



Department of the Treasury
Internal Revenue Service
Tax Exempt and Government Entities
PO Box 2508
Cincinnati, OH 45201

Number: **202126024**
Release Date: 7/2/2021

UIL Number: 501.00-00, 501.03-24, 501.30-30

Date:
04/06/2021
Employer ID number:
Form you must file:
Tax years:
Person to contact:
Name:
ID number:
Telephone:

Dear _____ :

This letter is our final determination that you don't qualify for exemption from federal income tax under Internal Revenue Code (IRC) Section 501(a) as an organization described in IRC Section 501(c)(3). 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 IRC Section 501(c)(3), donors generally can't deduct contributions to you under IRC Section 170.

We may notify the appropriate state officials of our determination, as required by IRC Section 6104(c), by sending them a copy of this final letter along with the proposed determination letter.

You must file the federal income tax forms for the tax years shown above within **30 days** from the date of this letter unless you request an extension of time to file. For further instructions, forms, and information, visit www.irs.gov.

We'll make this final adverse determination letter and the proposed adverse determination letter available for public inspection after deleting certain identifying information, as required by IRC Section 6110. 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.

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

Sincerely,

Stephen A. Martin
Director, Exempt Organizations
Rulings and Agreements

Enclosures:
Notice 437
Redacted Letter 4034
Redacted Letter 4038



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

Date:
 02/10/2021
 Employer ID number:

Contact person/ID number:

Contact telephone number:

Contact fax number:

Legend:

- B = Date
- C = State
- D = Date
- F = Software
- G = Company
- H = Company
- J = Medication
- K = Medication
- L = Company
- M = Countries
- N = Company
- P = Medication
- Q = Continent
- R = System
- S = Product
- T = Medicine
- U = Disease
- V = Disease

UIL:

- 501.00-00
- 501.03-24
- 501.30-30

Dear _____ :

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

Issues

Do you qualify for exemption under IRC Section 501(c)(3)? No, for the reasons stated below.

Facts

You formed as a Limited Liability Company on B in the state of C. You converted to a Nonprofit Corporation on D. Your Nonprofit Corporation Charter states that you are a public benefit corporation but has no specific purpose clause.

According to your narrative description of activities, you were formed to amplify health using technology, education and research. You intend to improve healthcare and outcomes in all countries, starting with

Each of these are targets for research, quality improvement, patient care facilitation, and education supported by you.

You currently maintain one corporate office and engage third-party contractors for various services, including software development, some administrative tasks, and medical professional consultations.

As of the date you submitted your application for exemption, you were engaged in several research initiatives.

You expect to be engaged on a variety of research engagements designed to improve healthcare outcomes in low-resource areas and help educate the world's network of physicians about how to improve healthcare.

F is used in all aspects of education and research, including data collection, data quality controls, data management, statistical analysis, reporting, and publication. Examples include the educational platform on your website used to disseminate knowledge and multiple research projects that are based on having a core registry

of patients and an expandable software platform that can manage new information about those patients to gain additional insights for patient care, quality improvement, and research. For example

As another example of how integrated the software is with each project, in your engagement with G (now a division of H) providers in all the countries involved in the study enter the data for the relevant patients into F, through which it can be analyzed by your research staff. You expect many engagements similar to the G engagement where your software facilitates the aggregation, analysis, and reporting of the information relevant to the study.

In addition to the use of the software for these specific studies, the software is made available for general quality improvement and patient care, not only to participants in the study, but to anyone, anywhere, for free, as long as they acknowledge the user agreement.

You provided a copy of the F End User License Agreement. The agreement states that users may use the software for any purpose expressly permitted by applicable law, including treatment, payment, and health care operations. It also provides that you may also place advertisements concerning the products and services of third parties throughout the software, so that users see them when they use the software product. You may also present to users, through emails, displays or advertisements, the opportunity to learn about, access, integrate with, or otherwise use services operated by third parties. If users choose to sign-up for or utilize a third-party service, that third-party service may be able to access the user's information. Although you may receive remuneration from the operators or sponsors of these third-party services, you do not endorse any of their products.

We asked you to explain how and by whom drugs were selected on which you perform testing and research. In your reply, you stated that most research in which you are involved focuses on improving supportive care, reducing abandonment of treatment, and making a correct diagnosis, but did not explain how or by whom the drugs were selected in your research contracts.

