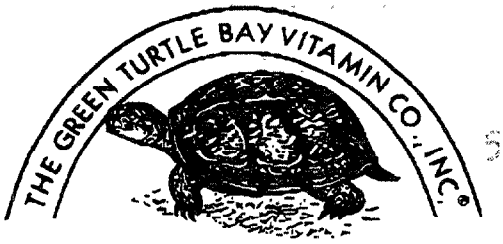

"ExtraOrdinary Nutrition for Ordinary People"

Attn: Richard A. Williams Jr., Ph. D
Attn: Peter Vardon
Director, Division of Market Studies
Office of Scientific Analysis and Support
Center for Food Safety and Applied Nutrition
330 C. Street
HFS – 726 SW\
Washington, D.C. 20204
Tel: 202-205-5329 Fax: 202-260-0794

August 31, 1999

Re: GMP regulations for dietary supplements that affect small businesses.

Dear Messrs. Williams and Vardon:

The Green Turtle Bay Vitamin Co. is a small business with three part time employees and myself. I work a separate full time job, with evenings and weekends devoted to running my company. We have only eight products, but I believe they are among the finest in the market place. We work with a medical doctor and chemist in developing our formulas. We contract out the manufacture of our products. The manufacturer we work with ships our products to our distributors and maintains our inventory for us.

Your proposed regulations would do us a great deal of harm. We do not sell a lot of products. As a result we have experienced that large manufactures are not interested in accommodating our requirements. They require larger purchases than we can afford to make; they do not have time to work with our requirements as there is not enough profit it our business for them. They try to direct us to accept generic products they manufacture and put our label on these products. We currently have a comfortable relationship with a small manufacturer who works with us to produce the products that we are proud to offer the public. In discussing the proposed regulations with our contract manufacturer, I do not believe this manufacturer can accommodate all your requirements.

96N-0417 C92

The Green Turtle Bay Vitamin Co., Inc., P.O. Box 642, 56 High St., Summit, NJ 07901 • Member *NNFA*
Telephone: 908-277-2240 800-887-8535 FAX: 908-273-9116
Internet: http://www.EnergyWave.com E-mail www.mail@EnergyWave.com

I have a problem with the amount of analysis that is proposed. As we only order small quantities of raw materials, we accept the analysis of the company selling these raw materials. In many cases these are the major drug companies, however in the case of herbs, these may come from other companies. We are very selective in the ingredients we select. For instance bee pollen from farms in our western states has not been as satisfactory as the bee pollen we have obtained from China. There are many ingredients in our formulas. To have each one analyzed would raise the price of our products five fold or more. Our products are already priced too highly for many that would benefit from them. In short, I think your proposed regulations would put us out of business.

Sincerely,

Karen Horbatt

Karen Horbatt
President

The Green Turtle Bay Vitamin Co., Inc.
P.O. Box 642
Summit, NJ 07902

Tel: 908-277-2240 Fax: 908-273-9116
Toll free: 800-Turtle-5 (800-887-8535)

Visit us on the Internet at www.EnergyWave.com
e-mail: webmaster@EnergyWave.com

Karen Horbatt founded the Green Turtle Bay Vitamin Co. because she was no longer able to purchase a *very special* vitamin formula. A local doctor, prior to his passing at a ripe old age had sold it. Because of her own personal experience with PowerVites' effectiveness and belief others would also benefit, she decided to manufacture this remarkable multi-vitamin. The new product contained improvements to the original formula based on the latest scientific findings. Although she began selling the product on a local basis, others soon became aware of PowerVites. Today, The Green Turtle Bay Vitamin Company sells its products across the states as well as internationally.

Additional products have been added, based on our customers' needs. Dr. Richard Podell, MD and clinical professor at the Robert Wood Johnson Medical School of NJ's University of Medicine and Dentistry, has acted as consultant in developing these formulas. Nutritionally aware, he has been a tremendous asset in separating hype from nutrients that are truly helpful.

The Green Turtle Bay Vitamin Co. is a member of the NNFA (National Nutritional Foods Association) adhering to true label practices. Our products have been found acceptable for use by members of The Feingold Association, an organization dedicated to the education of food allergies. You can find our products in health food stores and nutritionally aware pharmacies. Stores may order through health food store and drug wholesalers as well as from us directly.

