ROOT DIGGIN'
NATION

55 Main Street
St. Clair, MO 63077
(636) 629-7776

June 3, 2003

Docops Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Your recent publication of *Good Manufacturing Practices for the Dietary Supplement Industry* included some needed regulations; however, I think there are some proposals that need changes. I would like to see companies comply with the following:

1. Conduct dissolution and disintegration tests.
2. Conduct tests for stability with expiration date.
3. Insure production performance through the use of written Standard Operating Procedures.
4. Follow written sanitation procedures.
5. Utilize an on-site laboratory and quality control procedures.
6. Utilize the five points and not rely 100% on inspection of the finished production batches.

The economic impact of analysis is flawed because it does not address the above necessary procedures. It is my deepest concern that if your present proposals are carried out, it will have a severe negative impact on the companies we rely on for our quality products.

Please reconsider your proposals.

Sincerely,

Sue Irwin

Sue Irwin

96N-0417

C139