ORIGINAL

Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD

In re: FDA Advance Notice of Proposed Rule Making, 62 Fed. Reg. 5700 (Feb. 6, 1997); Current Good Manufacturing Practice in Manufacturing Packing, or Holding Dietary Supplements	)	Docket No. 96-0417

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SUPPLEMENTAL COMMENTS OF PURE ENCAPSULATIONS, INC.; DURK PEARSON AND SANDY SHAW; MINERAL RESOURCES INTERNATIONAL, INC; TRACE MINERALS RESEARCH, L.L.C.; AND AMERICAN NUTRITION CORPORATION

Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; Mineral Resources International, Inc.; Trace Minerals Research, L.L.C.; and American Nutrition Corporation ("Joint Commenters"), by counsel, pursuant to 21 C.F.R. § 10.20, and in response to 62 Fed. Reg. 5700 (Feb. 7, 1997), submit these supplemental comments in further response to the FDA's advance notice of proposed rulemaking in the above referenced proceeding. These comments supplement those originally filed by the Joint Commenters on May 7, 1997. They do so in two respects. They provide further expert economic assessment of the impact of the proposed Current Good Manufacturing Practice regulations (CGMPs), and they evaluate the option of relying upon Hazard Analysis and Critical Control Points (HACCP) regulation in lieu of the industry-sponsored proposal.

While the Joint Commenters oppose adoption of the "one-size-fits-all" Current Good Manufacturing Practice (CGMP) regulations proposed in the advance notice, they favor adoption of Hazard Analysis and Critical Control Points (HACCP) provided that the HACCPs are limited in their application to companies actually found to have sold contaminated or adulterated dietary supplements. This narrowly tailored approach avoids

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imposing regulatory costs and burdens on companies innocent of wrongdoing, focusing instead on those specific entities that cause harm. It avoids adoption of a "one-size-fits-all" approach, ensuring that remedies are tailored in each case to the specific problems presented. It avoids the adverse effects of decreased innovation, higher barriers to market entry, and market concentration that will result from adoption of the proposed CGMPs. Moreover, unlike the proposed CGMPs, it avoids the need for substantial financial resources and new inter-coordination with other agencies of federal, state, and local governments because it merely complements the agency's current case-by-case enforcement approach.

SUPPLEMENTAL COMMENTS

In the Joint Commenters' original submission, Steve H. Hanke, Ph.D. (Professor of Applied Economics at The Johns Hopkins University and former Chairman of the Council of Economic Advisors to the President) and Stephen J. K. Walters (Professor of Economics at Loyola College in Maryland) explained that the proposed CGMPs would adversely affect industry structure and conduct, resulting in a net loss in consumer welfare rather than a net increase. In these supplemental comments, they analyze the economic impact of the proposed regulations on the dietary supplement market. They find that the current dietary supplement market is populated by a substantial number of small companies (approximately 46% having fewer than 10 employees). They find the market to be highly competitive, with few barriers to entry, and with little concentration. They also find the emphasis on quality to be high in this market. As Dr. Harry G. Preuss (Georgetown University Professor of Medicine and Pathology) explained in the Joint

Commenters' original submission, the market is far safer than that for either foods in common form or drugs.

In this environment Drs. Hanke and Walters find that most firms lack the financial wherewithal to finance costs that would be associated with the proposed CGMPs. They conclude that the regulations will transform the market by reducing innovation, raising entry barriers, and increasing concentration to the detriment of consumers without producing any cognizable improvement in product quality. They write:

> Taken as a whole, this scholarly evidence leaves no doubt that regulation of the dietary supplements industry will have adverse structural effects on innovation and competition. It is clear that the proposed regulations will reduce the number of firms in this industry, concentrate industry employment and output to a greater extent among the industry's larger firms, and reduce the number of new product innovations and the speed with which they are brought to market. The only uncertainty is how great these effects will be.

See Exhibit A.