We asked if the results of your research are used in any way by the pharmaceutical companies in marketing applications to the Food and Drug Administration (FDA). In reply, you stated that because you have a focus on low-and middle-income countries, it would be unusual for your work to have FDA/EMA regulatory implications, but not impossible. For example, data and publications resulting from the L project can be combined with other data not evaluated by your team (e.g. safety data) and used to support FDA regulatory filings.

We asked if the research you conduct is connected to any FDA requirements related to testing for safety and efficacy. You replied that you have not conducted research related to such requirements.

You state in your application that you will retain ownership of intellectual property related to your research services, but those trademarks will not be marketed for profit. We asked for more information about who owns or will own the rights to intellectual property created through your research. You replied that your research does not create intellectual property or trade secrets.

You supplied a copy of your Master Services Agreement with L.

You provided a copy of your Master Services Agreement with G.

You provided a copy of the Services Agreement between you and N,

All your revenue is derived from the three service contracts you described in your application; almost half is from your contract with L. Most of your expenses are for compensation paid to employees and independent contractors.

Law

IRC Section 501(c)(3) provides, in part, for the exemption from federal income tax to organizations organized and operated exclusively for charitable, religious or educational purposes, provided that no part of its net earnings inures to the benefit of any private shareholder or individual.

Treasury Regulation Section 1.501(c)(3)-1(a)(1) provides that, in order to be exempt as an organization described in IRC Section 501(c)(3), 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.

Treas. Reg. Section 1.501(c)(3)-1(b)(1)(i) provides that an organization is organized exclusively for one or more exempt purposes only if its articles of organization:

- (a) Limit the purposes of such organization to one or more exempt purposes; and
- (b) Do not expressly empower the organization engage, otherwise than as an insubstantial part of its activities, in activities that in themselves are not in furtherance of one or more exempt purposes.

Treas. Reg. Section 1.501(c)(3)-1(c)(1) provides that an organization will be regarded as operated exclusively for one or more exempt purposes only if it engages primarily in activities which accomplish one or more of such exempt purposes specified in IRC Section 501(c)(3). An organization will not be so regarded if more than an insubstantial part of its activities is not in furtherance of an exempt purpose.

Treas. Reg. Section 1.501(c)(3)-1(d)(1)(ii) provides that an organization is not organized or operated exclusively for one or more exempt purposes unless it serves a public rather than a private purpose. To meet this requirement, it is necessary for an organization to establish that it is not organized or operated for the benefit of private interests.

Treas. Reg. Section 1.501(c)(3)-1(d)(2) provides that the term charitable includes the relief of the poor and distressed and promotion of social welfare through charitable activities.

Treas. Reg. Section 1.501(c)(3)-1(d)(4) defines the term "testing for public safety" as used in IRC Section 501(c)(3) to include the testing of consumer products, such as electrical products, to determine whether they are safe for use by the general public.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(i), in defining the term "scientific", provides that since an organization may meet the requirements of IRC Section 501(c)(3) only if it serves a public rather than a private interest, a "scientific" organization must be organized and operated in the public interest.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(ii) further provides that scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, as, for example, the ordinary testing or inspection of materials or products.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(iii) provides, in part, that scientific research will be regarded as carried on in the public interest if the results of such research (including any patents, copyrights, processes, or formulae resulting from such research) are made available to the public on a nondiscriminatory basis, if such research is performed for the United States, or any of its agencies or instrumentalities, or for a State or political subdivision thereof, or if such research is directed toward benefiting the public.

Revenue Ruling 65-60, 1965-1 C.B. 231, discusses an organization formed for the primary purpose of developing and disseminating a body of new knowledge relating to the social sciences. The organization's professional research staff consists of persons qualified by education and experience to perform scientific research in these fields. Activities of the organization consist of the performance of scientific research under the contracts with governmental agencies and the conduct of seminar courses attended by qualified members of the public. It performs no contract research for the private benefit of any person or organization, as distinguished from performing scientific research in the public interest. Results of the organization's research activities are communicated to the public through seminar courses, lectures, and public discussions, and through publications distributed free to depository libraries. Held, the organization qualifies for exemption from federal income tax as an educational and scientific organization described in IRC Section 501(c)(3).

Rev. Rul. 68-373, 1968-2 C.B. 206, holds that a nonprofit organization primarily engaged in testing drugs for commercial pharmaceutical companies does not qualify for exemption under IRC Section 501(c)(3). The organization's principal activity is clinically testing drugs for commercial pharmaceutical companies. These tests are required in order to comply with FDA requirements that drugs be tested for safety and efficacy before they can be marketed. The pharmaceutical companies select the drugs to be tested and use the results of the tests in their marketing applications to the FDA. In addition, the results of the tests are freely available for publication in various scientific and medical journals. All the organization's income is derived from the pharmaceutical companies in payment for testing services.

