HERBALIFE®

John Venardos | Vice President
Global Licensing Regulatory & Govt Affairs

Herbalife International of America INC
1800 Century Park East Century City CA 90067
T 310 410 9600 F 310 557 3916
E-mail JohnV@herbalife com

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

Re: Current Good Manufacturing Practices In Manufacturing, Packing, Or Holding Dietary Ingredients And Dietary Supplements

To Whom It May Concern:

Herbalife International, Inc. ("Herbalife"), the world's leading weight-loss company, hereby submits its comments regarding the captioned proposed regulation published at 68 Fed. Reg. 12158 (March 13, 2003) (the "Proposed Regulation"). Herbalife believes that these necessary improvements will help companies, such as ours, continue to offer consistent, high-quality dietary supplements produced to exacting standards by our contract manufacturers here at home and overseas. We share FDA's commitment to using these regulations as a tool to improving consumer health and well-being.

SUMMARY OF HERBALIFE'S RECOMMENDATIONS

I. Testing.

FDA should revise – and clearly demarcate – the testing obligations of end-use marketers, such as Herbalife, that are well down-stream in the vertical manufacturing chain from our contract manufacturers. Fairness dictates we must reasonably know where our responsibilities lie.

II. Certificates of Analysis.

In the Preamble, FDA indicates that Certificates of Analysis generally cannot be relied upon. In the course of its stakeholder meetings process, however, FDA representatives recognized that verified Certificates of Analysis, based on appropriate testing from suppliers who are audited by their customers as to their testing and manufacturing practices, are acceptable. The final rule should provide a "due diligence" road map for companies, such as Herbalife, so we can rely – in good faith – upon audited Certificates of Analysis from time-tested raw ingredient suppliers and contract manufacturers. As discussed below, Certificates of Analyses can be strengthened universally by containing more specific information regarding the analysis performed and by relying entities, such as Herbalife, taking steps to verify that suppliers' operations and testing procedures are appropriate. The position taken in the Preamble to the Proposed Regulation – that no reliance is good reliance – makes little sense, adds no

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demonstrable guarantee of product quality, and would not lead to any demonstrable health benefit to the ultimate consumers for our products. Furthermore, such a concept flies in the face of drug GMP standards.

III. Applicability to Whole Industry, Including Raw Material Suppliers and Foreign Firms.

The final rule must apply to the entire industry, including suppliers, and include a reliable enforcement plan to ensure proper compliance by foreign-based suppliers. If domestic companies, such as Herbalife, are to continue to offer high quality products, they must reasonably be able to rely upon quality assurances from suppliers and foreign firms. To make this system work, FDA must not exempt suppliers or remove foreign compliance obligations just because down-stream processing is performed in the U.S.

IV. Consistent Flexibility Across the Board.

FDA should impose one set of dietary supplement cGMPs applicable to all product categories. With proper flexibility, those regulations will adequately inform all companies subject to their purview. In this context, flexibility means recognizing that different companies operate under different circumstances and that, under those different circumstances, there may be different means appropriate to achieving the legitimate GMP ends. Thus, as discussed below, where possible, the final rule should refrain from being unnecessarily specific as to the means to achieve the legitimate GMP ends.

INTRODUCTION

Having been in business for more than 23 years, Herbalife today is the world's leading weight-loss company, with annual retail sales of nearly $2 billion. Our product portfolio includes high-quality conventional foods, dietary supplements and Outer Nutrition® products (otherwise known as cosmetic or personal care products) marketed through a global network of more than 1,000,000 independent distributors in 58 countries. Herbalife's dietary supplement products are produced by contract manufacturers operating both within and outside of the United States. The Company carefully monitors the quality standards employed by all of its contractors, many of whom already meet or exceed food and/or pharmaceutical GMP requirements.

The Proposed Regulation represents a commendable effort to achieving the important goals of protecting the public health by preventing adulteration, regaining public confidence in dietary supplements, and providing a mechanism for efficient enforcement of cGMPs. Herbalife shares a commitment to these goals.

