

A nonprofit organization primarily engaged in testing drugs for commercial pharmaceutical companies does not qualify for exemption under section 501(c)(3) of the Code.

Advice has been requested whether a nonprofit organization engaged in clinically testing drugs under the circumstances described below qualifies for exemption from Federal income tax under section 501(c)(3) of the Internal Revenue Code of 1954.

The organization's principal activity is clinically testing drugs for commercial pharmaceutical companies. These tests are required in order to comply with Food and Drug Administration requirements that drugs be tested for safety and efficacy before they can be marketed. The founder and principal investigator of the organization has been approved by the Food and Drug Administration as a qualified investigator.

The pharmaceutical companies select the drugs to be tested and use the results of the tests in their marketing applications to the Food and Drug Administration. 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.

Section 501(c)(3) of the Code provides for the exemption from Federal income tax of organizations that are organized and operated exclusively for charitable, scientific, educational, or testing for public safety purposes.

Section 1.501(c)(3)-1(d)(1)(ii) of the Income Tax Regulations provides that an organization is not organized or operated exclusively for 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.

Section 1.501(c)(3)-1(d)(4) of the regulations defines the term 'testing for public safety' as used in 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.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations in defining the term 'scientific' provides that since an organization may meet the requirements of 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.

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations 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.

Clinical testing is an activity ordinarily carried on as an incident to a pharmaceutical company's commercial operations. The fact that the testing must be done by highly qualified professionals does not change its basic nature. Therefore, such testing does not constitute scientific research within the meaning of section 1.501(c)(3)-1(d)(5)(i) of the regulations.

Until a drug is approved for marketing by the Food and Drug Administration, 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. Such testing principally serves the private interest of the manufacturer rather than the public interest.

Accordingly, the organization fails to qualify for exemption from Federal income tax under section 501(c)(3) of the Code.