In the Joint Commenters' original submission, the comparative safety assessment of Dr. Preuss revealed that dietary supplements are generally much safer than foods in common form. While over 9,000 people die every year from microbially contaminated foods, few dietary supplements have associated with them any deaths. Dried powdered or encapsulated nutrients (such as amino acids, vitamins, and minerals) and dried herbs used in most dietary supplements cannot support microbial growth.[1]

The manufacture of dietary supplement ingredients ranges from the relatively simple (e.g., evaporating water from Great Salt Lake brine) to the quite complex (e.g., synthesizing beta-carotene or producing arginine by fermentation). There is no "one-size-fits-all" prescription for quality control for the manufacture of dietary supplement

[1] Responsible herb suppliers perform tests for microbial contamination on herbs before selling them, and the herbs are often gassed or irradiated before sale to protect consumers.

ingredients, since there is a tremendous range of manufacturing processes and of potential attendant difficulties. With the exception of the 1989 contaminated tryptophan incident (which involved one manufacturer), dietary supplement ingredients have had very few quality problems that have affected human health. Indeed, soft cheese consumers in 1989 (or any other year) were at much greater risk of illness or death than tryptophan supplement consumers.

The Joint Commenters submit that it would be imprudent and illogical for the agency to require all dietary supplement companies to adhere to intensive and generally expensive Hazard Analysis and Critical Control Points (HACCP) quality control regulations, particularly if those regulations are more complex than those required for hydrated foods that can support microbial growth.[2] The existence of higher levels of safety in the dietary supplement market (as opposed to the food and drug markets) warrants avoidance of comprehensive and mandatory new regulations--ones that tax agency resources unnecessarily and impose huge new financial and regulatory burdens on companies yet produce no demonstrable overall improvement in quality or safety. Rather than impose the proposed CGMPs on the entire industry or require the entire industry to adhere to HACCP regulations, forcing all companies (the safe and the unsafe alike) to suffer new costs and burdens, the FDA should adopt a tailored approach aimed at specific wrongdoers. Such an approach complements current agency case-by-case enforcement, does not require the hiring and training of new personnel, does not require the creation of any new departments for investigation and enforcement, does not require new efforts at

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[2] In those relatively few supplements that have sufficiently high water activity to support microbial growth, the problem can be prevented in the same manner as with foods. Some supplements that are sold in aqueous solution or that are moist and are not pasteurized, retorted, irradiated, or otherwise treated to kill

intercoordination with other local, state, and federal agencies, and does not force those innocent of wrongdoing to bear costs that should be borne exclusively by the wrongdoers.

In that regard, the Joint Commenters recommend that the FDA not adopt the proposed CGMPs but instead: (1) authorize FDA to require any company actually found to have sold a contaminated or adulterated dietary supplement to develop and submit a Hazard Analysis and Critical Control Points quality control plan to the agency designed to eliminate the precise source of contamination or adulteration and to protect against a recurrence of the problem; (2) authorize FDA review of the plan and its implementation; and (3) mandate company revision of the plan if requested by FDA to protect public health. The focus should be upon those specific companies found to have harmed the public, not on all companies in the industry. Those specific companies should bear the entire cost of eliminating the harms they have created. A company responsible for causing harm to the public should be required to implement the same kind of quality control system improvements that would be required under similar circumstances for a food manufacturer.

CONCLUSION

In sum, the Joint Commenters urge FDA not to adopt the proposed CGMPs and instead to adopt narrowly tailored regulations that authorize the agency to require, as

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microbes may be vulnerable to microbial contamination. There is no evidence that such contamination is actually a significant problem in the dietary supplement industry.

explained above, the development of specific HACCPs by companies found to have sold adulterated or contaminated supplements.

Respectfully submitted,

PURE ENCAPSULATIONS, INC.;
DURK PEARSON and SANDY SHAW;
MINERAL RESOURCES INTERNATIONAL, INC.;
TRACE MINERALS RESEARCH, L.L.C.;
and AMERICAN NUTRITION CORPORATION,

By _____
Jonathan W. Emord, Esq.
Todd A. Harrison, Esq.
Claudia A. Lewis, Esq.

Emord & Associates, P.C.
1050 17th Street, N.W.
Suite 600
Washington, D.C. 20036
(202) 466-6937

Dated: June 6, 1997

EXHIBIT A

MEMORANDUM

To: Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

From: Steve H. Hanke, Ph.D.
Professor of Applied Economics
The Johns Hopkins University
Baltimore, MD 21218

and Stephen J.K. Walters, Ph.D.
Professor of Economics
Loyola College in Maryland
Baltimore, MD 21210

Re: "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements"--Comments
[Docket No. 96N-0417]
RIN 0910-AA59

Date: June 6, 1997

1. Introduction

This memorandum is a supplement to our earlier comments (dated May 7, 1997) regarding the FDA's proposed rulemaking to develop current good manufacturing practice (CGMP) regulations for dietary supplements and dietary supplement ingredients. We are grateful that the FDA has extended the time for filing comments in this proceeding.