However, the underlying economic impact cited by FDA accounts for but a fraction of the actual costs that would be borne by industry and, ultimately, by health-conscious consumers. As a rising tide of obesity besets this nation, that has the potential to spawn adverse health consequences, Americans are keenly interested in traditional products, such as ours, that help them achieve improved overall health. Specifically, FDA's proposed cGMP testing requirement alone would result in Herbalife incurring more than $2,500,000 in added testing expense without resulting in a tangible improvement in either product quality or consumer health.

Therefore, FDA must reorient the cGMP proposal so that companies can afford to help FDA achieve its compliance objectives. In addition, the changes in the final rule should look forward to the harmonization of manufacturing standards with authorities in Europe, Asia and elsewhere. Clearly, the supply chain for dietary supplement products has increasingly internationalized. Providing clear, strongly enforced guidelines with which natural product producers can live should remain a high priority goal.

COMMENTS

A. Preamble.

The Preamble to the Proposed Regulation presented an inaccurate assessment of the dietary supplement industry. First, FDA criticized market forces for failing to provide adequate incentives to ensure production of quality products. Second, FDA asserted the Proposed Regulation would correct this situation, by preventing adulteration and misbranding of dietary supplements by so-called "bad actors." Frankly, FDA's failure to adequately use its existing enforcement powers to reign in "bad actors" that market adulterated, misbranded products with inappropriate claims has contributed significantly to this problem.

B. Compliance with DSHEA

An overarching area of concern is the extent to which the Proposed Regulation is modeled after, and in some cases exceeds, GMPs for over the counter (OTC) drugs. In the Preamble, FDA said: (a) the dictionary meaning of "modeled after" suggests that proposed regulation should be "preliminarily patterned after" food GMP, and (b) because practical similarities exist between dietary supplements and drugs, hybrid food and OTC drug GMP requirements are necessary. When Congress passed the Dietary Supplement Health & Education Act (DSHEA) in 1994 by a unanimous vote, it limited FDA's discretion by requiring that the proposed cGMP Regulation "be modeled after" GMPs for food. This provision was drafted into

DSHEA to ensure that overly burdensome, drug-like GMPs not be adopted because: (a) such requirements were not necessary; and (b) unnecessary costs would push industry out of business and adversely impact consumers' choice of quality products. While Herbalife concurs some limited borrowing of appropriate concepts of OTC drug GMP regulations may be necessary, the Proposed Regulation should not be modeled after OTC drug GMPs and certainly should not exceed these standards in any respect.[1] To do otherwise is in clear violation of Congressional intent.

During the FDA stakeholder meeting process, when asked about the extent to which certain provisions not only depart from food GMPs but exceed or depart from OTC drug GMPs, some FDA representatives conceded that they had not read the OTC drug GMP regulations or made any comparison between OTC drug GMPs and the Proposed Regulation. Such concessions by agency personnel suggest a need for better internal coordination prior to allowing regulatory initiatives to enter the public domain.

Herbalife thus urges FDA first to consider how each provision of the Proposed Regulation compares with the food and OTC drug GMPs. Further, this is an especially propitious time to coordinate with CDER in light of the new GMP initiative underway in that center.

C. FDA's Flawed Economic Analysis

FDA's economic impact analysis, which is intended to justify the Proposed Regulation, is based upon incomplete information and grossly underestimates the cost of the regulation as proposed. For example, FDA's assumption that most firms (68%) follow GMP, and will not incur great costs, is flawed. Even FDA conceded that the underestimation of fiscal impact resulted from the lack of response (approximately 20% of the firms polled) to the survey upon which FDA heavily relied in its economic analysis.

FDA also significantly underestimates the cost of capital investments required by the Proposed Regulation. FDA estimate that large firms – such as Herbalife – would be required to expend an average of approximately $47,000 per firm. FDA's estimate, is quite simply, not accurate, as will be evident when economic impact surveys are submitted to the agency by the American Herbal Products Association and by the Council for Responsible Nutrition. Both of these organizations represent the broad dietary supplement industry. Preliminary indications, based on specific data provided by Herbalife and others, suggest industry (and ultimately consumers) will bear a much higher economic burden than that suggested by the agency.

