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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857
[Docket No. 99N-1174]

To Whom It Concerns:

The May 13, 1999 edition of the Federal Register contained an announcement [Docket No. 99N-1174] regarding a pair of meetings in a Stakeholder Outreach program. The Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) will hold public meetings to develop an overall strategy for achieving regulation of Dietary Supplements under the Dietary Supplement Health and Education Act (DSHEA). The announcement calls for written commentary while affording the chance to present in open discussion the matters of stakeholders in the industry. We at the Nutrilite division of the Amway Corporation (Nutrilite) welcome these opportunities. This document serves as written commentary in support of our oral presentation.

The Nutrilite division of the Amway Corporation is a leading and responsible manufacturer and distributor of quality Dietary Supplements and dietary ingredients. Nutrilite manufactures and sells Dietary Supplements extensively in the United States and in over 25 other countries. Our sales of Dietary Supplements in the United States constitute a major portion of our business. Nutrilite has manufactured and sold Dietary Supplements in the United States for over 60 years. This provides us with historical perspective and experience and allows us to participate fully in offering a meaningful perspective.

The mandates of the Nutrilite division and the entirety of the Amway Corporation include compliance with applicable regulations in the promotion and sale of all of our products, including Dietary Supplements. We are familiar with and make every effort to involve ourselves in regulatory direction and application. Additionally, we monitor the activities of our competition and other manufacturers and distributors of Dietary Supplements. Such monitoring includes watch over information concerning the composition and labeling of other products. Our foundation from the beginning is the attainment of optimal health for our consumers through provision of accurate and appropriate information, presented in simple terms that they can use to make solid health choices including useful and meaningful supplements. Nutrilite supplements are the finest in the world delivering meaningful potencies and materials to enhance the health of our consumers. Simultaneously, our promotional material remains conformant with applicable regulations. The combination of all the above facets of Nutrilite makes us highly qualified to offer comment and input to this process as described in the docket.

This commentary presents the general tenets Nutrilite applies in support of its positions first. Next is direct response to the questions posed by CFSAN in their announcement. The last section summarizes Nutrilite's position on the regulation of Dietary Supplements by FDA and the commentary preceding.

99N-1174 C3

General Perspective

The amendment known as DSHEA positively affected the Federal Food, Drug and Cosmetic Act (FDC Act) in that it clearly identified within the body of the law the requirements for Dietary Supplements as a separate class of food. The FDC Act as amended is the applicable reference in this discussion rather than narrowly focusing only on DSHEA. To this end, the FDA must take stock of the regulatory and statutory authority it currently holds and enforce applicable law and regulations. This first step appears to be the shortfall in the process.

The FDA currently has power to withdraw product and act against companies that produce unsafe product. The current low level of enforcement activities accounts for many of the negative circumstances used in popular media that characterize the Dietary Supplement industry as "unregulated." This lack of enforcement renders the industry *de facto* unregulated. The manufacturers of supplements rely on the FDA to enforce extant law and regulation in order to address the small minority who offers inappropriate product and claims. FDA has met with success and cooperation in instances where materials or product demonstrate safety concerns. Where there is enforcement, FDA should note that the responsible members of the industry cooperate and support the actions taken. However, when there is lack of enforcement, these same responsible members suffer more than either the consumer or the agency and more than those who avoid the enforcement action.

There is little justification to add more regulation to the governance of this industry when the extant regulations are not enforced. One potential outcome of this process is a series of regulations no more enforced than those already in existence. Another likely outcome is that FDA will ultimately receive enforcement resources in support of this wealth of new regulation. The enforcement of these regulations and the likely confusion they provide only cement the situation and degrade the cooperative efforts this industry has put forward.

Congress found during the passage of DSHEA that Dietary Supplements are safe across a broad range of category and intake. Congress also found that Dietary Supplements are of benefit to the consumer in the areas of health care and potentially economically beneficial through reduction of health care costs. Congress also found that there is need to allow dissemination of accurate information about Dietary Supplements so that the consumer can make informed choices. Congress lastly cited that the FDA is empowered to and should take swift action against products that are unsafe. All of these findings and the letter of the law itself must be considered by FDA as it determines what strategies should be employed in further regulating this industry.

The overall perspective offered here by Nutrilite is that the Dietary Supplement industry is regulated though not currently governed by enforcement activities from FDA. The strategies for the future, therefore, must begin with the enforcement of existing law and regulation.

Questions from FDA

1. In addition to ensuring consumer access to safe dietary supplements that are truthful and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy include?

