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Specialists For The Pharmaceutical Industry

Telephone: 402-269-3195 1877 Midland Street, P.O. Box 326, Syracuse, NE 68446-0326 Telefax 402-269-3196

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To: Dockets Management Branch (HFA-305)
Food and Drug Administration
5830 Fishers Lane; Rm 1061
Rockville, MD 20852

From: Mark Pieloch
Pharma Chemie Inc.
1877 Midland Street
P.O. Box 326
Syracuse, NE 68446-0326

Subject: Public Comment on Docket No. 96N-0417; RIN 0910-AB88 Proposed Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

This letter is being written to provide comment to the Food and Drug Administration on Docket No. 96N-0417; RIN 0910-AB88 entitled the proposed guidelines of Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.

The following overview comments are provided:

1. The original passage of DSHEA in 1994 stated that guidelines should be established and implemented by FDA that follow Food cGMPs. The proposed guidelines as they are currently written are not at all similar to Food cGMPs, but instead are very similar to Drug cGMPs. Thus, these proposed guidelines have gone far beyond what Congress had initially intended by the passage of DSHEA, since these proposed guidelines are not even close to Food cGMPs. These proposed guidelines are just another example of an increasing federal bureaucracy that limits growth and opportunities for small businesses and heavily favors large multi-national corporations.

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2. There is agreement between the dietary supplement industry and FDA that some type of proposed guidelines are needed to further regulate the dietary supplement industry, but these guidelines should be modeled more closely to Food cGMPs than Drug cGMPs. If this would occur, small businesses would have a much more level competitive market to compete against large multi-national corporations. As the proposed guidelines are written, these guidelines (which are very similar to Drug cGMPs) heavily favor from a competitive perspective large multi-national corporations that have the financial resources and most often approved Drug cGMP facilities, that are not present or available to smaller domestic corporations. Thus, if the current proposed guidelines are implemented, numerous small domestic businesses will cease to exist, while large multi-national corporations will prosper significantly.

3. It should be noted that if the current proposed guidelines are implemented, the loss of domestic employment will be significant from small dietary supplement businesses. It should be noted that small businesses within the United States of America account for more than 60% of all employment and that the loss of this domestic employment is not very well thought out, especially during our current economic problems of high unemployment and a stagnant economy.

4. If the proposed guidelines are implement and numerous small dietary supplement businesses cease to exist, the loss in employment will not be gained by the domestic hiring from large multi-national corporations. These large domestic multi-national corporations will move the manufacture and packing operations of dietary supplements from within the United States of America to cheaper labor markets, such as Mexico, Central America, the Pacific Rim, etc. Domestic employment is what employs Americans and it is these Americans that pay taxes in the United States of America that pays for our government and public services. The loss in domestic manufacturing sector jobs within the dietary supplement industry will be significant and this industry will follow the path of previous manufacturing sector industries such as textiles, electronics, computers, etc.

5. To help better regulate the dietary supplement industry, FDA should implement guidelines similar to the current Food cGMPs and then start an active enforcement program to back up compliance with the guidelines. Having more and stricter guidelines without adequate enforcement is just another example of increasing federal bureaucracy. If FDA would actively enforce the guidelines that currently exist under Food cGMPs for the dietary supplement industry, most of all of the problems seen with dietary supplements over the past ten years would have been prevented or greatly reduced. Even with passage of the new proposed guidelines on dietary supplements that FDA is seeking, FDA would not have prevented hardly any more of the problems that have been experienced within the last ten years within the dietary supplement industry.

6. Unfair international trade practices will exist, if the proposed guidelines are passed regulating dietary supplements that are produced within the United States of America and are sold internationally compared to a foreign dietary supplement company selling products internationally outside of the United States of America. These proposed guidelines will increase the cost of doing business of a domestic dietary supplement firm that is selling product on an international basis, while a foreign dietary supplement firm will have lower costs since it will not be required to comply with the stricter FDA guidelines. This fact will result in a decrease of domestic exports, a loss in domestic employment, and a decrease in tax revenues to the United States of America. With our balance of trade at an all time record level of imports exceeding exports, passage of the proposed guidelines would just make this situation even worse.

7. If these proposed guidelines are implemented, the guidelines should be written to exclude or have different criteria for small businesses. Levels of employment or dollar sales could be target points for categorizing a business as small. This tiered enforcement would be similar to other government practices as it relates to OSHA, the American Disabilities Act, Family Leave Act, etc.

The following comments are directed at the seven specific categories within the proposed guidelines as follows:

1. Personnel

The proposed guidelines relating to personnel is something that is similar to Drug cGMPs, but it does not have a significant capital or ongoing operational cost associated with it. It should be remembered that "people" are the number one factor that can make or impact the quality of any given product! Even with the best equipment, the best facilities, the best documentation controls, the best distribution capabilities, overall quality in any product is based on the quality of the person producing the product. Thus, requirements for personnel practices, hygiene, adequate training, etc are the most critical aspect that should be controlled in any new proposed guidelines.
The "people" factor is by far the most important criteria for a quality outcome/product, as seen in our own American Revolutionary War. The British Empire had the most capital (physical plants), the largest army and navy (equipment and utensils), the best weapons (equipment and utensils), the most regimented with detailed warfare manuals and strategies (documentation and recordkeeping), but lacked the one trait that eventually led to the American patriots winning the Revolutionary War - that being the quality of the American patriotic people, whether they were soldiers, scholars, ship builders, or manufacturers. It was the quality of the individual that could not be replaced with any amount of financial resources, facilities, equipment, or documentation. Being an American, investing in our own people is our greatest strength and attribute.