The products are advertised on local and national radio stations. Articles about them have appeared across the country. Our founder was featured in the August 30, 1998 issue of the national publication, *Parade Magazine*. PowerVites was requested and used in the 1996 Olympics by athletes from Russia, Ukraine, Georgia and Panama.

Mission Statement: To provide unique, effective, natural supplements that improve well being and make nutritional supplement choices easy ones. Simply stated, we offer *ExtraOrdinary Nutrition for Ordinary People* (this does not mean our customers are ordinary, as in reality they are well versed in nutrition –they just don't want to take a gazillion pills).

Three successful entrepreneurs followed their hearts to start businesses in fields in which they had long-standing personal interests. Here's how they did it:

They Weren't Afraid To Take A Chance

BY JOAN WILEN AND LYDIA WILEN

"IT STRUCK ME AS OUTRAGEOUS that dancers should be expected to perform artistic and athletic miracles in shoes made from flimsy materials," says Eliza Gaynor Minden, who started her own small business to manufacture and sell the Pointe Shoe, her redesign of the traditional ballet shoe. "Because dancers are artists, no one paid attention to their physical needs as athletes."

As a young girl, Minden was introduced to the world of dance as a student in her mother's ballet school in Southport, Conn. She knew she wanted to do something in the performing arts but not as a performer. After graduating from Yale with a liberal arts degree, she worked for three years as the manager and administrator of dance companies. Minden says that's where she learned that 80 percent of professional dancers suffer ankle injuries that could be prevented with more protective shoes.

"I was bold enough to think I could successfully improve the traditional pointe shoe—for several reasons," says Minden, 39, who lives in New York City. "I knew the dancer's side from my own experience as an amateur. My family's energy-efficient lighting business made me familiar with blueprints, prototyping and the process of applying for a patent. And my liberal arts education taught me how to teach myself."

Bob Page is the founder of Replacements Ltd. in Greensboro, N.C.—the world's largest supplier of discontinued china, flatware, glassware and collectibles. "I thought if I could devote my time to doing what I love, I could make a living at it," he says.

After being rejected for a loan because the Small Business Administration didn't believe in his idea, Bob Page persuaded a building owner to lend him retail space.

Eliza Gaynor Minden displays her redesigned version of a traditional ballet shoe. "Because dancers are artists," she says, "no one paid attention to their physical needs as athletes."

For her redesigned pointe shoe, Eliza Gaynor Minden sought information from several sources. "I talked with a ski-boot designer, a sail-maker, an engineer and a plastics specialist."

Minden consulted dancers and ballet teachers about her new shoe design, but she also sought information from unrelated sources. "I talked with a ski-boot designer about foam, a sail-maker about thread, an engineer about the physics of the toe box, and plastics specialists about materials." Now, after just five years, her wholesale and mail-order business has 20 employees. It grossed more than $1 million in sales last year.

Succeeding against the odds

"My friends and family discouraged me from quitting my job as an auditor for the State of North Carolina," says Bob Page, "but I thought, if I could devote my time to doing what I love, I could make a living at it—even though it wouldn't be as much as I would earn as a CPA." Today, his company, Replacements Ltd., is the world's largest supplier of discontinued china, glassware, flatware and collectibles.

It all started in 1978, when Page bought a part interest in a Greensboro antique shop. "A customer gave me an assignment to find missing china pieces for her," he recalls. "She then recommended me to friends, and I just kept getting requests." In 1981, Page was ready to turn his weekend hobby into a full-time business. He quit his job and, with less than $5000 in cash and a meager inventory, founded Replacements Ltd.

Page went to the Small Business Administration for a loan, but it turned him down, saying the idea would never work. Undaunted, he persuaded the owner of a commercial building to lend him retail space. By placing small ads in magazines, he built a customer base and grossed more than $150,000 in sales in just his first year. Page, 53, now employs a workforce of more than 500. Last year, Replacements Ltd. grossed more than $57 million in sales.

Making a good product better

"One fateful day in 1990, I called my doctor's office to place my usual order for his private-label vitamin pills," says Karen Horbatt, 54, of Summit, N.J. "After 15 years of calling in those orders, the telephone number was no longer in service." She learned that the elderly doctor who supplied her vitamins had died.