Rev. Rul. 76-442, 1976-2 C.B. 148, states that a nonprofit organization whose primary activity is the offering of free legal services for personal and estate planning to individuals who wish to make current and deferred gifts to charity as part of their overall tax and estate planning does not qualify for exemption under IRC Section 501(c)(3).

Better Business Bureau of Washington D.C., Inc. v. United States, 326 U.S. 279 (1945), held that the presence of a single nonexempt purpose, if substantial in nature, will preclude tax exemption under IRC Section 501(c)(3).

In B. S. W. Group, Inc. v. Commissioner, 70 T.C. 352 (1978), the organization provided consulting services for a fee to various tax-exempt and non-profit organizations. The organizations fees were set at or close to cost. The court concluded that those activities are not inherently charitable because they are of the type typically conducted by for-profit organizations. Even though the organization argued that its fees may in fact be lower than those charged by other firms, the court concluded that it was not enough to prove that organization's purposes are primarily exempt. The Court concluded that the petitioner is not an organization described in IRC Section 501(c)(3) because its primary purpose is neither educational, scientific, nor charitable, but rather commercial.

In Schoger Foundation v. Commissioner, 76 T.C. 380 (1981), it was held that if an activity serves a substantial nonexempt purpose, the organization does not qualify for exemption even if the activity also furthers an exempt purpose.

In Old Dominion Box Co. v. United States, 477 F.2d 340 (1973), the court held that operating for the benefit of private parties constitutes a substantial non-exempt purpose.

In Washington Research Foundation v. Commissioner, T.C. Memo 1985-570 (1985), the Tax Court held that an organization that facilitates transfer of technology from nonprofit organizations' labs for public use through licensing arrangements with private industry did not qualify for exemption under IRC Section 501(c)(3), because the immediate benefit of its activities rebounds to private industry and the nonprofit research institutions and only indirectly to the general public. It was found that these activities are commercial in nature and not in direct furtherance of exempt purposes.

Application of law

IRC Section 501(c)(3) and Treas. Reg. Section 1.501(c)(3)-1(a)(1) set forth two main tests for an organization to be recognized as exempt. An organization must be both organized and operated exclusively for purposes described in Section 501(c)(3). Based on the information you provided in your application and supporting documentation, we conclude that you fail both tests.

Your Articles of Incorporation do not include a clause that limits your purposes to one or more exempt purposes. Therefore, you have not satisfied the organizational test described in Treas. Reg. Section 1.501(c)(3)-1(b)(1)(i).

Per Treas. Reg. Section 1.501(c)(3)-1(c)(1), you are not operated exclusively for one or more exempt purposes because more than an insubstantial part of your activities involves providing research services in a commercial manner; providing software to facilitate private practices of doctors, nurses, pharmacists; and creating educational content under contract for a fee, none of which are in furtherance of exempt purposes.

A substantial part of your activities are research projects for sponsoring pharmaceutical companies. You are providing a service for a fee for the pharmaceutical companies which is supplemental to their commercial operations and to the marketing of their products. Clinical testing to determine the efficacy of drugs is merely a service performed for the pharmaceutical companies and serves the private interests of the pharmaceutical

companies rather than an exclusively public purpose and is not scientific research with the meaning of Treas. Reg. Section 1.501(c)(3)-1(d)(5)(i).

Until a drug is approved for marketing by the FDA, it is not a "consumer product" available for general use by the public. The clinical testing of a drug for safety and efficacy in order to enable the manufacturer to meet FDA requirements for marketing is not "testing for public safety" as defined by Treas. Reg. Section 1.501(c)(3)-1(d)(4), but is merely a service performed for the manufacturer. Per Treas. Reg. Section 1.501(c)(3)-1(d)(1)(ii), you are providing a service for a fee to the pharmaceutical companies and therefore serving the private interests of the pharmaceutical companies rather than the public interest. Your research is not regarded as being carried out in the interest of the public because you are limited to when and what you are allowed to publish. Further, you have no rights to the resulting intellectual property created through your research. It remains the sole property of the sponsoring pharmaceutical company. See Treas. Reg. Section 1.501(c)(3)-1(d)(5)(iii).

You are operating in a manner similar to the organization described in B.S.W. Group, Inc. The contracts you submitted show that you conduct research for pharmaceutical companies for a fee. While you do create some educational content yourself,

Your primary purpose is therefore not scientific, but rather commercial.

