and plan for market execution under your direction for divesting to an interested company will be developed early in the process. When the product is ready for market and revenue is established or a buyer is identified, your development partners will be prioritized for reimbursement of incurred costs. Your agreement with the inventor will include some form of royalty tied to revenue, their contribution to the development process, and timing of settlement with partners participating in the product’s development.

After settlements, including royalties, you intend to reinvest the remaining and ongoing proceeds into future idea development. You will also provide modest compensation for your principals. Any product selected will be thoroughly vetted for market need, user acceptability and cost impact to the healthcare system related to the product value. Resources for product development, patent and other legal, regulatory pathway, quality system development, and manufacturing will be identified and engaged as required. Preliminarily a market assessment will be conducted to determine if you will source distribution or will identify a buyer for the technology. If the company chooses to initially distribute the product, you will identify independent sales resources and or companies that are interested in adding the “new” product to a complimentary product portfolio. Marketing may be a combined function of yourself and the distribution channel(s) chosen, or it may be handled exclusively by you or exclusively by the channel(s). You may determine that licensing the technology or selling the technology to a company will provide the best overall value. In these scenarios, some or all of the

product development, regulatory, quality and manufacturing responsibility may be transferred to the licensee or acquirer.

You propose to reimburse the product(s) inventor, based on:

1. Prevailing market for royalties which currently range from 5% to 10% of revenue or profit,
2. The inventor's contribution to product development or other expertise, and
3. The length of the negotiated royalty contract.

There are no other fees, unless you are providing a service workshop or other such offering. The cost of service offerings will vary based on content, time and resources required. Costs for facilities and outside resources will be passed on at your cost. Costs for programs will include a nominal profit that will be reinvested into the company's projects.

You plan to advertise the products and services you offer. You will have mailing lists and flyers for program content to advertise your services. You will solicit and advertise for potential donation and communicate directly with interested parties. You believe that through successful product development you can expand your outreach advertising to important resources. If necessary, you will advertise products to appropriate media such as convention exhibits, product literature, mailings, and product videos to educate users.

There will be no distinguishing characteristics between sales of your devices versus those of other competing entities. Sales proceeds will be managed like any other business, but your emphasis will be to put as much back into product development and service offerings development as possible. Sales will cover product development, regulatory pathway costs, quality systems development, patent and legal expenses, royalties, cost to manufacture and distribute, and nominal management stipends. Sales will be used to grow the educational seminars and additional research and development efforts on orphan products.

You may license your intellectual property to generate additional revenue. You will determine value using a discounted cash flow method by evaluating the market size, the ability to penetrate the market based on a percentage of growth to the market based on the navel product which will allow an approximate total value. You will discount the total value to take into account sales and marketing risk, time to market based on regulatory approval of FDA, strength of patents, cost of goods, and likelihood of success. You will use experience in guiding you to a reasonable return on the investment.

You anticipate additional income from membership fees. Your expenses will be for network development, rent, marketing materials, program management, data management, employees and office equipment.

Law

Section 501(c)(3) of the Code describes corporations organized and operated exclusively for charitable purposes no part of the net earnings of which inures to the benefit of any private shareholder or individual.

Section 1.501(c)(3)-1(a)(1) of the income tax regulations states that, in order to be exempt as an organization described in section 501(c)(3) of the Code, an organization must be both organized and operated exclusively for one or more of the purposes specified in such section. If an organization fails to meet either the organizational test or the operational test, it is not exempt.

Section 501(c)(3)-1(c)(1) of the regulations provides that an organization will be regarded as "operated exclusively" for one or more exempt purposes only if it engages primarily in activities that accomplish one or more of such exempt purposes specified in section 501(c)(3) of the Code. An organization will not be so regarded if more than an insubstantial part of its activities is not in furtherance of an exempt purpose.

Section 1.501(c)(3)-1(d)(5)(i) of the income tax regulations provides that a scientific organization, as with other organizations described in IRC 501(c)(3), must be organized and operated in the public interest. This means that organizations that primarily pursue business purposes or that serve substantial private interests are not entitled to exemption under IRC 501(c)(3). Hence, scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations such as the inspection of products or the designing of equipment. Reg. 1.501(c)(3)-1(d)(5)(ii).

Revenue Ruling 65-1, 1965-1 C.B. 226, 1965 WL 2846, holds that an organization which promotes and fosters the development and design of machinery in connection with a commercial operation, and in connection therewith has the power to sell, assign, and grant licenses with respect to its copyrights, trademarks, trade name or patent rights, does not qualify for exemption from Federal income tax under section 501(c)(3) of the Internal Revenue Code. The successful development of such machinery is expected to ultimately result in reducing the cost of the particular crops to the public.