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[1] For purposes of these comments, the term "exceed" means to have more specific or more stringent requirements that OTC drug GMPs.

D. FDA Should Modify and Clarify the Testing Obligations

Testing is the area in which the proposal can benefit most from clarification and increased flexibility. When combined with proper process control through written procedures and documentation, these changes will meet the legitimate quality goals of GMP while significantly cutting the unnecessary testing costs mandated by the proposed regulation.

Section 111.35 of the Proposed Regulation and the policy stated in the Preamble, as currently drafted, would require the following:

- That manufacturers establish specifications as to the identity, purity, quality, strength and composition of components, dietary ingredients and dietary supplements upon receipt, in process (with respect to dietary ingredients and dietary supplements), and in the finished product (with respect to dietary ingredients and dietary supplements).

- That manufacturers ensure, through testing or examination, that the products comply with the specifications, as follows:

- Test each finished batch, and

- If the manufacturer can document that any specification cannot be tested on a finished batch because there is no scientifically valid analytical method, perform testing upon receipt and in-process (at points where control is necessary).

In the Preamble, FDA discusses its effort to create "flexible" testing standards. Some aspects of the proposal, however, are less flexible than OTC drug GMP requirements. Our own experience is such that the cost of the testing requirements, as proposed, is significant and much higher than FDA estimates in its economic analysis. The requirement that manufacturers conduct analytical tests on each component or ingredient in each batch is costly and unnecessary. It is not uncommon for some combination dietary supplements to contain 35-40 separate ingredients. Please note our specific testing cost calculations will be reflected in economic impact assessments being prepared for submission to the FDA by the American Herbal Products Association and by the Council for Responsible Nutrition.

The testing aspect of the Proposed Regulation could be less costly and more flexible, and still achieve the goals of GMP, if the FDA were to make the rule more consistent with OTC drug requirements in the following respects: (1) creating a more flexible standard for testing of non-dietary ingredients and components; and (2) permitting strong supplier certifications that demonstrate that certain ingredients have been tested and meet specifications and, where appropriate, allowing such test results to ease the cumulative and unnecessary testing

burdens on other companies down the supply chain. The Proposed Regulation also should clearly identify the testing obligations of entities at different points in the supply chain.

1. Appropriate Supplier Certification of Test Results Should be Allowed

The Preamble to Proposed Regulation states that entities may not rely upon Certificates of Analysis determining the identity, purity, quality, strength and composition of dietary ingredients or dietary supplements. During the course of the FDA stakeholder meeting process, however, FDA representatives clarified FDA's position, indicating an acceptance of the concept that, while traditional certificates of analysis may not be appropriate, certified test results will be acceptable if (a) the manufacturer or its designee inspects the supplier's laboratory and verifies that the supplier complies with GMP and (b) the manufacturer maintains documentation that appropriate testing was performed and showed that the product meets specifications.

Attachment 1 is a model of what we believe to be an acceptable Certificate of Analysis under the final rule. The ingredient used in this example is milk thistle dry extract, with the following specifications: (1) physical/chemical test; (2) assay; (3) microbiology and (4) storage conditions. This document demonstrates that batch number 372021of the ingredient was tested and that such testing revealed that the ingredient was acceptable given the established specifications.

The use of Certificates of Analysis in this context will be most effective if companies who wish to rely upon such certifications are required to reasonably audit their suppliers certification to ensure accuracy and quality. Reasonable follow up can be a flexible concept, but should consist of, among other things: verification testing at appropriate intervals; auditing the supplier's laboratory at appropriate intervals to ensure compliance with GMPs; and review documentation supporting certifications given in connection with previous shipment lots. The concept of appropriate intervals to perform such verification is flexible and should depend upon the degree to which the supplier has established a record of reliability.

Herbalife is encouraged that supplier certifications will be acceptable. Herbalife is concerned about a couple of related issues, and recommends the following. First, the final rule should make clear that supplier certifications of test results are acceptable. Second, the final rule should make clear that analytical tests for specifications do not have to be repeated in the finished product manufacturing process. If an appropriate test regarding specifications has been conducted by the supplier and the manufacturer maintains the appropriate back up documentation, further specification testing, except identity examinations and process control to verify that the correct ingredients are added, is not necessary.

