Amway® NUTRILITE® DIVISION

Amway Corporation — Nutrilite Division • 5600 Beach Boulevard • PO Box 5940 • Buena Park CA • 90622-5940 • (714) 562-6200

June 5, 1997

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857
Subject: FDA Docket Number RIN 0910-AA59
Comments for Filing – "Current Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Supplements; Proposed Rule

To the U.S. Food and Drug Administration:

In the Federal Register of February 6, 1997 (62 Federal Register 5700-5709), the U.S. Food and Drug Administration (FDA) announced that it is considering whether to institute rulemaking to develop Current Good Manufacturing Practice (CGMP) regulations for dietary supplements and dietary supplement ingredients. FDA requested comments on whether it should do, and if it should do so, on what constitutes CGMPs for these products. These comments are submitted to FDA's request.

Amway Corporation – Nutrilite Division (hereinafter Amway/Nutrilite) is a leading and responsible manufacturer and distributor of quality dietary supplements. Amway/Nutrilite manufacture and sell dietary supplements in over 20 countries as well as the United States. Our sales of dietary supplements in the United States constitute a major portion of our business. Amway/Nutrilite have manufactured and sold dietary supplements in the United States for over 60 years. This provides us with historical perspective and experience necessary for effective comment to this notice.

In addition to the manufacture and distribution of dietary supplements in the United States and other countries throughout the world, Amway/Nutrilite manufactures botanical dietary ingredients for exclusive use in the NUTRILITE® brand of dietary supplements. This manufacture includes the growing, processing and incorporation of these plant materials as a key component of our dietary supplements. This practice is our foundation and has been for over 60 years. This experience yields a total perspective relative to the manufacture of dietary ingredients that are botanical in origin and their subsequent incorporation in dietary supplements.

The Nutrilite division of Amway Corporation maintains pharmaceutical manufacturer's licenses at its manufacturing facilities in California. These licenses are renewed annually and are maintained through application of appropriate CGMP in the manufacture of our dietary supplements. Additionally we are inspected routinely by the Australian Therapeutic Goods Administration (TGA) and are an approved manufacturer of therapeutic goods for that market. This provides us with a clear perspective on the design, application and understanding of CGMP.

The combination of all the above facets of Amway/Nutrilite renders us highly qualified to comment on this proposal. In summary, we are: a long-term manufacturer of both dietary supplements and dietary ingredients; a qualified manufacturer of pharmaceuticals both domestically and internationally and holder of a notable single-company perspective in the industry for comment of issues relative to the manufacture of botanical dietary ingredients and their subsequent incorporation in finished-form dietary supplements.

We have (I) several fundamental general comments, (II) responses to the nine specific questions raised by FDA's ANPR and (III) a listing of some of the specifics in the proposal that show clear difference between the proposal and CGMP regulations for other foods. The following presents these matters as specified.

I. General Comments

A. Issuance of Regulations Would Be Premature

Our fundamental reaction to FDA's announcement is that it is premature at this point for FDA to publish proposed regulations. There are several reasons for this. The most critical are that first, there is no urgent public health reason to do so: second, the technical details of the initial proposal are better refined outside of the rulemaking process.

Regarding public health priorities, we note that there are other segments of the food industry, such as, for example, the nonpasteurized juice industry and the seafood industry, which have experienced notable problems with CGMPs, inclusive of repeated reports of illnesses and even deaths that might have been prevented with improved manufacturing controls established by regulation. There is no such history with respect to dietary supplements. The dietary supplement industry has a strong record of producing its products without notable CGMP problems.

Congress with the passage of DSHEA in 1994 authorized FDA to create CGMPs for dietary supplements. This authorization was not a mandate in large measure because Congress found these products "safe within a broad range of intake, and safety problems with the supplements are relatively rare." When the American Association of Poison Control Centers' database is examined, it is noted that the reports of serious adverse events for dietary supplements are rare and comparable to foods. The 1995 reports clearly show that consumption of dietary supplements poses no greater risk to the public than the consumption of food. As an industry, we acknowledge that the single greatest event demonstrable to date involves the accidental ingestion of iron by children. The fact that industry acted voluntarily prior to rulemaking is evidence that industry does intend to take action when a problem is demonstrated.

The industry presentation to FDA continues to demonstrate its position as a responsible group of companies and trade associations. The further refinement of the document submitted to FDA by industry and subsequently published as part of the ANPR would only serve to enhance the ultimate outcome of rulemaking. Regulations tend to become permanent fixtures and are difficult as well as expensive to revise. Prior to rulemaking, the more resource-efficient method would be for industry to assure itself of the validity of all aspects of the document inclusive of the refinement of the proposals. This better occurs

outside the rulemaking process. There remains significant discussion within industry as to the "currentness" of these CGMP. FDA's receipt of additional comments from all sources including trade associations, indicates that the proposal needs refinement and thus is not yet ready for the rulemaking process.