The further regulation of Dietary Supplements must begin with enforcement of the current law and regulations. This will insure the presentation of safe products to the consumer. Additional

strategies for restricting either the flow of meaningful products or information runs counter to the intent of DSHEA and must be avoided at all costs. The primary role of FDA is to insure the continual flow of safe and meaningful products. Regulation beyond this scope becomes superfluous.

2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate? Which specific tasks should FDA undertake first?

The criteria for prioritization as shown by FDA are:

1. Enhancement of consumer safety
2. Development of health-related product labeling regulation
3. Improvement in efficiency of operation
4. Closure on unresolved regulatory issues

These criteria are adequate to encompass FDA's agendas. The last criterion stated is the one that challenges industry most. There are hosts of items that exist as unresolved. The second criterion also touches a nerve within the industry and is a part of the fourth criterion in that it is technically unresolved.

The criteria for moving forward must begin, as FDA correctly notes, with safety enhancement. We recommend that the second criterion be the improvement not only of efficiency of operation but specifically efficiency of enforcement. This addresses the matters of perception of the industry while positively affecting the products offered. When FDA identifies products that demonstrate safety challenge, it is far better to act than to jawbone in public forum concerning the specific issue and matter. The development of health-related product labeling regulation need not even appear as part of the criteria for prioritization. Referencing DSHEA again, the intent was to allow the flow of accurate and appropriate information to the consumer. If this criterion remains at all, it should be considered as a last interest before action.

Closing unresolved regulatory issues requires definition and understanding before we can support its inclusion as one of the criteria. The resolution of three critical matters comes immediately to mind. If these are the only matters that FDA considers unresolved, then it is the intended resolution of these specifics that is of most relevance as opposed to setting priority for resolution. Specifically:

- Regulation of the so-called "structure/function" claims. This issue is unresolved only in that FDA has not seen its clear path as withdrawing the proposal in its entirety. The response they received for their efforts to redefine fundamental terms for its own use indicates the lack of support for continuing with the proposal. DSHEA passed with existing definitions for some essential terms (disease most importantly). The reading of the entirety of the FDC Act as amended by DSHEA also plays a role in the massive negative response FDA received. Therefore, if withdrawal of this regulation is the resolution, there is no support of establishing "resolution" as a criterion for regulatory action.

- Enactment of the requirements from the FDA Modernization Act (FDAMA). This matter remains unresolved only in that FDA has again chosen to approach the matter with a redefinition aspect while ignoring the intent of the law. The authoritative statement scheme out of FDAMA allows FDA to act and mandates swift action. The clarification FDA offered in its perspective of what such a statement is and is not runs counter to the intent of both FDAMA and DSHEA. This regulatory resolution looks similar to the one immediately above. One best approach is to withdraw the proposals offered. Another, potentially more beneficial, is to move the process forward but with recognition of the mandates within the law. Whether this constitutes sufficient justification to establish resolution as a prioritization criterion is not obvious.

- Progress on establishing Dietary Supplement Good Manufacturing Practices (GMP) regulations. This topic is one that is not stagnant and thus need not attain the visibility suggested in the placement of a prioritization criterion. The FDA should view the state of play from a circumspect view. The industry offered a set of GMP for consideration. These guidelines had not been used to physically assess their practicality in application. FDA published the ANPR with additional commentary not broadly supported by industry. Industry today is beginning to enact its original proposal (already with some minor modifications) through trade association self-regulation. This enactment allows for gathering of data and information concerning the validity of each aspect of the proposal in application. It is premature to prioritize additional regulatory action on this matter. Examples of establishment of GMP for industries always involve enactment by the industry independent of regulatory action. This is the current state of play for Dietary Supplement GMP. Prioritizing regulatory action on this matter is premature and thus not supportive of having a criterion for such action within FDA's assessment.

As concerns, the second issue in the question, the following offers brief notation of tasks for FDA's activity. This not-all-inclusive list demonstrates where FDA's first tasks reside, in descending order of priority.

- FDA should enforce its existing regulations in support of industry's requests. In other words, industry can find itself willing to assist FDA in identifying the challenges posed by the less-than-responsible members and request that swift action occur within the confines of the current law and regulation. Such enforcement activities come with support from industry and cooperation of the industry and its trade associations.

- FDA needs to work with industry to determine its overall strategy. This present dialog is an important beginning to such cooperation. The effort folds in the Stakeholder Outreach issue published in the CFSAN "A" list of priorities. This strategy needs to be a solid and clear reflection of DSHEA and the industry can best serve FDA in monitoring such conformance and definition.

- FDA needs to reassess and re-perform its adverse event reporting system for Dietary Supplements. The system currently provides too rapid dissemination of often-unsubstantiated information to too public and swift a venue (the Internet).