In this comment, we provide additional details on the likely economic impact of the proposed regulations. We begin with a description of the current structure of the dietary supplements industry and then discuss the implications for this industry structure should the proposed regulations be implemented.

We conclude that the proposed regulations will have significant anticompetitive effects in this industry. In the short run, the regulations will put the industry's smaller firms at a serious disadvantage relative to larger firms; over time, this will lead to major equity losses, insolvencies, and job losses among these firms. But, if history is any guide, in the long run even larger firms will share in these equity losses because regulatory compliance costs will put them

at a competitive disadvantage vis-a-vis foreign producers in an increasingly global marketplace.

2. Current Industry Structure

As we noted in our previous report, the dietary supplements industry resembles what economists might call a "competitive ideal." The industry contains many sellers, all acting independently, and none (thus far) exercising dominant market power. As a result, competition in this market is vigorous, and consumers benefit from high rates of innovation, high product quality, and competitive pricing.

Of course, this industry involves many levels and types of firms--from those specializing in resource extraction, to processing and manufacturing firms, to wholesalers and distributors, to retail outlets. Given the variety and dynamism of the firms in this market, and the large number of products involved, structural data on this industry can be fragmentary. The Economics and Statistics Administration of the U.S. Department of Commerce does, however, gather information which should help us place the manufacturing level of this industry in perspective. In its *Census of Manufactures* (performed every five years) and *Annual Survey of Manufactures*, the Commerce Department measures employment levels, materials costs, value of industry shipments, and many other variables for hundreds of industries. Of particular interest here is the data relating to "Industry 2833--Medicinals and Botanicals."[1]

This industrial classification is, in some respects, both broader and narrower than we would like for a precise characterization of the dietary supplements market. Industry 2833 is "made up of establishments primarily engaged in (1) manufacturing bulk organic and inorganic medicinal chemicals and their derivatives, and (2) processing (grading, grinding, and milling) bulk botanical drugs and herbs. Included in this industry are establishments primarily engaged in manufacturing agar-agar and similar products of natural origin, endocrine products, manufacturing or isolating basic vitamins, and isolating active medicinal principals such as alkaloids from botanical drugs and herbs."[2] Thus, it may include some manufacturers of product lines that are not, strictly speaking, dietary supplements, and miss some firms that manufacture products which might be subject to the proposed regulations.

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[1]For additional information on industry-level statistics, see the *Standard Industrial Classification Manual: 1987*, available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, stock no. 041-001-0031402.

[2]U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, *1992 Census of Manufactures, Industry Series: Drugs*, MC92-I-28C, Issued June 1995, p. 28C-3. Note: agar-agar is defined as "a gelatinous material derived from certain marine algae and used as a base for bacterial culture media and a stabilizer and thickener in many food products."

Given these limitations, we should interpret this industry-specific data carefully. Nevertheless, it seems quite clear that this is a healthy, growing industry populated by a large number of small firms. The data contain little evidence of the kinds of "market failures" that are commonly advanced as causes for regulation of some kind. Consider[3]:

The value of shipments originating in the industry grew from $445.2 million in 1967 to $7,037.9 million in 1995, a compound annual growth rate of 10.4% annually. Clearly, consumer acceptance of the industry's products has been growing strongly. Often, the absence of "perfect information" about product quality in markets for *experience goods* such as dietary supplements is invoked to justify product quality regulation. But information about product quality is never perfect; the only relevant question is whether transactors are able to take sufficient steps to cope with normal information asymmetries and sustain beneficial market exchange. The proof of the pudding is in the eating: this sort of robust growth is wholly inconsistent with a diagnosis that information problems in this market call out for regulation.

The number of companies in the industry grew from 112 in 1967 to 208 by 1992. This signals that there are (currently) no major artificial barriers to entry into this market, an important guarantor of vigorous competition. Indeed, it may be the absence of such barriers that is making life relatively unpleasant for larger firms in the industry; erecting regulatory barriers to open competition is, as we noted in our initial comment, an increasingly popular competitive strategy.[4]

There is no evidence that the industry is (currently) experiencing a strong trend toward larger-scale enterprises as market demand grows. The number of establishments with 20 employees or more was actually lower in 1992 than in 1982 (74 to 94), while the number of employees in the industry grew from 8,400 in 1967 to 13,000 by 1992. Total industry employment by 1995 was 14,300.