Better Business Bureau of Washington D.C. v. United States, 148 F.2d 14, 16 (D.C. 1945). The Bureau has no shares of stock and no part of its earnings inures to the benefit of any private shareholder or individual. The Bureau work serves primarily to promote ethical business practices. Nonetheless, the Supreme Court held that since the activities of the Bureau are motivated by a commercial purpose, the organization does not operate exclusively for educational purposes. Note also that business leagues, chambers of commerce, and boards of trade are exempt from income tax under section 501(c)(6) of the Code, but are not charitable organizations as described in section 501(c)(3) of the Code.

B.S.W. Group, Inc. v. Commissioner, 70 T.C. 352 (1978), the court found that a corporation formed to provide consulting services did not satisfy the operational test under section 501(c)(3) of the Code because its activities constituted the conduct of a trade or business that is ordinarily carried on by commercial ventures organized for profit. Its primary purpose was not charitable, educational, or scientific, but rather commercial. In addition the court found that the organization's financing did not resemble that of the typical section 501(c)(3) organizations. It had not solicited, nor had it received, voluntary contributions from the public. Its only source of income was from fees from services, and those fees were set high enough to recoup all projected costs and to produce a profit. Moreover, it did not appear that the corporation ever planned to charge a fee less than "cost." And finally, the corporation did not limit its clientele to organizations that were section 501(c)(3) exempt organizations.

Federation Pharmacy Services, Inc. v. Commissioner, 72 T.C. 687 (1979), the court upheld the Commissioner's denial of exemption under section 501(c)(3) of the Code. The organization was organized to operate a pharmacy to sell drugs at discount prices to elderly and handicapped persons. The court reasoned that the organization operated its business primarily for commercial purposes, in competition with profit-making drug stores. The mere fact that products sold by the organization were helpful to health did not necessarily entitle it to exemption under section 501(c)(3).

In reaching its conclusion in *Federation Pharmacy Services*, the court reasoned,

It is clear that petitioner's exclusive purpose for being, its *raison d'etre*, is to sell drugs, an activity that is normally carried on by a commercial profitmaking enterprise. It does not serve as an adjunct to a larger exempt entity. It operates in the manner of an old-fashioned cooperative. We fail to see how the fact that it happens to deal in drugs can convert it to a section 501(c)(3) organization. If it could be so converted, then so could a store selling orthopedic shoes, crutches, health foods, or any other product beneficial to health. Virtually everything we buy has an effect, directly or indirectly, on our health. We do not believe that the law requires that any organization whose purpose is to benefit health, however remotely, is automatically entitled, without more, to the desired exemption. We have been cited no evidence that Congress intended to exercise its grace in such an expansive manner.

Airlie Foundation v. I.R.S., 283 F. Supp. 2d 58 (D. D.C. 2003), the District Court found that the organization was formed principally to organize, host, conduct and sponsor educational and other charitable functions on its facilities. The organization's patrons were not limited to tax-exempt entities, but included patrons of a private and corporate nature. The organization paid significant advertising and promotional expenses and derived substantial income from weddings and special events held at its conference center. The court determined that the organization's activities competed with a number of commercial, as well as non-commercial entities, which strongly evidenced a commercial nature and purpose. The court concluded that although the organization carried out a number of charitable and educational activities, these were incidental to its primary activity of operating a for-profit conference center.

Application of Law

You are not described in Code section 501(c)(3) because you are not operated exclusively for charitable and educational purposes. You do not meet the provisions of Section 1.501(c)(3)-1(a)(1) of the regulations and fail the operational test. Per section 1.501(c)(3)-1(c)(1) of the regulations more than an insubstantial part of your activities are devoted to a non-exempt purpose, here, the identification, development, promotion and sales of medical devices. Your activities support the development of medical devices through counseling/advising companies. You have indicated there are no limitations placed on who may receive these services in terms of a company's charitable qualifications. You seek out vendors to invest resources in potential products, take ownership for developing and pushing the product forward to market, and identify buyers for the product. You will advertise the product to expand your outreach increasing resources. You have stated your products and sales will not differ from any competitor in the market, and proceeds will be managed like any other business. While portions of your activities involve education in the form of counseling to start-up businesses, more than an insubstantial amount of your activities are devoted to non-exempt purposes under 501(c)(3).

Also, per Section 1.501(c)(3)-1(d)(5)(i) of the income tax regulations, you are not serving scientific purposes exempt under 501(c)(3) in that you are primarily conducting activities that serve the private interests of businesses and development partners. Scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations such as the inspection of products or the designing of equipment.