- FDA needs to solidly support efforts both domestically and internationally concerning the use of sound science to make regulatory decisions where risk may be involved. The international component must be in conjunction with industry efforts through such forums as TABD and through the *Codex Alimentarius* Commission.

- FDA needs to withdraw its proposed structure/function proposed rule. The attempt posed was far from capable of attaining successful regulation. The best course of action is withdrawal and then act in concert with the letter of the law and the cooperation of industry.

- FDA needs to readdress the priority of action on Dietary Supplement GMP. As noted earlier, the process is currently in the hands of the industry and deceleration of regulatory activity is the current best approach while working with industry on its self-regulation activities.

- FDA needs to establish a mechanism for working with industry on all matters of regulatory action and enforcement. This may take the form of working through a Dietary Supplement Advisory Committee. However, the establishment of such a committee in and of itself cannot be the lone step in the process. Such establishment must include participation of the most knowledgeable and assertive members of industry providing a clear understanding of the matters and the respect of FDA.

- FDA needs to bring closure to the ephedra situation. This closure must conform to the determinations of industry in its evaluations and not become a precedent for restrictions of dietary ingredients. There is much distance to cover regarding the final rule and working with industry (particularly those responsible manufacturers who include ephedra in their product line) is mandatory.

- FDA should take steps to clarify the boundaries among the current product categories from among conventional foods, Dietary Supplements and OTC drugs. This work likely should involve the establishment of additional categories along the continuum. Such an establishment might take the following form from foods to drugs:

CONVENTIONAL FOODS ↔FUNCTIONAL FOODS ↔DIETARY SUPPLEMENTS↔HERBAL PREVENTIVES↔TRADITIONAL MEDICINES↔OTC DRUGS

This product categorization incorporates overlap up to the transition to OTC Drugs where clear delineation must occur. The other aspect is that these categories require a supporting structure of claims that do not currently exist.

3. What factors should FDA consider in determining how best to implement a task (i.e., use of regulations, guidance, etc.)?

FDA must always consider the safety aspect first in its assessment for action. While stating the obvious with that overriding parameter, the next steps are important. FDA should work specifically with industry in detail as it determines its actions and activities. This comes along with a better

understanding and recognition of the intent of Congress with the passage of DSHEA and FDAMA. The requirements out of both these amendments were not mandates for generation of a plethora of regulations. The requirements were more along the lines of assessing the need for and offering guidance to industry. Industry can and should play an active role through open invitation from FDA in creating any regulatory document.

The last factor that FDA needs to consider in the matter is a most important one. The needs of the consumer are foremost in the minds of industry as they were in Congress when DSHEA passed. Restriction triggered the passage of DSHEA and FDAMA. The benefits offered by a host of meaningful supplements meet these consumer needs. Available information sufficient to convey these benefits is a part of this benefit. These benefits sit alongside safety in importance since, as Congress understood, these products are inherently safe. FDA must remember this as it deliberates on future regulatory strategies.

4. What tasks should be included under the various Dietary Supplement program elements in the CFSAN 1999 Program Priorities document?

The preceding information serves to fill in the answer to this question. The answer presented here points to the already stated opportunities and tasks. Looking at the Program Priorities:

CFSAN "A" LIST

1. Ephedra. The task is defined in the section covering question 2. The task is not merely the completion of the rulemaking but the requirement to address the industry's knowledge and findings along with the responsible manufacturers of these supplements.

2. New Dietary Ingredients. The requirement for swift review comes from the law. FDA is acting in accordance with this law. The only potential additive might be issuance of some guidance on FDA's determination of what the safety criteria must be.

3. Nutrient Content/Health Claims. Clarification of the FDAMA provision as noted previously is necessary. This must occur, again as noted before, without redefining terms. A simple enactment of the law as passed is sufficient while extending the coverage to Dietary Supplements.

4. Overall Strategy. The first priorities are sufficiently outlined in the answer to question 2 above. Addressing the items that are in the CFSAN list but not in the "first" tasks cited above:

    - Laboratory capabilities. FDA, as part of its dialog with industry, should come to understand what methods are necessary to adequately support its enforcement activities.

    - Research needs. This matter is not specifically addressed and remains a relatively low priority from industry's perspective. Resources are perhaps better expended in other areas.

5. Stakeholder outreach. FDA should focus attention to this effort. Direct and open communication is necessary. FDA should prioritize its efforts in regulatory action to include this as a first step before attempting to promulgate regulations.

6. Citizen's petition. FDA should incorporate its efforts in stakeholder outreach to support the response to this petition.

