Select Solutions, Inc.

August 1, 2003

To:

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

From:

Ronald Vincent, C.P.A.
On behalf of Health Concerns, Inc.

Introduction

I am writing to comment on the proposed cGMP regulations on behalf of my client Health Concerns, Inc. I have been associated with Health Concerns, Inc., who manufactures and distributes herbal and dietary supplements, for most of their 18 years. I have read the proposed regulations and also attended the public meeting held in Oakland, California on May 6, 2003. I was asked specifically to comment on the economic impact of the proposed regulations on Health Concerns, Inc.

In reviewing the proposed cGMP regulations there are numerous issues that would have a direct negative impact on my clients business and result in an extraordinary administrative burden. However, the single most significant factor would be the economic impact. I have outlined below the critical points in their production process that would give rise to increased costs and have quantified how I have arrived at those cost estimates. In total, after full implementation, they expect to incur annual increased costs in excess of $1,000,000. Costs of even half that amount would destroy the economic viability of their company and the business would fail.

Manufacturing Model

First, one of the overriding concerns is that the proposed regulations appear to be based on a model that assumes that the manufacturing process is fully contained and controlled by a single manufacturing entity. That is, a single company receives the raw materials and then formulates, processes, packages and ships the finished product. Below is a copy of the slide showing "Representative Manufacturing Steps" as presented by the FDA at the May 6, 2003 public meeting in Oakland, California.

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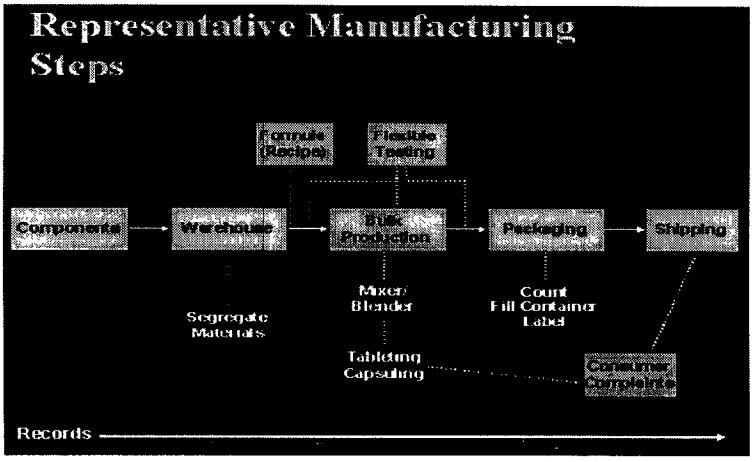


While all the steps in the above are a reasonable depiction of the manufacturing process, an assumption that all of the processes occur under the control of a single entity is not. Were this the case, costs and recordkeeping requirements would be more manageable. Unfortunately, this is not the reality for most manufacturers of dietary supplements and is certainly not the case for Health Concerns, Inc.

Cost Analysis - Recordkeeping

A thorough analysis of operations confirms that their products are composed of about 1,000 separate ingredients and are provided by more than twenty different suppliers. Given the multiple batches run for various products, they must track over 3,000 items annually. In addition, these raw materials are then routed to a variety of vendors for bulk production and others for packaging with the finished product coming to them for distribution.

Based on this model, consider the costs for recordkeeping. It is my understanding that the traditional Certificates of Analysis will not be acceptable under the proposed regulations. Therefore, whatever testing is done at the vendors/suppliers will have to be documented and duplicated for inclusion in master manufacturing and batch controls records. Furthermore, copies of the testing documents alone are not satisfactory but annual visits and inspections to the vendor/suppliers will be required to verify that the testing documents are supported by adequate controls which will have to be monitored. As a result, Health Concerns, Inc. would need to add at least a half time person just to monitor the testing of the vendor/suppliers. Because many of these companies are out of state one would expect that such site visits would average three days. With an assumed 20 site visits a year, costs would be:

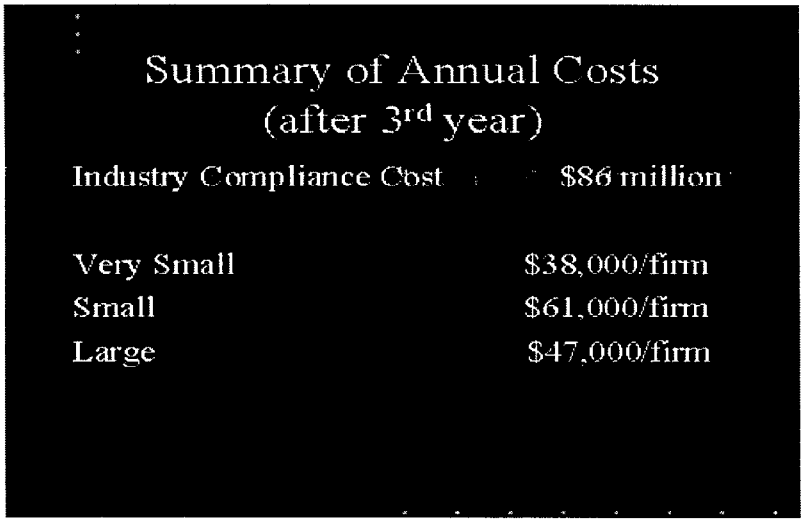
Cost Item	Cost	Unit	Total Cost
Inspector	$40,000	½ Time	$20,000
Site Visits:			
Transportation (Plane, Rental Car)	650	20	13,000
Lodging & Meals Per Diem	$125	60	7,500
Total			$40,500