"I tried other vitamins," says Horbatt, "but none made me feel as good." She decided to find the lab that had made the vitamins for the doctor. "I remember calling the New Jersey State Department and asking if there was someone who regulates vitamins and who would know where they were made," she recalls. "After the man stopped laughing, he mentioned something about a needle in a haystack."

Horbatt managed to get a list of laboratories. But, as a single mother with a full-time job as a business research analyst, she had to steal a moment here and there to call the laboratories. Finally, after two years of calling, Horbatt found someone who knew about the doctor's vitamins. "That's when it hit me," she says. "I thought, 'If these vitamins worked so well for me, surely they'd benefit others too.'"

Horbatt invested $2000 to market the vitamins in and around her community. She worked with a chemist at the laboratory and was able to improve on the original formula. An artist designed a logo and label, and Horbatt was in business, selling vitamins to neighborhood pharmacies and health-food stores. "An article I wrote for my local paper about my experience finding the right lab boosted sales," says Horbatt.

Her company—Green Turtle Bay—now has distribution outlets worldwide and offers mail-order sales as well. And Karen Horbatt has expanded her product line to include herbal-based supplements.

"So many people—especially women—have the inner resources to make it on their own but don't know they do, because they've never put themselves to the test," says Horbatt. "I guess I'm one of those exceptions."

For more information on how to start your own business, write to the Small Business Administration, Dept. P, 409 Third St., S.W., Washington, D.C. 20416; call 1-800-827-5722; or visit *www.sba.gov* on the Web.

The Wilen sisters are the authors of several books, including "Folk Remedies That Work" (HarperCollins).

Karen Horbatt is the founder of Green Turtle Bay, a company that sells vitamins and herbal-based supplements. "So many people have the inner resources to make it on their own but don't know they do, because they've never been put to the test," she says.

Karen Horbatt worked with a chemist at the lab and was able to improve on the original vitamin formula. Shortly after, she was in business—selling vitamins to neighborhood pharmacies and health-food stores.

What You Can Learn From The Entrepreneurs...

- BE PERSISTENT. [illegible]
- BE HUMBLE AND OPEN-MINDED. [illegible]
- GET ENOUGH EXERCISE.

—Eliza Gaynor Minden

- ALWAYS EXCEED THE EXPECTATIONS OF YOUR CUSTOMERS. [illegible]
- LOVE YOUR WORK. [illegible]
- KEEP YOUR INTEGRITY. [illegible]

—Bob Page

- EXPECT DIFFICULTIES. [illegible]
- NETWORK. [illegible]
- TREAT PEOPLE WELL. [illegible]

—Karen Horbatt

Food and Drug Administration
Center for Food Safety and Applied Nutrition

Office of Special Nutritionals
Regulatory Branch, HFS-456

TO:

Name: Peter Vardon

Organization: _____

Phone: 205-5329

Fax Number: 260-0794

Number of pages: 4

Date: 8-24-99

FROM:

Name: Karen Strauss

Phone: (202) 205-5123

Fax Number: (202) 260-8957

Mailing Address:

200 "C" Street, S.W.
HFS-456
Washington, D.C. 20204

If you do not receive all of the pages, please call (202) 205-5123

Comments: Attached are 2 comments sent to OSN by Dockets

Karen

Herbal Alternatives USA

"We bring you *Herbal Solutions™*"

July 20, 1999

Dockets Management Branch (HFA-305)
Docket Number 96N-0417
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

I am writing to express my concerns to CFSAN regarding the negative economic impacts that any proposal to establish "good manufacturing practice regulations" for dietary supplements would have on my small business, as well as other small businesses in the industry.

Increased regulations, quite simply, will increase costs. Small companies may be forced out of business if they cannot bear the costs necessary to comply with the new regulations. These regulations will hurt small businesses, and would not necessarily improve quality for consumers. There is something to be said for small, "homemade" style of manufacturing. Consider your local mom & pop bakery. Their cookies may not be as uniform as Keebler's, but their customers are not expecting them to be—and that certainly does not mean the quality is not equal, if not better, to the large, national brands. If you try to regulate the local small bakery on the same scale as you do the large national brands like Nabisco or Keebler, you will undoubtedly kill the small, local stores. The same holds true for small manufacturers of herbal supplements.