The industry is showing a trend toward use of higher-skilled, better-paid employees and more costly inputs. For example, from 1977 to 1992, average hourly earnings of production workers climbed from $7.44 to $18.91, a compound annual growth rate of 6.4%. (By comparison, average hourly earnings of workers in all industries showed a compound annual growth rate of 4.8% over the same period.) In addition, costs of materials as a percent of value

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[3]Sources for all following data: U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, *1982 Census of Manufactures, Industry Series: Drugs*, MC82-I-28C, January 1985; *1992 Census of Manufactures, Industry Series: Drugs*, MC92-I-28C, June 1995; *1995 Annual Survey of Manufactures, Statistics for Industry Groups and Industries*, M95(AS)-1, February 1997, various tables and pages.

[4]See, in addition to the papers cited in our earlier comment, Peter Pashigian, "Reply: The Effect of Environmental Regulation on Optimal Plant Size and Factor Shares," *Journal of Law and Economics*, 29 (1986), pp. 201-09.

of shipments grew from 39% in 1977 to 50% in 1992. Such indicators are consistent with an industry in which market-based quality assurance mechanisms (described in detail in our earlier report) are functioning well.

Perhaps the best evidence of the competitive structure of this industry is the large number of small enterprises which inhabit it, and the relatively limited degree to which employment and output are concentrated among very large firms. As Table 1 shows,[5] of the 225 establishments in this industry as of 1992 (the latest year for which such data are available), 46% had fewer than 10 employees; only 8.9% had more than 100 employees.

Table 1

Industry Statistics by Employment Size of Establishment, 1992

Firms with...	Number of Firms	% of Total Employment	% of Total Shipments	% of New Cap. Expends.
1 to 4 emps.	62	0.77%	0.37%	0.16%
5 to 9	42	2.31%	0.91%	0.27%
10 to 19	47	5.38%	5.55%	0.80%
20 to 49	29	6.92%	2.83%	0.91%
50 to 99	25	14.62%	10.16%	4.25%
100 to 249	10	n.a.	n.a.	n.a.
250 to 499	4	n.a.	n.a.	n.a.
500 to 999	3	n.a.	n.a.	n.a.
1000 to 2500	3	n.a.	n.a.	n.a.
1 to 100	205	30.00%	19.80%	6.39%
100 to 2500	20	70.77%	80.20%	93.59%

Concentration is so low in this industry (i.e., there are so few large firms), that privacy concerns prevent the Commerce Department from reporting employment, production, and investment data for the larger firms in the industry (e.g., the three establishments with over 1,000 employees). The 20 establishments with over 100 employees account for 70.8% of total industry employment, 80.2% of the total value of shipments. and 93.6% of new capital expenditures. By contrast, in Industry 2834--Pharmaceutical Preparations--establishments with over 100 employees account for 91.2% of industry employment, 93.5% of shipments, and 94.2% of new capital

[5]Source: *1992 Census of Manufactures*, Table 4, p. 28C-12.

expenditures.

The data summarized in Table 1 also show that the smaller firms in this industry tend to be more labor-intensive than the larger firms. Establishments with less than 100 employees account for 30% of industry employment, but just 19.8% of the value of total shipments and only 6.4% of new capital expenditures. This reflects a fundamental fact of economic life for small businesses: significant investments in capital and other overhead costs are problematic at small scales of operation, since these discrete investments cannot be spread over large sales volumes. Anything that increases overhead costs--such as additional or new regulatory compliance burdens--places such smaller firms at a significant competitive disadvantage vis-a-vis their larger rivals, as we noted in our earlier report. Let us now consider these effects in more detail.

3. Economic Impact of Proposed Regulations

There is ample scholarly research demonstrating that regulatory compliance costs tend to reduce innovation rates, raise entry barriers, and increase concentration in affected industries.

One of the most authoritative studies on this point was conducted by Grabowski and Vernon (G&V) in 1976. G&V developed a model suggesting that increased regulation in the ethical drug industry might lead to the concentration of innovational outputs in fewer and larger firms. In their model, "[a]s innovational projects become riskier and more expensive, the minimum scale at which R&D can be undertaken without exposing a firm to a high variance in earnings will also increase."[6] G&V tested their model for both U.S. and U.K. firms. In the U.S., they found that increased regulation had produced a "quite dramatic" shift in the structure of innovation toward larger firms, and an increase in the concentration of innovational outputs in the industry. By contrast, innovational outputs had become less concentrated in the U.K.--where regulatory intensity had not changed--in the same period. Further, G&V found that increased regulation had reversed a trend toward diminished concentration of sales in this industry in the U.S., resulting (with a time lag) in increased concentration of sales over time. Finally, increased U.S. regulation produced a steady erosion of the position of U.S. firms in the U.K. market--i.e., increased U.S. regulatory compliance costs appeared to put U.S. firms at a competitive disadvantage in the global marketplace. G&V noted that stepped-up U.S. regulation in the ethical drug market had led some firms to move R&D and production facilities abroad, leading to reduced domestic production and employment in this industry, an "unintended side effect of regulation that would have to be weighed against the positive benefits of regulation."[7]