Third, similar to OTC drug GMP, once a supplier of "inactive" raw materials (in this context, non-dietary ingredients) has been demonstrated by testing to be reliable, "skip lot" testing to periodically re-verify the reliability of a supplier, as opposed to analytical testing each batch, should be permitted. See, 21 C.F.R. § 211.84.

2. The Final Rule Must Clearly Demarcate the Different Testing Responsibilities that Correspond With Different Roles in the Supply Chain

The Proposed Regulation does not make clear which testing obligations correspond with which roles in the supply chain. Nor does it make clear that only one party in the supply chain needs to perform certain tests with regard to certain ingredients. The final rule must make different obligations correspond with different roles in the supply chain, and should clarify that such obligations only fall on one party to perform such testing so long as parties down the supply chain verify that such testing was performed. Herbalife recommends the following structure:

- Most of the testing obligations should be the responsibility of entities "upstream" in the supply chain, such as raw ingredient suppliers and contract manufacturers. This would be most efficient because these parties can realize economies of scale.

- Entities with roles "down" the supply chain from finished product manufacturing, such as entities that only bottle and/or label dietary supplements, should have testing obligations commensurate with their role in the manufacturing process, such as purity testing and periodic stability testing.

- End-use marketers, such as Herbalife, that obtain finished dietary supplements from contract manufacturers, and do not bottle or label such product, should be permitted to rely on test reports from upstream suppliers, provided that: (a) the covered entity inspects the suppliers' facilities and verifies compliance with GMPs; (b) the covered entity maintains documentation that appropriate testing was performed and showed that the product meets specifications; and (c) the covered entity establishes the reliability of the suppliers' analysis through appropriate verification and re-verification of test results at appropriate intervals.

3. Testing Requirements Regarding Non-Dietary Ingredients and Components Should be More Flexible

For purposes of analytical testing requirements, the Proposed Regulation makes no distinction between dietary ingredients, non-dietary ingredients and components in dietary supplements, imposing the same standard regardless of what the ingredient may be. If this is not modified in the final rule, this aspect of the dietary supplement GMP Regulation will be more stringent than its counterpart the OTC drug GMP regulations. OTC drug GMP regulations have more flexible testing standards for "inactive" ingredients, which are analogous to non-dietary ingredients in the dietary supplement context. For "inactive" ingredients, a "reasonableness" standard is in place, which recognizes the goal of providing reasonable certainty that the product contains what the company says, which can be accomplished through reasonable identity testing, but does not require analytical testing of each and every component or ingredient. Certain parts of the Preamble note that varying tests may be appropriate for different types of ingredients as far as identity testing. This should be the case for non-dietary ingredients under the final rule.

D. Process Control: Documentation/Written Procedures

The Proposed Regulation requests comments regarding the necessity of written procedures and documentation in certain aspects of operations. In manufacturing, documentation and written procedure requirements have several key functions. One major function is to inform employees of exactly what they should be doing, step by step, to maintain consistent quality products. Another important function is to demonstrate, for enforcement or other purposes, that GMPs are being followed. Thorough documentation also allows greater trace ability. In light of the importance of procedures and documentation to achieving the goals of GMP, Herbalife believes that written procedures and documentation should be required at every key point of the manufacturing process. In the overall scheme of assuring consistently manufactured, quality products, process control through appropriate written procedures and documentation is a more effective means of achieving GMP goals than some of the exhaustive and unnecessary testing requirements proposed by FDA.

E. Herbalife Supports Applying the Proposed Regulation to the Entire Industry, Including Suppliers and Foreign Firms

Proposed section 111.1 indicates that the Proposed Regulation is intended to cover all manufacturers, suppliers and other entities "if you manufacture, package, or hold a dietary ingredient or dietary supplement." The Preamble to the Proposed Regulation indicates that this section also applies to foreign firms that manufacture, package or hold dietary ingredients and dietary supplements that are imported or offered for import into the U.S., unless such products are "imported for further processing and export under section 801(d)(3) of the act".