The small company that manufactures the products that I distribute has been making the products since 1992. The company makes the herbal supplements in the traditional Native American preparation process that has been used for hundreds of years. To suggest that they need to be regulated insults both the company and its customers.

To continue to protect the consumer, I recommend continuing to evaluate the kinds of claims that can be made on product labels. A customer then knows what they are purchasing, including whether the goods inside are standardized or not, or meet some kind of quality control. Let us allow companies to provide the information to consumers, and allow consumers to make educated decisions. Increased regulations will destroy many small businesses (the lifeblood of our economy), and will destroy choice for consumers as well.

Thank you for taking my thoughts into consideration .

Best regards,

Brenda Busch
President

96N-0417

C88

[illegible] Clarey Avenue
[illegible], FL 32806
800-[illegible] • 407-648-8778
E-mail: herbal@[illegible]
Web Site: http://www.[illegible]
Fax: 407-648-5454

PHARMA CHEMIE
Specialists For The Pharmaceutical Industry
Telephone: 402-269-3195 1877 Midland Street, P.O. Box 326, Syracuse, NE 68446-0326 Telefax 402-269-3196

July 8, 1999

To: Center for Food Safety and Applied Nutrition (CFSAN)
From: Mark Pieloch; President of Pharma Chemie Inc. MP

Subject: Proposed CGMP Regulations for Dietary Supplements

I am writing to FDA in response to a letter that I received this past week regarding FDA's Center for Food Safety and Applied Nutrition's (CFSAN) interest in establishing current good manufacturing practice (CGMPs) regulations for the dietary supplement industry.

From this letter Pharma Chemie Inc. would like to make the following points known:

1. The establishment of drug CGMPs on the dietary supplement industry would have a very negative impact on the dietary supplement industry. The cost of administering drug CGMPs would be cost prohibitive, since dietary supplements sell for a fraction of the price of drug products. By implementing drug CGMPs on the dietary supplement industry, the cost of nutritional/dietary supplements would increase significantly to the consumer within the United States of America. The higher cost of implementing industry compliance with drug CGMP regulations would cause higher consumer product prices, which would result in less of these products being available to the bulk of consumers within this country.

2. Dietary supplements are in fact sold more often as nutritional or food supplements, rather than as drug products. Thus, dietary supplements would be best regulated under food CGMPs. The use of food CGMPs would be best for the industry and the consumer. The cost of all dietary supplement manufacturers to implement food CGMPs would be minimal, thus dietary supplement product prices should not rise significantly to the consumer. The use of food CGMPs would provide the dietary supplement industry with regulations that would address consumer product safety issues, while maintaining an industry environment beneficial to the consumer from a product pricing perspective.

3. The implementation of food CGMPs would have a minimal impact on small business entities, such as Pharma Chemie Inc. We currently already produce all of our dietary supplements following at a minimum food CGMPs and would have no compliance issues with all dietary supplement manufacturers following food CGMPs.

96N-0417

C87

PHARMA CHEMIE

Please consider this letter as a response to CFSAN's request for comments on the issue of CGMPs for the dietary supplement industry. I will be unable to attend FDA's July 12, 1999 public meeting in Las Vegas due to previous commitments and the short leadtime of notification of this meeting.

Mark Pieloch

PERFORMANCE RESEARCH LABORATORIES, INC.

NUTRITIONAL AND PHARMACEUTICAL PRODUCTS GROUP

Corporate Office: 430 Colorado Ave, Suite 203 • Santa Monica, California • USA 90401
Telephone: (310) 394-0164 • Fax: (310) 394-2003

Regional Office (Asia): 10th Floor Sagittarius Building 3 • H.V. Dela Costa Street
Salcedo Village, Makati, Metro Manila • Philippines
Telephone: 632-813-3983 or 632-812-9895 • Fax: 632-818-4192

FAX COVER SHEET

Attention:	Mr. Peter Vardon
Company:	Food and Drug Administration
Fax #:	(202) 260-0794
Date:	August 16, 1999 (3:30 PM)
Number of Pages	Four (4) Page including cover

Dear Ted,

Formulas data as requested. Still need to give Cholesterol formula more thought. Those are all quoted as good to excellent formulas (potency) using top quality ingredients. A starting point. Much to consider with regard to usage patems, dosage, quantities, packaging, etc.