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[6]Henry G. Grabowski and John M. Vernon, "Structural Effects of Regulation on Innovation in the Ethical Drug Industry," in Robert T. Masson and P. David Qualls, eds., *Essays on Industrial Organization in Honor of Joe S. Bain*, New York: Ballinger (1976), p. 190.

[7]Grabowski and Vernon, *op. cit.*, pp. 192, 195, 203, 205.

Many other studies have shown that increased regulation has significantly reduced the number of new drug products brought to market and delayed their introduction. Wiggins, for example, found that "regulation has reduced introduction rates by roughly 60%. Approximately one-fifth of this reduction was the previously ignored effect of regulation on research spending."[8] Other studies have documented the shift in drug innovation leadership resulting from expanded regulation. For example, between 1962 and 1965, mutually-available drugs (i.e., those approved for sale in both countries) were introduced 6 months earlier in the U.S. than in the U.K.. Between 1966 and 1971, that relationship was reversed: mutually-available drugs were introduced 15 months earlier in the U.K. than in the U.S. More recently, between 1977 and 1987, mutually-available new drugs were on the market an average of five years sooner in Britain.[9]

Taken as a whole, this scholarly evidence leaves no doubt that regulation of the dietary supplements industry will have adverse structural effects on innovation and competition. It is clear that the proposed regulations will reduce the number of firms in this industry, concentrate industry employment and output to a greater extent among the industry's larger firms, and reduce the number of new product innovations and the speed with which they are brought to market. The only uncertainty is how great these effects will be.

A prospective assessment of the structural effects of regulation has not, to our knowledge, ever been published in the scholarly literature. Nevertheless, some estimates of the likely magnitude of these effects can be made by extrapolating some of the findings of the retrospective impact studies.

The most useful study for this purpose was conducted by Thomas in 1990. Thomas calculated the highly differential impacts of FDA regulations on pharmaceutical firms of various sizes, concluding that smaller U.S. pharmaceutical firms had "suffered devastating reductions in research productivity because of FDA regulations."[10] By contrast, the regulations bestowed a competitive advantage on larger firms, enabling them to increase their share of the market by an amount sufficient to offset their declines in research productivity. (These inter-firm effects should not be taken to mean that the consumer welfare effects of the increased regulation were

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[8]Steven N. Wiggins, "Product Quality Regulation and New Drug Introductions: Some New Evidence from the 1970s," *The Review of Economics and Statistics*, 58 (November 1981), pp. 615-19, at p. 619. See also Henry Grabowski, John Vernon, and Lacy Glenn Thomas, "Estimating the Effects of Regulation: An International Comparative Analysis of the Drug Industry," *Journal of Law and Economics*, 21 (April 1978), pp. 133-64.

[9]Sam Kazman, "Deadly Overcaution: FDA's Drug Approval Process," *Journal of Regulation and Social Costs*, 1 (September 1990), pp. 35-54, at pp. 38-40.

[10]Lacy Glenn Thomas, "Regulation and Firm Size: FDA Impacts on Innovation," *RAND Journal of Economics*, 21 (Winter 1990), pp. 497-517, at p. 497.

ambiguous; expected higher prices for old products and reduced availability of new products lead to unequivocally negative welfare consequences for consumers.)

Thomas also found that, while "FDA regulation has provided a competitive advantage for larger U.S. pharmaceutical firms over their smaller domestic competitors... this same regulation also very likely provides a competitive *dis*advantage for larger U.S. firms against larger foreign firms... . With the rapid globalization of competition in the ethical drug industry, the benefits [to large firms] from the domestic advantage provided by regulation have in all likelihood been long since offset by the international disadvantage."[11] In fact, the evidence supports this view: Thomas estimated the effects of the expanded regulation on the real market value of common equity of U.S. pharmaceutical firms. Over the period 1963 to 1974, the average equity value of the largest U.S. firms climbed 76%, while mid-size U.S. firms' equity values climbed 35% and small firms' values *fell* 41%. From 1974 to 1980, however, both large- and mid-size U.S. firms' equity values fell slightly--by 17% from peak 1974 levels--while equity values for the smallest U.S. firms fell an additional 72%. Clearly, the era of stepped-up FDA regulation in this industry has, in the long run, been no blessing for large firms, and a catastrophe for small ones.