You are like the organization described in Rev. Rul. 68-373 because a substantial part of your operations consists of conducting clinical trials for pharmaceutical companies.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(ii) states that scientific research does not include activities of a type ordinarily carried on as an incident to commercial operations. Clinical testing is an activity that is normally carried on as an incident to a pharmaceutical company's commercial operations.

Therefore, the testing you conduct is not considered scientific research under IRC Section 501(c)(3). You are not like the organization in Rev. Rul. 65-60, who conducted research for governmental agencies.

Similar to Old Dominion Box Co., your operations benefit private parties and constitute a substantial nonexempt purpose. You are also similar to the organizations in Better Business Bureau of Washington D.C., Inc. and Schoger Foundation because your activities serve substantial nonexempt purposes and because you have failed to establish that you are organized or operated exclusively for the benefit of public interests rather than those of the pharmaceutical companies you are working for. As in Washington Research Foundation, the immediate benefit of your activity rebounds to private industry. Treas. Reg. Section 1.501(c)(3)-1(d)(5)(iii) provides, in part, that scientific research will be regarded as carried on in the public interest if such research is directed toward benefitting the public.

As described in Treas. Reg. Section 1.501(c)(3)-1(d)(2), your activities do not exclusively further charitable purposes. Like the organization in Rev. Rul. 76-442, you are providing free software, F, to the public. Although it is available for free, the provision of this software to the public does not further a charitable purpose itself nor is it directed toward benefitting a charitable class. As in Rev. Rul. 76-442, you are providing a commercially available product to individuals and businesses that can afford it. Doctors, nurses, and pharmacists can use the software to operate and improve their private practices. The fact that it is available to everyone for free does not

make it a charitable activity or one that promotes social welfare within the meaning of Treas. Reg. Section 1.501(c)(3)-1(d)(2).

Conclusion

Based on the facts and circumstances presented, you do not qualify for exemption from federal income tax as an organization described in IRC Section 501(c)(3). You are not organized or operated exclusively for exempt purposes as set forth in Section 501(c)(3). Your formation document does not limit your purposes to those described in Section 501(c)(3), causing you to fail the organizational test. You fail the operational test because you are formed to provide services for a fee in a commercial manner to pharmaceutical companies for their private benefit. Your activities are not considered scientific research. The software you provide also does not further an exclusively charitable purpose, as it can be used by anyone interested. For these reasons, you do not qualify for exemption under Section 501(c)(3).

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.

If you don't agree

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

- Your name, address, employer identification number (EIN), and a daytime phone number
- A statement of the facts, law, and arguments supporting your position
- A statement indicating whether you are requesting an Appeals Office conference
- The signature of an officer, director, trustee, or other official who is authorized to sign for the organization or your authorized representative
- The following declaration:

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

Under penalties of perjury, I declare that I have examined this request, or this modification to the request, including accompanying documents, and to the best of my knowledge and belief, the request or the modification contains all relevant facts relating to the request, 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 they haven'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 gave us a basis to reconsider our determination. If so, we'll continue to process your case considering the information you provided. If you haven't given us a basis for reconsideration, we'll send your case to the Appeals Office and notify you. You can find more information 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 later because the law requires that you use the IRC administrative process first (IRC Section 7428(b)(2)).

Where to send your protest

Send your protest, Form 2848, if applicable, and any supporting documents to the applicable address:

U.S. mail:

Internal Revenue Service
EO Determinations Quality Assurance
Mail Stop 6403
P.O. Box 2508
Cincinnati, OH 45201

Street address for delivery service:

Internal Revenue Service
EO Determinations Quality Assurance
550 Main Street, Mail Stop 6403
Cincinnati, OH 45202

You can also fax your protest 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 they received it.

You can get the forms and publications mentioned in this letter by visiting our website at www.irs.gov/forms-pubs or by calling 800-TAX-FORM (800-829-3676). If you have questions, you can contact the person listed at the top of this letter.

Contacting the Taxpayer Advocate Service

The Taxpayer Advocate Service (TAS) is an independent organization within the IRS that can help protect your taxpayer rights. TAS can offer you help if your tax problem is causing a hardship, or if you've tried but haven't been able to resolve your problem with the IRS. If you qualify for TAS assistance, which is always free, TAS will do everything possible to help you. Visit www.taxpayeradvocate.irs.gov or call 877-777-4778.

Sincerely,

Stephen A. Martin
Director, Exempt Organizations
Rulings and Agreements