Will get you the catalogue info tomorrow.

Best Regards,

Ed

Comments made by
Edward M. Lieskovan, Pharm.D., MBA
Small Dietary Supplement Industry Businessman, Consultant &
Adjunct Associate Professor of Clinical Pharmacy Practice
Regarding:

Current Good Manufacturing Practice In Manufacturing, Packaging, or Holding Dietary Supplements as printed in the Federal Register Vol. 62, No. 25 Thursday February 6, 1997 / Proposed Rules

General Comments

There is no doubt in my mind that the Dietary Supplement industry need GMP's of the type proposed in the referenced document. Presently a great number of suppliers of raw materials and manufacturers and packagers of finished dosage forms seem to operate without the knowledge of or without any concern for policies and procedures that I feel are essential to safety, potency and quality.

At the same time, there are facilities that operate under drug licenses or self imposed "GMP's" and dedicate a great deal of effort to produce products that are safe, meet appropriate potency standards, and are of an overall excellent quality. The higher costs associated with operating a GMP type facility put many diligent companies at a competitive disadvantage to those that operate in a haphazard manner. T he poorly run facilities put the entire industry in jeopardy by fostering doubt in the publics mind as to the safety, potency and quality of all Dietary Supplements. The poorly run facilities also are more likely to subject the public to a potentially higher safety risk due to their lack of knowledge and the desire to acquire it, a general lack of accountability, a greater tendency to make mistakes and a relative reduced ability to detect mistakes, and in many cases, I believe, a tendency to put profit ahead of professional ethics, common sense, good science and the simple desire to do things correctly.

We need mandatory Nutritional GMP's if our industry is to continue to grow and prosper in an organized and responsible fashion. The products that we are capable of bringing to market are just to important to the public good to be treated carelessly. Our industry needs to be committed to sound GMP policy, and the enhanced safety, potency, reliability, accountability and overall quality that a professional and well defined system of operating policies can help to insure.

Lets get these GMP's going as soon as possible.

Specific Comments

In the context of the remarks made above, I would like to thank the FDA for recognizing the vast gap that exists between large and medium sized Dietary Supplement Companies and small companies (under 20 million dollars in annual sales) with regard to their ability to comply with several selected policies that have been outlined in the Proposed Nutritional GMP's.
As an entrepreneur, small businessman, and consultant to a number of small Dietary Supplement companies, I am not anxious to see policies adapted that will drive small companies out of business. Small companies make up a very large segment of this industry and we need to be able to bring them under a GMP policy that will provide the desired outcome (improved safety, potency, quality, accountability, etc.) without subjecting them to an unrealistic compliance burden. If approaches can be found that will allow the most critical safety, quality and potency issues to be addressed in an adequate manner (a statistically acceptable manner) that also lessens the economic compliance burden for small companies, then I think we need to find them and adopt them without delay.

My specific suggestions are as follows:

1) GMP Policy Implementation Period

The overall provisions of the proposed Dietary Supplement GMP's are reasonable and acceptable and should be implemented as soon as possible. An implementation period of approximately 24 month should be adequate for any company (large or small) that is serious about the responsibilities inherent in the operation of their business and is committed to follow this policy.

2) Large versus Small Company Compliance Strategies

Large companies have more resources (human expertise and capital) to direct toward GMP implementation issues and are very capable of creating their own internal implementation policies, quality control and laboratory processes and procedures, and other compliance methodologies. Small companies do not typically possess the depth or diversity of human expertise and capital resources to allow them to easily deal with the creation or implementation of policies that may put a great deal of developmental burden on the company itself. Small companies will need help with issues like; testing standards for raw materials and finished product stability issues. The FDA can play a very critical and helpful role in this regard by working with industry groups to help establish methodologies, standards and other criteria that can be directly implemented by small companies without the need for extensive internal development. Large companies can create their own compliance procedures while small companies will need assistance in this regard if the outcome is to be reliable and of benefit to the company and the general public.

3) Quality Control Testing of Raw Materials

Please refer to the section titled
"Production & Process Controls,
part c, Handling and Storage of Raw Materials # 1-10

I believe that written policies are very important. As long as an adequate implementation period is provided, GMP's should mandate that all company compliance policies be in writing.

1-6 seem acceptable as written.