Please note that we are talking only about the inspection portion of the added costs. Further compliance costs would be incurred due to the volume of paperwork necessary to document each suppliers tests of identity and composition of raw materials and each processing vendors documentation of additives, measures and processing. This would require at the least another half time clerks position ($15,000) and estimated annual overhead of $5,000.

Therefore, before any discussion of testing, we can estimate that recordkeeping by itself could increase annual costs by $60,500 [Inspection - $40,500; Recordkeeping - $20,000].

FDA Annual Costs

The following slide from the May 6, 2003 public meeting on the proposed regulations was presented by the FDA:



According to this presentation, the total annual cost of implementation is roughly equal to what I believe would their costs would be simply to ***document*** what is being proposed.

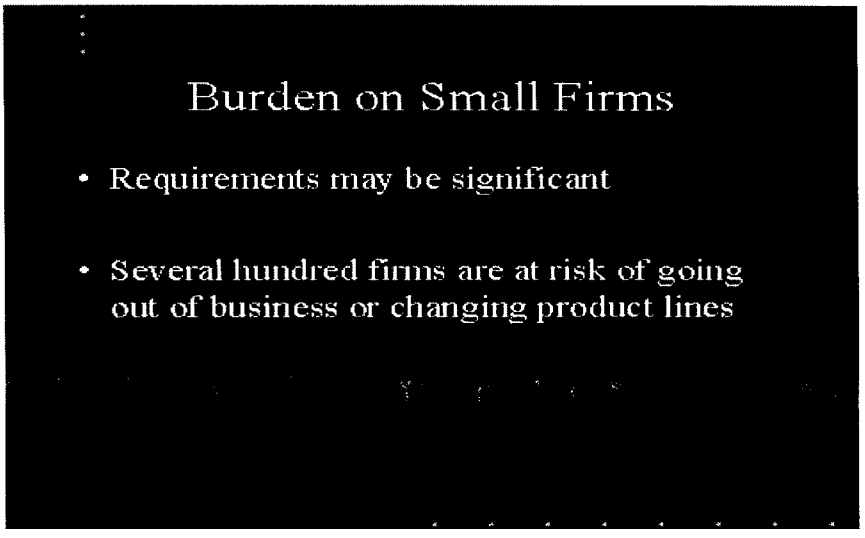
Cost Analysis – Testing

While the recordkeeping costs are substantial, the potential testing costs are astronomical. Consider that Health Concerns, Inc. would necessarily need to contract a testing lab to test products for adulteration such as heavy metals, pesticides and microbiological contamination. Also consider that a complete panel of tests could cost $1,000. They produce a minimum of 500 batches of finished product a year. Therefore to test every finished batch could cost in excess of $500,000 per year. Referring to the FDA's "Representative Manufacturing Steps" above, they could conceivably be looking at testing at the raw material level which could triple or quadruple the costs.

Health Concerns, Inc.'s current testing costs are a fraction of these proposed amounts because they employ random sampling methods which provides excellent controls coupled with virtually no negative outcomes. Even if they decided and were allowed to test on a finished goods basis, their suppliers would probably be forced to test at the raw materials basis, duplicating testing and increasing raw materials costs.

The Burden on Small Firms

Below is another of the slides from the presentation by the FDA at the May 6, 2003 public meeting on the proposed regulations:



Based on this slide, the FDA presumes that one of the inevitable outcomes is the bankruptcy of a significant portion of the dietary supplement industry. By there own research, the FDA identifies only 1,600 firms in the industry The loss of 300 companies is more than 18%. And if, as I clearly believe, their compliance cost figures are woefully inadequate, many more companies will be destroyed to satisfied the draconian measures of the proposed regulations.

Our position is that through the efficient use of random sampling and the reliance on valid testing and controls of our suppliers and vendors, the dietary supplement industry can provide an extremely high level of safe and effective products, properly labeled and free of adulteration. And we can do so without the unreasonably burdensome requirements of the proposed regulations.

Sincerely,

Ronald Vincent, C.P.A.

Submitted in both Hard Copy and E-document form.