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Monday, June 02, 2003

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

Dear Sir or Madam,

I am writing this letter to express comments in regard to your recent publication of GMP for the Dietary Supplement Industry. I applaud your publication of proposed regulation, but request that you re-think the proposal in the following manner.

I believe that it is important that manufacturers of dietary supplements be required to:

- Conduct dissolution and disintegration testing of supplements. What good is any inspection program if the product contains the labeled amount but never dissolves in the body and is not available for absorption? Just ask the septic tank cleaners who remove intact Centrum vitamin tablets from people's septic tanks.
- Conduct stability testing and label their products with real expiration dates.
- Insure production performance through the use of written SOPs.
- Develop, validate and follow written cleaning and sanitation procedures.
- Utilize and on-site lab and quality control department.
- Utilize the above 5 points as part of a comprehensive quality control program – not rely so totally as proposed on 100% inspection of finished production batches.

The economic impact analysis that you have included in the proposed regulations is flawed because it does not address the above necessary components in the quality control program. In addition, the economic analysis that you have done, dramatically underestimates the costs that would be require to implement your proposal. I am concerned that because the proposal and economic analysis is flawed, this could have a negative impact on the choices of supplements that I rely on for my customers.

I request that you incorporate my comments into a revised set of regulations and revise the economic impacts to more accurately reflect the true cost of the program.

Having been involved with the implementation of HIPAA regulations in our pharmacy, seeing the economic impact, the negative effect on patient care and the destruction of our valuable natural resources for the mindless printing of notices of practice and acknowledgment forms which are

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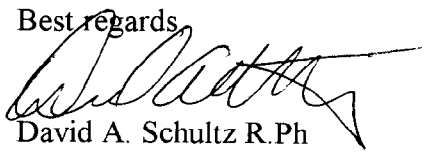
laughed at and ignored by 90% of the public, I think that a hard look at the benefits versus harm needs to be conducted. As with HIPAA, a good intentioned law needs to be thoroughly thought out so we can continue to provide high quality supplements and improve the quality of life at a reasonable cost to our patients.

Best regards,



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