



1817 6 SEP 25 P2:43

SEP 22 2006

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

Dear Sir/Madam::

This is in response to your submission to the **Food and Drug Administration (FDA)** received on September 13, 2006. It is not clear what the purpose of the submission is. However, if it is intended to be the submission pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)), it does not meet the requirements for that submission under 21 CFR 101.93(a).

21 CFR 101.93(a)(3)¹ requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) of this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the name or signature of the responsible individual as required by the regulation; as such, it does not certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the product that is the subject of the notification to regulation under the drug provisions of the Act.

¹You can access the Code of Federal Regulations at
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm>.

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Please contact us if we may be of further assistance.

Sincerely yours,



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

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New York District Office, Office of Compliance, HFR-PA240