

NO PROTEST RECEIVED
Date... 12/30/96
Signature... [REDACTED]
[REDACTED]
[REDACTED]
D00

[REDACTED]

[REDACTED]
[REDACTED]

CP:E:EO:T:2

SEP 16 1996

Dear Applicant:

We have considered your application for recognition of exemption under section 501(c)(3) of the Internal Revenue Code.

The information submitted indicates that you were incorporated in the State of [REDACTED] on [REDACTED]. On [REDACTED], you amended your articles of incorporation to include a section 501(c)(3) purpose limitation and also a section 501(c)(3) dissolution provision.

Your purposes as initially stated in your articles of incorporation were "to develop and disseminate information on the safety, efficacy, and cost effectiveness of medical technology for the worldwide health community and to operate and promote the [REDACTED], an international testing program, to ensure the safety, efficacy, and acceptability of medical devices."

Your principal activity is the provision of medical equipment testing services to both foreign and domestic manufacturers that desire to sell medical devices in the United States. The United States Food and Drug Administration (FDA) has set standards that must be met by all manufacturers desiring to sell medical equipment in the United States. You also apply certain international equipment safety standards that meet the approval of the FDA in your testing and certification procedures. You are not yourself involved in the setting of safety standards for equipment. Your income consists entirely of fees for the provision of testing services. All of your expenditures are in support of your testing services. Earlier, you engaged in a program of providing representation of manufacturers to the FDA in device certification matters. This program was minor in scope, and now no longer exists. You publish a newsletter that is directed to manufacturers of medical equipment, and which highlights your knowledge of the FDA and of its regulations pertaining to medical equipment.

Section 501(c)(3) of the Code provides for the exemption from federal income tax of corporations organized and operated

exclusively for testing for public safety and certain other purposes.

Section 1.501(c)(3)-1(d)(4) of the Income Tax Regulations provides that the term "testing for public safety", as used in section 501(c)(3) includes the testing of consumer products, such as electrical products, to determine whether they are safe for use by the general public.

Rev. Rul. 68-373, 1968-2 C.B. 206, held that an organization primarily engaged in testing drugs for commercial pharmaceutical companies did not qualify under section 501(c)(3) of the Code. The Food and Drug Administration required that the drugs be tested for safety and efficacy before they could be marketed. The founder and principal investigator was approved by the FDA as a qualified investigator. The pharmaceutical companies selected the drugs to be tested and used the results in their marketing applications to the FDA. All the organization's income was derived from the pharmaceutical companies in payment for testing services. The organization itself did not devise standards for the testing of drugs. The Service reasoned that 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" but is merely a service performed for the manufacturer, principally serving the manufacturer's private interest.

Your activities are similar to those of the organization described in Rev. Rul. 68-373 in that you do not devise product standards. Also, your activities involve testing and certification of a product preparatory to its qualification under FDA regulations for sale in the United States. Consequently, it cannot be said that you are testing "consumer products" available for use by the general public. You are performing a service for medical equipment manufacturers that principally serves the private interests of those manufacturers.

Accordingly, your activities do not constitute "testing for public safety" within the meaning of section 501(c)(3) of the Code and section 1.501(c)(3)-1(d)(4) of the regulations.

Contributions to you are not deductible under section 170 of the Code.

You have the right to protest our ruling if you believe that it is incorrect. To protest, you should submit a statement of your views, with a full explanation of your reasoning. This

[REDACTED]

statement must be submitted within 30 days of the date of this letter and must be signed by one of your officers. You also have a right to a conference in this office after your statement is submitted. If you want a conference, you must request it when you file your protest statement. If you are to be represented by someone who is not one of your officers, he/she must file a proper power of attorney and otherwise qualify under our Conference and Practice requirements.

If you do not protest this proposed ruling in a timely manner, it will be considered by the Internal Revenue Service as a failure to exhaust available administrative remedies. Section 7428(b)(2) of the Code provides, in part, that a declaratory judgement or decree under this section shall not be issued in any proceeding unless the United States Tax Court, the United States Claims Court, or the District Court of the United States for the District of Columbia determines that the organization involved has exhausted administrative remedies available to it within the Internal Revenue Service.

If we do not hear from you within 30 days, this ruling will become final and copies will be forwarded to your key District Director. Thereafter, any questions about your federal income tax status should be addressed to that office. The appropriate State officials will be notified of this action in accordance with section 6104(c) of the Code.

Sincerely yours,

(signed) [REDACTED]

[REDACTED]
Acting Chief, Exempt Organizations
Technical Branch 2