2. Physical Plants

The proposed guidelines relating to physical plants is closer to Drug cGMPs than Food cGMPs, but what is requested is not unrealistic. Some provisions need to be modified for small businesses, but overall compliance is possible and feasible, but compliance will have a significant cost. The cost analysis that was presented by FDA was very financially conservative. Having just made significant physical plant investments in upgrading our facilities here, the cost is at least three (3) times higher than what the government analysis has estimated that it would cost. This three (3) times what the government estimated in costs is also based on physical plant/facilities construction and upgrades in a rural county in Nebraska, where construction labor rates are significantly lower than the national averages and significantly lower than would be found in major metropolitan areas, the east coast, and west coast regions. The government should increase the cost for facility upgrades to at least $ 200 per square foot from its current value of approximately $ 50 per square foot.

To help small businesses make these facility upgrades, the FDA needs to work in conjunction with the Internal Revenue Service (IRS) to allow for a much more rapid depreciation and expensing of these facility costs. Current IRS guidelines state that facility upgrades can be depreciated over 39 1/2 years. Let us be realistic, FDA's guidelines will not remain unchanged for 39 1/2 years. Thus, prior to requiring new facility upgrades, FDA needs to reach an agreement with the IRS on accelerating facility upgrade depreciation schedules from 39 1/2 years to a more realistic five (5) to ten (10) year depreciation schedule.

3. Equipment and Utensils

The proposed guidelines relating to equipment and utensils is between Food cGMPs and Drug cGMPs. What is proposed is feasible and realistic for both small and large multi-national corporations. The costs of complying with this requirement will be moderate from both a capital cost and ongoing costs perspective, but these costs will lead to higher quality products being produced.

4. Production and Process Controls

The proposed guidelines relating to production and process controls are very close to Drug cGMPs and are not very similar to Food cGMPs. Having stated this, this section needs to be totally rewritten to approach closer to Food cGMPs verses Drug cGMPs.

The use of master and production batch records with its associated documentation is a very feasible and quality attribute to adopt. This one attribute, master and production batch record documentation, probably has the second greatest impact on overall product quality only being surpassed by the quality of the "people" manufacturing the product. The costs of complying with this requirement will be minimal from both a capital cost and ongoing cost perspective.

The establishment of a "Quality Control" person/group is also a positive attribute. The costs of complying with this requirement will be significant from both a capital cost and ongoing cost perspective.

The specific points that need to be modified significantly that are almost identical to Drug cGMPs, have to do with raw material ingredient testing, in-process product testing, and active ingredient finished product testing. The costs for a small business to implement these additional analytical testing requirements will be very significant and will result in numerous businesses being unable to afford such costly analytical testing requirements. The cost analysis that the government provided is very flawed and does not accurately reflect the true costs of conducting these costly analytical testing requirements.

The cost analysis provided by the government estimated that the average cost of raw material, in-process, or active ingredient analytical testing was about $ 50 per test per ingredient and that the average product had about two actives or two tests required per product. The actual costs whether you conduct your own analytical testing in-house or at a contract testing facility, are about at least three (3) times what the government analysis claims and may be as high as eight (8) times depending upon the ingredient being tested and the number of actives within a product formula. Thus, this requirement needs to be dropped and replaced with a statement that allows a manufacturer to use in place the raw material or active ingredient's Certificate of Analysis in place of specific additional analytical testing.

This specific proposed requirement would have the greatest impact on small businesses and would be the one most important compliance point proposed that would put small dietary supplement firms out of business. The mathematics behind this is very simple. If a small dietary supplement firm produces approximately 300 batches per year and its sales are about $ 1,500,000, then the average sales is about $ 5000 per batch. It is not feasible or practical that the small firm will be required to spend most likely between $ 300 to $ 800 in testing per batch prior to releasing it for commercial sale. Thus, the cost of analytical testing for a small dietary supplement firm would range between 6% to 16% of total sales, which would eliminate any profit that the small dietary supplement firm may have realized from the sale of the product. Large, multi-national corporations have significant economies of scale over smaller dietary supplement firms, since large firms batch sizes are at a minimum ten (10) times larger than what is produced by a small dietary supplement firm and thus the cost of analytical testing for the large firm would only be between 0.6% and 1.6% of sales, which is a significantly lower cost that favors the large, multi-national corporation.

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5. Holding and Distributing

The proposed guidelines relating to holding and distributing is very similar to Drug cGMPs and not very close to Food cGMPs. What is proposed is feasible, but the degree of detail required is unrealistic for small dietary supplement firms. These guidelines should be rewritten and be more similar to Food cGMPs. The costs of complying with this requirement will be moderate from both a capital cost and ongoing costs perspective, but these costs will lead to higher quality products being produced.

6. Consumer Complaints

The proposed guidelines relating to consumer complaints is very similar to Drug cGMPs and not very close to Food cGMPs. What is proposed is feasible, but would add significantly to tracking a potential problem in the market place. The degree of detail required is slightly unrealistic for small dietary supplement firms, but these guidelines could be rewritten to be more user friendly with some degree of flexibility allowed. The costs of complying with this requirement will be minimal from both a capital cost and ongoing costs perspective.

7. Records and Record Keeping

The proposed guidelines relating to records and record keeping is very similar to Drug cGMPs and not very close to Food cGMPs. What is proposed is feasible, but would add significantly to tracking a potential problem in the market place. The degree of detail required is slightly unrealistic for small dietary supplement firms, but these guidelines could be rewritten to be more user friendly with some degree of flexibility allowed. The costs of complying with this requirement will be minimal from both a capital cost and ongoing costs perspective.

I hope that you will consider the various points that I have addressed in this letter of public comment relating to Docket No. 96N-0417. Thank you for your time on this matter.

Best Regards,

Mark Pieloch

Mark Pieloch; MS, MBA, RPh, APICS
President, Pharma Chemie Inc.