



SEP 28 2007

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Leonard Tabachnik
Medicine Chest, Inc.
P.O. Box 14, Knickerbocker Station
New York, New York 10002

Dear Dr. Tabachnik:

This is in response to your submission to the Food and Drug Administration (FDA) received on September 6, 2007. In our September 22, 2006 letter to you, FDA advised you that if your submission was intended to be the submission required under 21 U.S.C. § 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and Title 21 of the Code of Federal Regulations (21 CFR) Part 101.93(a) it did not meet the requirements for that submission. Accordingly, a failure to submit a notice in compliance with those requirement **MAY** (emphasis added) subject the product that is the subject of the notification to regulation under the drug provisions of the Act. It is still not clear whether you intend this document to constitute the aforementioned submission.

Dietary supplements are regulated under the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321 et. seq.), as amended by the Dietary Supplement Health and Education Act of 1994. Regulations implementing certain requirements of the Act are published in Title 21 of the Code of Federal Regulations (21 CFR). Generally, there is no requirement for premarket review or approval of dietary supplements. It is the manufacturer's responsibility to ensure that its products are in compliance with applicable requirements of the Act and regulations promulgated under the Act. FDA does not approve dietary supplements or their ingredients. Accordingly, your belief that the Agency "has prevented Medicine Chest, Inc. from marketing its first product" is simply unfounded. FDA's letter served only to advise you of your apparent failure to fully comply with the notification requirement in 21 CFR 101.93(a).

A product may be subject to regulation not as a food or dietary supplement, but as a drug if certain claims are made for it. Under the Act, an article that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man is a drug. Further, under the Act, an article that is other than food and that is intended to affect the structure or any function of the body of man, is also a drug. See 21 U.S.C. § 321(g)(1). A drug must be shown to be safe and effective for its intended use and must be approved by FDA before it may be lawfully marketed.

Under 21 U.S.C. § 343(r)(6) the labeling of dietary supplements may, under certain circumstances, bear statements that: 1) claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States; 2) describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans; 3) characterize the documented mechanism by which a nutrient or dietary

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ingredient acts to maintain such structure or function; or 4) describe general well-being from consumption of a nutrient or dietary ingredient. Section 343(r)(6) also provides that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. Claims made pursuant to section 343(r)(6) do not require prior approval from FDA. Other information on structure/function claims can be found at <http://www.cfsan.fda.gov/~dms/sclmguid.html> and <http://www.cfsan.fda.gov/~dms/dsclmgui.html>.

In your letter, you present a number of legal reasons that you believe the claims you intend to make are permissible under the Act. Some are not material because they are related to products such as topical drugs and medical devices that are subject to completely different statutory requirements than are dietary supplements. Others are based on incorrect interpretations of the legal authorities that govern FDA's determinations on whether a claim is or is not a disease claim as that term is defined in 21 CFR 101.93(g). In general, the legal and Constitutional issues you raise were addressed in detail by FDA in the preamble to the final rule on structure/function claims that was published in the January 6, 2000 Federal Register (65 FR 1000 at 1033). You should refer to that document for more information on this matter.

It appears that you intend to make claims that your product is intended to act to alleviate leg cramps. You further state that such claims are claims under 21 U.S.C. § 343(r)(6) because they claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States. The information in your letter is not sufficient for us to comment on whether that is the case or not. However, we would note that some cases of leg cramps that you cite, for example those that are a consequence of diabetes, would not be such a claim but rather appear to be disease claims as that term is defined in 21 CFR 101.93(g) in that this category of leg cramps is a consequence of a disease that is itself a disease. We would recommend that before you proceed, you may find it helpful to consult an attorney with experience in this area of food and drug law.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140