CFSAN "B" LIST

The elevation of field assignments is a part of enforcement with a prioritization scheme. This task should be undertaken by FDA. However, it should address issues of industry's identification before marching off on less-informed concerns from within FDA itself. Dieter's teas and folic acid-containing products may not be the first, best targets of concern. Dialog with industry directly and through trade associations (not exclusively one avenue) is a must.

5. Are there current safety labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure, for example, that consumers have confidence that the products on the market are safe and truthfully and not misleadingly labeled?

This is a challenging question. Part of that challenge comes from the presentation. If FDA is unaware of situations where action is necessary, that does not speak well of the enforcement aspects of the agency. We will offer some perspectives of where initial prioritization of FDA enforcement activities should occur:

- Products deliberately flouting the labeling regulations and making blatant drug claims.
- Products delivering materials known to be unsafe without equivocation.
- Products delivering materials that are new, unreviewed dietary ingredients.
- Products that make use of science not in direct support of the positions and claims of the specific product inside the package.
- Products that deliver less than the required quantities of components shown on the label.

In many of these examples, we as industry are willing to offer specific guidance as to the products specifically at issue. This is an extension and intention of the spirit of self-regulation. Industry should use the resources of FDA for efficient enforcement as required. This combination of efforts is not truly self-regulation nor is it intended as exclusively external-regulation. The best characterization of this form of activity is likely **cooperative regulation**. This is a spirit to yield a better future for industry and the consumer alike.

6. Toward what type or area of research on Dietary Supplements should FDA allocate its research resources?

The important areas of research that FDA can and should expend its research efforts are in the areas of the impact of labeling. The determination of the success of the Supplement Facts box as

presented and regulated provides important information for the industry. The evaluation of the other requirements of the Dietary Supplement label also is of interest. Determination of how effective the FDA's current labeling regulations are at conveying meaningful information to the consumer is the most beneficial aspect of their potential research.

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

The issues of enforcement having high priority require novel efforts to move in this direction. The effective use of resources in this realm includes involvement specifically of the industry as a whole. As noted previously this model comes toward self-regulation but puts the efforts and onus of enforcement where it properly belongs – with the FDA. The accomplishment of this comes from in-depth and specific cooperative efforts with FDA on matters that require enforcement. This means first an establishment of trust and knowledge between industry and FDA. Next is the determination of how best to communicate to FDA the needs for enforcement action. Finally is the agreement on agendas for future regulatory structure. This closes the loop toward the enforcement side of the coin.

What the finished model looks like is different from the existing models in industry today. Some examples exist with different industries and different regulatory agencies but none are as cohesive as this proposal. The model outlined here is:

Industry identification of enforcement challenges that threaten the industry.

Industry notification of the need for action on enforcement level.

FDA acts swiftly with industry cooperation in the enforcement arena.

FDA working with industry to determine next areas of regulatory need that could lead to enforcement actions.

The additional areas of cooperation that lead to efficient use of resources are in the areas of working in the international arena. There are initiatives across the globe that FDA can participate in to the benefit of industry overall. This too requires working with industry to allow them to identify the matters and present the briefings required for action. FDA then acts as appropriate for the benefit of itself and the industry in fostering a consistent agenda from the United States outward. This dissemination of the concepts of DSHEA requires FDA to accept these concepts but the benefits are worth it.

The overall specific needs for efficiency improvement are the FDA's acknowledgement of subject-matter expertise in the industry. This acknowledgement will then lead to cooperative efforts in the areas of regulatory generation and ultimately enforcement. The opportunities first exist in enforcement and outreach activities that result in the attainment of FDA's goal – an effective regulatory structure for the Dietary Supplement industry governed by the FDC Act as amended by DSHEA.

SUMMARY AND CONCLUSIONS

The overall aspects of FDA's discussion are to determine ways to regulate. The responses contained here demonstrate two things.

1. The objectives need to be more aligned with the concepts and intent of the law and its enforcement.

2. The industry is desirous of working toward enforced scheme of regulations that positively affect the industry and consumer.

The most common elements of the proposals and responses here are in the areas of cooperation. This offering does not come lightly. The franchise that is the Dietary Supplement industry must be supported by both the industry itself and the governing regulatory body. This partnership is one that yields benefits to all parties involved. The focus and areas of disagreement are not inconsequential, but the offering from FDA for its stakeholder meetings indicates desire, as does this commentary. Implementation of a strategy that yields cooperative regulation fits the needs and serves as a model for all other industry/regulatory interactions of the future.

We trust this input to be useful in your considerations.

Sincerely,

James C. Lassiter
Senior Manager
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