Herbalife supports FDA's proposal to apply the final rule to all companies that participate in the dietary supplement industry, including raw material suppliers and foreign firms. Herbalife understands that some raw material suppliers will take the position that they should be exempt from complying with dietary supplement GMPs, arguing, among other things, that, because the ingredients they supply are used in conventional foods and dietary supplements compelling them to comply with special rules for dietary supplement ingredients may be too costly and, therefore, may make it unfeasible to continue to supply dietary supplement ingredients.

Herbalife disagrees with raw material suppliers who assert that an exemption is warranted. Exempting raw material suppliers from the final rule would hinder the goal of ensuring quality and would be inefficient economically. Raw material suppliers are key to ensuring quality. Due to their position in the supply chain – they often possess greater expertise regarding their ingredients and are able to take advantage of economies of scale – raw material suppliers usually are in the best position to evaluate a raw material properly. Indeed, this is the reason verified certificates of analysis from raw material suppliers are at the core of the alternative testing approach recommended by Herbalife.

The suppliers' feasibility concerns are better addressed, not by an undue exemption, but by building more consistent flexibility the rule, like food GMPs and as Herbalife proposes. Another component of the feasibility concern of suppliers is that the final rule must ensure a level playing field for responsible suppliers by enforcing the final rule against foreign suppliers, some of whom have a history of using lower pricing from non-compliance to undercut the prices of responsible suppliers who comply with GMP. Thus, Herbalife is concerned about the lack of a plan to enforce the Proposed Regulation with respect to foreign firms. Because foreign suppliers and manufacturers conduct a significant amount of business in the United States, a lack of incentive to comply with and/or failure to enforce the Proposed Regulation with regard to foreign firms will undermine the effectiveness of the GMPs and result in an unfair advantage for foreign suppliers and manufacturers over their domestic counterparts.

With the internationalization of the supply chain for dietary supplements, the GMP system will not function effectively if foreign suppliers and manufacturers are given a "free ride" with respect to GMP standards in the United States. Without an enforcement mechanism in place in the final rule, FDA would essentially give that "free ride" to foreign suppliers at the expense of down stream U.S.-based entities and, possibly, the integrity of GMPs in the dietary supplement industry.

Thus, Herbalife recommends that the final rule apply to raw material suppliers and include a mechanism for enforcing GMPs with regard to foreign firms.

F. Personnel Qualification Requirements May Exceed Those of OTC Drug GMP

The personnel qualification requirements, set forth in proposed Sections 111. 12 and 111.13, appear to exceed the requirements of their counterparts in OTC drug GMP regulations. These sections as drafted, would require that employees and supervisors have the "training and experience" to perform their respective duties. While at first blush this appears to be fine, a comparison of this proposed language with the counterpart language in OTC drug GMP regulations leads to the conclusion that the proposal exceeds the relevant requirement in OTC drug GMP, which requires "education, training and experience, *or any combination thereof.*" This alternative language provides greater flexibility without sacrificing the quality goals of GMP. Accordingly, Herbalife recommends that the language in proposed Sections 111.12 and 111.13 be revised to state "training and experience, *or any combination thereof.*"

G. Requirements Regarding Product Returns

Proposed sections 111.85 and 111.35(i) require a material review and disposition decision (involving the Quality Control (QC) group) regarding any returned product and that returned product may not be salvaged, unless (1) evidence from their packaging indicates that they have not been stored under improper storage conditions and (2) tests demonstrate that the product meets all specifications for identity, purity, quality, strength and composition.

As drafted, these two sections appear to require that practically no product can be salvaged that has been returned because companies receiving returns often can't verify the conditions under which such products have held (unless such products were held in a place such as a pharmacy) and every product returned would need to be retested for specifications.

At the May 6, 2003 FDA stakeholder meeting in Oakland, when interested stakeholders inquired about the extent to which testing would be required of returned product, the FDA panel responded that the extent of testing requirements would depend upon the reason that such products were returned. This type of a reasoned approach is much more practical than the approach that appears to be suggested in the actual language of the proposed sections 111.85 and 111.35(i). The rule should be clarified in its final form to take these practical issues into account and allow flexibility as to when returned product must be tested.