You are similar to the organization in Revenue Ruling 65-1 in that you are promoting the design and development of medical devices, with any potential operators, and will sell or grant rights to these devices. Similar to the ruling, even though the intent was to generate machinery that would ultimately

benefit the public, the organization was still found to not be exempt due to the commercial operations undertaken. While your products may have the public as the end user benefitting from lowered costs, or better products, etc., your method of operations are not distinguishable from similar commercial operations and therefore do not qualify.

You are similar to the organization denied exemption in B.S.W. Group, Inc. v. Commissioner. More than an insubstantial amount of your activities constitute the conduct of a trade or business ordinarily carried on by commercial ventures organized for profit. You seek out resources such as vendors of products willing to invest time and resources for commitment to payment at a future time. You will have development partners who will be reimbursed for incurred costs. You intend on committing royalties once a product generates revenue. Products selected for development will be vetted for market need and user acceptability. If you decide to distribute a product yourself you will identify sales resources or companies looking for new products. In all, these are indicative of practices that are commercial, rather than charitable, educational or scientific in nature. Further, you intend on licensing products for revenue – the only other estimated source of funds being member contributions.

You are similar to the organization in Airlie Foundation in that the clientele or customer you intend on serving are not limited, you will advertise your services, products created will provide you with substantial income, and you will be competing with other medical devices created and sold by outside commercial entities. Together, these indicate a commercial nature and purpose. Your purpose is to develop and sell medical devices, an activity that is normally carried on by a commercial profitmaking enterprise. Your primary purpose is not charitable or educational but commercial to develop products to put to market and sell. The educational activity of advising companies you are working with is only to help bring a product to market. Further, per Federation Pharmacy Services, merely serving the health industry does not immediately entitle an organization to exemption under 501(c)(3).

As held in the Better Business Bureau case, you are not exempt because you are motivated by a commercial purpose of sales to a niche market at a profit to you and the inventors who receive royalties. Therefore, you do not operate exclusively for any 501(c)(3) purposes.

Conclusion

You do not qualify for exemption under section 501(c)(3) of the Internal Revenue Code because you do not meet the operational test. You are serving primarily non-exempt purposes that are commercial in nature.

If you don't agree

You have a right to file a protest if you don't agree with our proposed adverse determination. To do so, you must send a statement to us within 30 days of the date of this letter. The statement must include:

- Your name, address, employer identification number (EIN), and a daytime phone number
- A copy of this letter highlighting the findings you disagree with
- An explanation of why you disagree, including any supporting documents
- The law or authority, if any, you are relying on

- The signature of an officer, director, trustee, or other official who is authorized to sign for the organization, or your authorized representative
- One of the following declarations:

For an officer, director, trustee, or other official who is authorized to sign for the organization:

Under penalties of perjury, I declare that I examined this protest statement, including accompanying documents, and to the best of my knowledge and belief, the statement contains all relevant facts and such facts are true, correct, and complete.

For authorized representatives:

Under penalties of perjury, I declare that I prepared this protest statement, including accompanying documents, and to the best of my knowledge and belief, the statement contains all relevant facts and such facts are true, correct, and complete.

Your representative (attorney, certified public accountant, or other individual enrolled to practice before the IRS) must file a Form 2848, *Power of Attorney and Declaration of Representative*, with us if he or she hasn't already done so. You can find more information about representation in Publication 947, *Practice Before the IRS and Power of Attorney*.

We'll review your protest statement and decide if you provided a basis for us to reconsider our determination. If so, we'll continue to process your case considering the information you provided. If you haven't provided a basis for reconsideration, we'll forward your case to the Office of Appeals and notify you. You can find more information about the role of the Appeals Office in Publication 892, *How to Appeal an IRS Decision on Tax-Exempt Status*.

If you don't file a protest within 30 days, you can't seek a declaratory judgment in court at a later date because the law requires that you use the IRS administrative process first (Section 7428(b)(2) of the Code).

Where to send your protest

Please send your protest statement, Form 2848, if needed, and any supporting documents to the applicable address:

U.S. mail:

Internal Revenue Service
EO Determinations Quality Assurance
Room 7-008
P.O. Box 2508
Cincinnati, OH 45201

Street address for delivery service:

Internal Revenue Service
EO Determinations Quality Assurance
550 Main Street, Room 7-008
Cincinnati, OH 45202

You can also fax your statement and supporting documents to the fax number listed at the top of this letter. If you fax your statement, please contact the person listed at the top of this letter to confirm that he or she received it.

If you agree

If you agree with our proposed adverse determination, you don't need to do anything. If we don't hear from you within 30 days, we'll issue a final adverse determination letter. That letter will provide information on your income tax filing requirements.

You can find all forms and publications mentioned in this letter on our website at www.irs.gov/formspubs. If you have questions, you can contact the person listed at the top of this letter.

Sincerely,

Director, Exempt Organizations

Enclosure:
Publication 892