Dietary Supplement

Dickens, Annie E

From: Jeri Heyman [aloedoc@aol.com]
Sent: Tuesday, June 10, 2003 3:57 PM
To: Dickens, Annie E
Subject: Comment submitted via CFSAN QA-ASK

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Comment:
Referance to Docket NO. 96N-0417
Concerning the proposed regulations for dietary supplements: I am opposing The new strict and costly propsed manufacturing regulations. I believe it will make many supplements cost ineffective and put many manufacturers and small businesses out of business. This is un-American and unnecessary. I believe the Good Manufacturing Practices regulations would be sufficient - but it was never put into effect on a widespread basis. I propose that the GMP be enforced and perhaps have spot checks of finished products occassionally instead of requiring each batch of product to be so completley analyzed for each ingredient. I agree that we need manufacturers to be kept honest and 'spot checking' can do that as well as requiring every single batch to be tested.
The Good Manufacturing Practices regulations I would think can sufficiently keep products safe and honest labeling. Having each batch tested puts the little guy out of business as it is too costly. I also believe that whole herbs should be considered foods as they are not synthetic "ingredients" that need to be standardized. What you are proposing are regulations that are necessary for

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drugs and 'nutriceuticals that have isolated, or synthesized materials in them. I believe that food supplements should be classified differently. Thank you for your consideration. Sincerely, Dr Jeri Heyman, PhD President, Herbal Answers Inc