Let us suppose that the proposed CGMP regulations have structural effects on the dietary supplements industry which are similar to those Thomas found for previous FDA regulatory efforts. That is, suppose, over a period ranging from one to two decades following the initiation of a new regulatory regime, that the equity values of small firms in this industry would fall by 83.3% from peak (pre-regulatory) levels.[12] This would, clearly, have a devastating effect on the solvency of these small firms (which, for present purposes, will be defined as establishments with less than 100 employees). It is certainly possible--though unlikely--that all such firms would survive, though in a much (83.3%) poorer and smaller form. At the other extreme, it is possible that the equity losses would be concentrated, effectively wiping out 83.3% of these firms. More likely is an intermediate scenario, where the competitive disadvantages described earlier lead to the gradual insolvency and exit of 40 to 45% of these firms, with the remainder surviving in some form. Referring back to Table 1, we see that this would reduce the number of small establishments in the industry from 205 to the range of 123-133; unless the insolvencies were concentrated among the smallest of these establishments, anywhere from 1,520 to 1,710 jobs would disappear as a result, with additional job losses resulting from downsizing at the surviving small firms.

Such estimates are, of course, speculative. However, confirmation that they are reasonably accurate comes from the comments submitted earlier by officials of Pure Encapsulations, Inc.

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[11]Thomas, *op. cit.*, p. 514.

[12]See Thomas, *op. cit.*, Table 5, p. 512.

("Pure"), a Massachusetts-based manufacturer of dietary supplements.[13] Pure, with 35 employees, is clearly one of the smaller firms that will be put at a severe competitive disadvantage by the proposed regulations. Pure estimates that the immediate effects of the proposed regulations might include a 35% reduction in its product line, possible price increases ranging from 30 to 200%, or increased inventory costs ranging from $0.5 to $1.5 million per year. Such near-term effects are certainly consistent with the kinds of equity value reductions identified by Thomas's study; in a longer-run scenario, as regulatory intensity increases, it is eminently reasonable to suppose that such effects would grow and threaten Pure's survival.

4. Concluding Remarks

In our earlier (May 7) report, we stressed that the proposed regulations are unlikely to enhance consumer safety; we pointed out that replacing market-based quality- and safety-assurance mechanisms with apparent regulatory oversight poses significant risk of offsetting behavior by consumers that could lead to lower levels of safety and product satisfaction than currently prevail in the industry. Thus, the social benefits of the proposed regulations are difficult to detect--and may be negative.

In this report, we have enumerated the social costs of the regulations in more detail. We believe it is certain that the proposed regulations will disturb a welfare-maximizing equilibrium in an industry that is competitive, innovative, rapidly growing, and consistently meeting consumers' expectations about product quality. In the short run, the regulations will tilt the competitive playing field in this industry in favor of mid- and large-sized firms, and will enable these firms to benefit from higher prices for two reasons: (a) higher (regulatory compliance) costs will force the "competitive fringe" of smaller firms to raise prices across the board, or to withdraw from certain product markets altogether; (b) over time, reduced rates of innovation will enhance the market power of older product lines.

In the longer run, and especially if--as is the historical pattern--regulatory intensity increases over the years, this trend will have a devastating impact on the solvency of the industry's smaller firms. It is not unreasonable to suppose that 40 to 45% of these firms may, over time, become insolvent, taking with them 1,520 to 1,710 jobs; additional job losses are likely among the surviving small firms.

But, if history is any guide, the long run will also see adverse competitive effects spread to the industry's larger firms, as regulatory compliance costs put them at a competitive disadvantage vis-a-vis foreign manufacturers in an increasingly global economy. Thus, losses of

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[13]See Appendix C in "Comments of Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; Mineral Resources International, Inc.; Trace Minerals Research, L.L.C.; and American Nutrition Corporation," *Before the Food and Drug Administration*, Docket No. 96-0417.

equity value can be expected to spread to these firms over time. If, as we suggested earlier, these firms have advocated regulation in pursuit of short-run competitive advantage over their smaller rivals, it is likely they ultimately will come to regret this strategy.