Thus, Herbalife recommends that proposed section 111.85(b)(2) be changed to state: "Tests, which only are required to be conducted to the extent that product is returned for a GMP related reason, demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition."

H. One Set of Appropriately Flexible Standards is Better than Different Standards for Different Segments of Industry

The Proposed Regulation creates uniform standards for dietary supplements and dietary ingredients. It does not create different standards for different types of dietary supplements or dietary ingredients, or different standards based upon company size. The Preamble requests comment regarding the extent to which different standards for GMP should apply to different segments of the industry, specifically asking for comment regarding the plausibility of treating different dietary ingredients (such as animal-derived dietary ingredients as opposed to vitamins and minerals) differently, or whether distinctions should be made upon company size or for different phases of production.

Herbalife does not believe FDA should create different GMP standards for different segments of the industry, whether those differences are based upon the type of dietary ingredient (animal-derived dietary ingredient versus vitamins/minerals versus herbs or botanicals), or based upon the size of various companies. Herbalife supports one set of GMPs to be applied to the entire dietary supplement industry. The key to having one set of GMPs that achieve the goals of GMP in such a diverse industry (in terms of types of ingredients and types of companies) is setting flexible rules. One set of appropriately flexible standards will be more efficient and less confusing to industry.

Moreover, the manner in which the proposal places greater or less stringent requirements on different *phases* of the process is appropriate. For example, the proposal places more stringent requirements on the manufacturing phase of the process, as opposed to the holding and distributing phase of the process. This approach is appropriate because manufacturing is the phase with the greatest danger of adulteration.

I. Cleaning and Sanitation

Cleaning and sanitation is another area in which greater flexibility and less specificity is warranted. The proposed regulation states the following with regard to sanitation:

1. Definitions:

a. Sanitize means to adequately treat equipment, containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact surfaces that when evaluated for efficacy, yield a reduction of five logs, which is equal to 99.999% reduction, of representative disease micro-organisms of public health significance and substantially reduce the numbers of other undesirable micro-organisms, but without adversely affecting the product or its safety for the consumer.

b. Contact surface means any surface that contacts a component, dietary ingredient, dietary supplement, and those surfaces from which drainage onto the component, dietary ingredient, dietary supplement, or onto surfaces that contact the component, dietary ingredient, or dietary supplement ordinarily occurs during the normal course of operations. Examples of contact surfaces include, but are not limited to, containers, utensils, tables, contact surfaces of equipment, and packaging.

2. The batch production record must contain "the date and time of the maintenance, cleaning and sanitizing of the equipment and processing lines used in producing the batch."

Herbalife has several concerns regarding proposed Section 111.3. First, the proposed definition of "sanitize" is inappropriate in that this proposed definition is not modeled after food GMP nor OTC drug GMP. This definition would make the sanitation requirement for dietary supplements more stringent than OTC drugs GMP because it is more specific than OTC drug GMP in its requirement of a 5 log reduction of representative disease micro-organisms of public health significance.

The Preamble states that this standard was borrowed from the FDA Food Code because, like food served in restaurants and nursing homes, dietary supplements are not processed further before consumption. This line of reasoning does not take into account that dietary supplements are no different than drug (or even many other food) products in this regard. Thus, a departure from modeling this section after food GMP, and exceeding OTC drug GMP, is not warranted. As discussed above, this type of departure from the limitation that the dietary supplement GMP regulation "shall be modeled after CGMP for food" violates the limits of FDA's legal authority under DSHEA.

Additionally, Herbalife is concerned that the proposal, as drafted, may require that production stop while companies sanitize all equipment and processing lines to achieve the "5 log reduction" discussed above, and the unnecessary additional cost of such production "down time" will be significant.

The final rule should focus on the end goal: to ensure that contact surfaces are cleaned and sanitized appropriately. Thus, with respect to the definition of "sanitize", Herbalife recommends that the final rule be written as follows: "'Sanitize' means to adequately treat equipment, containers or utensils by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer." This language, which is the exact language used in the ANPR and is more modeled after food GMPs, is much more flexible without compromising the quality goals of GMP as it still mandates "effective" sanitation without overly specifying the means to achieve the goal.

