



DEPARTMENT OF HEALTH & HUMAN SERVICES

144A-305
Public Health Service

Food and Drug Administration
Rockville, MD 20857

SEP 27 2002

Michael F. Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C. 20009-5728

Re: Docket No. 00P-1668

Dear Dr. Jacobson:

This letter responds to your citizen petition dated December 5, 2000, requesting that the Food and Drug Administration (FDA) take enforcement action against garlic-containing dietary supplements that are misbranded because their labeling contains unauthorized health claims and/or false or misleading structure or function claims linking the ingestion of garlic to cholesterol levels, heart disease or cardiovascular health.

In accordance with Title 21 of the Code of Federal Regulations (21 CFR) section 10.30(e)(3), this letter is to advise you that FDA is denying your petition.

A citizen petition provides a mechanism for individuals to ask that the agency take administrative action such as initiating a proceeding to issue, amend, or revoke a regulation or order. See 21 CFR § 10.3, § 10.25(a), and § 10.30(k). It is not the appropriate vehicle to seek enforcement action (see 21 CFR 10.3(a); an administrative action "does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral"). Accordingly, we are denying your petition.

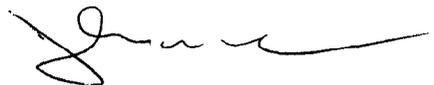
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FDA, however, will review the information contained in your petition about particular products and claims. As with any complaint we receive about an FDA-regulated product, we will consider whether a violation of the Federal Food, Drug, and Cosmetic Act has occurred and, if so, whether regulatory action is warranted in light of FDA's enforcement priorities and resources.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John M. Taylor". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

John M. Taylor
Senior Associate Commissioner
for Regulatory Affairs