7 (i, ii, iii) seem acceptable as written. Most reliable raw material suppliers provide Certificates of Analysis that provide test results and data for filth, microbiological, toxins. Large companies with significant in-house labs and professional staffing will most likely repeat these tests on every incoming batch of raw materials. Because many small companies do not have adequate laboratory facilities or expertise to perform these tests in a reliable manner it is often necessary to for them to send materials to an outside laboratory for testing. This is an acceptable process for the purposes of validating a supplier and establishing the reliability of the Certificate of Analysis that they provide but it would present a huge economic and logistical burden if the small company was forced to send out samples of every incoming batch of raw materials. Small companies tend to purchase raw materials in small quantities (often in kg or tens or kg quantities) for a specific order, rather than buying in large bulk quantities for multiply orders. These small purchase quantities result in lab cost adding a very significant burden to the per Kg cost of the raw material. The use of outside labs also takes extra time which can cause significant delays in production that can make a small company uncompetitive.

The use of outside labs for the validation of a supplier should be acceptable to most small companies (economically feasible) as long as supplier Certificates of Analysis, once validated, can be acceptable to the fulfillment of the testing policies.

The FDA can play a valuable role in expediting this process by working with Raw Material suppliers to set minimum standards for bulk ingredient testing so that small manufacturers with limited economic leverage can be assured of getting the documentation they need to comply with the regulations. Large companies would also benefit from this effort but it is not so critical to them because they have enough purchasing power to demand this type of performance from suppliers as a requirement for doing business with them.

I would also like to see a Domestic Testing requirement for all raw materials originating outside of the USA. This would help insure more reliable and accountable Certificate of Analysis data than that which is obtained overseas and simply photocopied onto the suppliers letterhead. I would like to know who tested the material so they can be help accountable if results prove to be in error. I am sure that both the FDA and our insurance carriers would find this to be of value.

7 (iv) Identity Testing of Raw materials

Many small companies do not have the in-house capabilities for running sophisticated tests for an ever increasing range of raw materials. Outside testing of every (small) batch of raw materials could drive them out of business due to the economic burden associated with the costs and delays that this could cause. Large companies order large batches which are then approved once and may be used in dozens of formulations. Small companies order raw materials on more of an "as needed basis" and might end up paying for many more test procedures. The constant delays associated with this constant testing of small batches would be a cash flow and logistical nightmare for small companies.

Presently I utilize simple, non-instrumental methods for verifying the identity of raw materials. The parameters that I utilize for this purpose include: color, particle size (powder, granular, etc.) odor, taste (as appropriate), etc. These simple measures have allowed errors to be recognized in a number of instances. It would be very helpful if the FDA and Suppliers could work out a simple system of non-instrumental analysis of raw materials that would serve to reveal typical mix-ups & validate identity beyond any reasonable doubt when all documentation supports the finding. The FDA might also work with industry to help develop simple and inexpensive instrumental tests methodologies (using inexpensive equipment) that would provide even greater insurance of correct raw material identity. This type of thing could be phased in to allow small companies to respond appropriately. I would love to attend a joint FDA / Industry / Laboratory sponsored symposium that would cover this topic. Maybe a whole series of symposiums.

7 (v) The use of supplier Certificates of Analysis, from validated suppliers is essential to a sound and economically feasible GMP policy for Small Companies.

All other parts of Section C - Production and Process Controls are acceptable.

Please refer to the section titled
"Production & Process Controls,
part d, "Manufacturing Operations, # 1-17

1-10 seems reasonable

11 Written Procedures for the testing of finished products.
Many small facilities do not have elaborate in-house laboratories and do not have the ability to do comprehonsive analysis of finished products. Please keep this factor in mind when you finalize this part of the GMP's I believe that elaborate testing is not necessary to establish finished product quality if other aspects of the manufacturing process are properly managed. Impute data can be very valuable with appropriate mixing and limited finished product testing. Many testing procedures that involve instrumental analysis will need to be sent to an dependent laboratory by small companies and this could result in runaway costs if the requirements are not carefully controlled.

