



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 9 1999

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Mr. John E. Buttolph
Health Product Claims Alert
Box 398
Los Olivos, California 93441

Re: Docket No. 99P-2554

Dear Mr. Buttolph:

This letter responds to your citizen petition dated July 29, 1999, requesting that the Food and Drug Administration (FDA) take administrative action against E. Excel International, a manufacturer and distributor of dietary supplements.

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, without prejudice, your petition.

You requested that the agency take the following administrative actions against E. Excel International, Inc.:

1. enjoin E. Excel from manufacturing, selling, and distributing its products until such time as it complies with the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act);
2. require E. Excel to submit a public statement that its previous labels, labeling and other promotional materials contained unlawful, misleading or unsubstantiated health claims;
3. levy appropriate financial penalties and fees on E. Excel for its unlawful practices; and
4. require E. Excel to provide consumers who have purchased E. Excel's products the opportunity to refund their purchases.

The FDA does not have the legal authority to take the actions you request in your petition through the administrative procedures available to it. Only through judicial proceedings can FDA seek actions such as those you request. A citizen petition provides a mechanism for individuals to ask that the agency initiate a particular administrative proceeding, for example, to issue, amend, or revoke a regulation or order. See 21 CFR § 10.3 and § 10.30. It is not the appropriate vehicle to seek judicial remedies such as you are asking from FDA. Accordingly, we are denying your petition without prejudice.

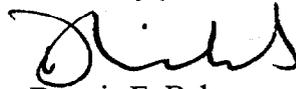
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FDA will, however, review the information contained in your petition. Ultimately, whether FDA would pursue a regulatory action would depend on our judgment as to whether the facts available to us warrant the agency proceeding with a regulatory action.

Sincerely yours,



for
Dennis E. Baker
Associate Commissioner
for Regulatory Affairs