J. Phase In Time

The Proposed Regulation contemplates phasing in the applicability of the final rule over 3 years, based upon the size of the companies. Under the Proposed Regulation, potential enforcement of the rule may commence against large firms (firms with 500 or more employees) within one year of the rule becoming final. The rule would also be phased in for small firms (20-499 employees/2 years) and very small firms (up to 19 employees/3 years).

Herbalife is concerned that one year is not sufficient time to phase in complete compliance with all of the changes necessitated by the Proposed Regulation. As discussed above, FDA has underestimated the cost and extent of the changes that would be necessary at most companies in the industry if the Proposed Regulations becomes final.

Herbalife also is concerned about treating firms differently based upon size. The result of phasing in enforcement of the rule in the manner proposed would be to create an advantage in the marketplace for small and very small firms who would have incentive to sell cheaper products that are not manufactured in accordance with GMP while large firms endure the increased GMP-related costs for 1 or 2 years.

Herbalife recommends that the final GMP rule be phased in over a period of 2 years for the entire industry, without regard to size of the company.

V. CONCLUSION

The Dietary Supplement Health and Education Act and lessons learned from implementation of the OTC drug GMP regulations should instruct FDA to modify and clarify the Proposed Regulation so the regulations achieve the goals of GMP in an efficient manner that does not impose undue burdens on the industry. This balance can be achieved by drafting greater flexibility into the rule, especially in the testing scheme, strengthening such process controls as written procedures and documentation in key operations, and ensuring that the final rule not exceed OTC drug GMP requirements in any respect. Effective enforcement, including enforcement against foreign firms, will also be key to the integrity of the final rule.

Respectfully submitted,

John P. Venardos

XYZ Company

CERTIFICATE OF ANALYSIS

3 March 2003 020995

PRODUCT: MILK THISTLE DRY EXTRACT **CODE**: 345006

BATCH: 372021 **QUANTITY:** **OUR REF.** **YOUR ORDER**

CUSTOMER:

1. **PHYSICAL CHEMICAL TEST**	METHOD	SPECIFICATIONS	RESULTS
1.1. ORGANOLEPTICS CHARACTERS:		Fine powder, brownish yellow color, characteristic odor	Conforms
1.2. IDENTIFICAION:	USP	Meets requirements	Conforms
1.3. LOSS ON DRYING:	USP	<5.0%	0.25%
1.4. PESTICIDE RESIDUE	USP	Meets requirements	Conforms
1.5. HEAVY METALS	USP	<20 ppm	<20 ppm
1.6. ORGANIC VOLATILE IMPURITIES	USP	Meets requirements	Conforms

2. **ASSAY**	METHOD	SPECIFICATIONS	RESULTS
2.1. SILYMARIN, CALCULATED AS SILYBIN*:	USP	90 to 110%	100%

3. **MICROBIOLOGY:**	METHOD	SPECIFICATIONS	RESULTS
3.1. BACTERIAL COUNT	USP	NMT 10^4 per g	5,300 per g
3.2. YEAST & MOLD COMBINED	USP	NMT 10^3 per g	90 per g
3.3. ENTEROBACTERIAL COUNT	USP	NMT 10^3 per g	30 per g
3.4. E. COLI	USP	ABSENCE	Not detected
3.5. SALMONELLA	USP	ABSENCE	Not detected

4. **STORAGE CONDITIONS**: Should be kept at room temperature in a tight container protected from freezing, excessive heat, light and moisture.

MANUFACTURING DATE: **APPROVAL DATE**:
RETESTING DATE:

RELEASED

* calculated as silybin on the dried basis, consisting of not less than 20.0 percent and not more than 45.0 percent for the sum of silydianin and silychristin, not less than 40.0 percent and not more than 65.0 percent for the sum of silybin A and silybin B, and not less than 10.0 percent and not more than 20.0 percent for the sum of isosilybin A and isosilybin B.