Please refer to the section titled
"Quality Control & Laboratory Operations,
part d, Expiration Dating # 1-2

The establishment of rational criteria for the Expiration Dating of many dietary supplements often presents a significant challenge to small companies, and quite possible to large companies as well.
The potency and expiration testing of most drugs and single entity nutritional products is pretty simple as the analysis can be conducted in pretty much a textbook manner. Complex multi ingredient Vitamin, Mineral and Herbal products are often much more difficult because of significant interference created by the various ingredients. I have spend a small fortune with independent labs trying to get a correct analysis of a product that contains a very accurately known quantity of various vitamins and or minerals. This type of analytical procedural development is very costly for large companies and next to impossible for small companies. Botanical testing of multiple herb products is even more complex and is in some cases pretty much impossible even with virtually unlimited resources. When you can't get an adequate analysis on the day of manufacture, it is impossible to achieve the degree of consistency that is necessary to detect ingredient potency loss during a normal expiration trial. Rolling the dice is almost as reliable as the known scientific methods for the dating of some multiply ingredient botanical formulations. Many companies (large and small) just give their "properly formulated and manufactured" product two (2) year expiration dates as a policy because they can not establish a reliable means of arriving at a more scientific or supportable expiration date.

Small companies that must send this type of work to outside laboratories will be unable to comply with Expiration Dating Policies unless the requirements can be greatly relaxed. Small companies will need a great deal of assistance if they are to comply with even the most minimal standards for expiration date testing.

The scientific problems associated with rational expiration dating for complex dietary supplement formulations are not the only problem. Because of the nature of the industry and the market, our industry relies heavily upon contract manufacturers for finished products. A typical contract manufacturer produces finished products for a great number of "brand" companies that range in size from large (100's of millions in annual sales) to very small (tens of thousands of dollars in annual sales). Batch sizes for typical tablet and capsule products range in size from maybe 100,000 dosages to tens of millions of dosages with the typical batch size for small customers being less than 500,000 dosages. These products may be manufactured on a regular basis or they may be isolated single runs that are never repeated.

Rigorous Expiration Date testing would be very difficult, both financially and logistically, for a company to provide when they are manufacturing a batch of 100,00 - 250,000 tablets for a new customer (or even a large existing customer for that matter) and have no idea as to whether they will ever receive a second order for this product (frequently they will not because of short product cycles and consumer driven trends). The finished product may be all sold by the time even accelerated testing can be accomplished and subsequent orders may be for new versions of the product or for totally different product altogether.

On small batches, good expiration date testing could easily double the price of the product on a per thousand cost basis. Customers are generally not willing to pay for this type of testing (it would put them out of business) and manufacture's can not afford to pay for it either because of their tight margins.

The only people who can currently both afford traditional stability testing and have the resources to attempt it on complex products are the very largest brand name companies (Amway, Herbalife, etc.) or the large pharmaceutical companies. Rigorous Expiration Date testing requirements could drive all but the largest companies out of business and result in the Dietary Supplement industry being absorbed by drug companies. The consumer would not benefit from this outcome as prices would go up and the wide range of available products and innovative new product development would be diminished.

Small, and for that matter, even large Dietary Supplement companies (all of whom are dwarfs when compared to the drug companies) will need a great deal of assistance from the FDA if a ration and affordable method of determining reliable expiration dates is to be developed.

I feel that until science can deliver a miracle, we should be allowed to use available ingredient stability data to project a conservative but reasonable expiration date if our product are formulated to contain a minimum of 100 % of the label value at the time of manufacture. Good companies already utilize overages to provide for full potency throughout the lifetime of their products, and beyond (based on conservative expiration dating) and I believe that this approach is a responsible and acceptable one in consideration of the economic and scientific limitations that are currently present.

Longer expiration dating could be optional for those companies that can afford to invest in the development of reliable testing methods.

Closing Remarks

Please keep in mind that we are a industry in development and that we are anxious to move forward at a rate that can be supported by good science and a reasonable investment of time, effort and capital.

Your reasonable approach to GMP's will without a doubt, add value, safety and quality to the products we offer. Most of use (particularly the small companies) do not have access to rocket engines to propel us into the stratosphere in a single bound. We do however have strong legs and a determined attitude and are willing to climb a staircase of undefined length, one step at a time.

Thank you for your kind consideration of these comments and please accept my apology for taking so long to get them to you. I have a business to run and never have enough hours in the day to accomplish as much as I would like to.

Best Regards,

Edward M. Liesk[illegible]an, Pharm.D., MBA