B. Before Regulations are Issued, the Industry Should Develop Experience With Uniform Trade Association Guidelines

The relationship between FDA and Industry has matured in recent years to one of acknowledged cooperation. We strongly urge FDA to continue in this spirit and first partner with the trade associations that represent the industry along with leading manufacturers such as Amway/Nutrilite and allow industry to develop experience with a workable set of CGMP guidelines. This is not an unprecedented request and has worked well in the cosmetics industry with trade association vigilance and application of guidelines for manufacture applied and supported through the CTFA.

The history of the document submitted to FDA by industry is very short. It is very much a brand new document. At this preliminary stage in the evolution of CGMPs for dietary supplements, there are many provisions that may seem appropriate in the abstract but that experience may eventually show should be revised or refined in some respect. Some of these particulars are noted in section III. FDA will receive comment from trade associations and other responsible members of industry comments that identify opportunity for such changes at this very preliminary stage of the regulatory process. We strongly believe that rather than evolve dietary supplement CGMPs through an elaborate, resource-intensive and time-consuming process of issuing and revising regulations, the process is best accomplished by having the major dietary supplement industry trade associations issue their current proposed concept for CGMPs as uniform guidelines for the industry. Through a data and information gathering experience and process, testing the appropriateness of each of the items in the proposal a wealth of information is obtained prior to entering the rulemaking process. This assures the industry of conformance with fewer significant challenges out of enforcement by the requirements of law.

The letter and spirit of DSHEA stipulate that any CGMP issued for the manufacture of dietary supplements must be modeled after CGMP for food. The proposed concepts in the proposal from industry incorporate several items that are not from food CGMP and about which there may be uncertainty at this time (see section III). There is no urgent need to rush to judgment about this matter. Instead, we believe the reasonable and most appropriate course would be an evaluation of this new text in the trade association document (emphasis on the word "new") with testing for appropriateness through application of uniform industry guidelines for the next three years. This allows extensive experience by a greater number of companies living with the realities of the new provisions. The result of such a process, we strongly believe, is a document and set of guidelines that are current, appropriate and meaningful.

C. Any CGMPs Proposed Should be Appropriate for Food Products, Not Drugs

Dietary supplements often consist of substances that are not found in any pharmaceutical compendia. Included in these dietary ingredients may be plant materials such as dehydrated garlic powder or alfalfa. It is wholly inappropriate to expect these to be manufactured in accordance with criteria developed with respect to pharmaceutical active ingredients. For

example, it may be reasonable to expect under drug CGMPs that each batch of a drug product be analyzed for the identity and strength of each active ingredient prior to release of the batch for shipment. For example such a requirement is wholly unnecessary and inappropriate for a dietary supplement that includes alfalfa, watercress and parsley. Indeed, there may be no feasible way to analyze a batch of such tablets for identity and strength.

The purpose of much of the data and recordkeeping requirements of drug CGMPs that carries over into the proposed dietary supplement CGMPs results directly from acknowledgment that drugs are inherently less safe than foods. The mandates come forth as a result of the need to prevent errors and/or know what went wrong in the manufacture of the drug and how to identify who is in possession of the subsequently dangerous entity. Again, Congress was quite specific in the description of dietary supplements as inherently safe entities. Because these products are generally safe, indeed identified within DSHEA as foods and not drugs, there is no need to populate the practices of the manufacturers of such products with requirements and personnel solely for regulatory conformance at the level typical of drug products. The costs associated with such population will be passed along to the consumer and serve little purpose beyond avoidance of regulatory action. The focus needs to be kept on what is needed for the manufacture of these food products.

D. Any CGMPs Should Be for the Manufacture of Dietary Supplements, Not for the Manufacture of Dietary Ingredients/Raw Materials

Amway/Nutrilite strongly believes that any CGMPs issued should apply to the manufacture of dietary supplements and not to the manufacture of dietary ingredients. The DSHEA clearly defines both these entities as separate and distinct. DSHEA further goes on to allow that FDA "may by regulation prescribe good manufacturing practices for dietary **supplements.**" [Emphasis added.]

We note that the CGMP regulations for drugs (as noted earlier is clearly more in need of such requirements and for which there is more strict regulatory restriction and control) apply only to "drug products," not to the manufacture of ingredients that are subsequently to be used in the manufacture of a finished pharmaceutical.

Specific inclusion of dietary ingredients under the CGMP umbrella is inappropriate, since many of these materials are clearly identified as foods or food products today. They are manufactured in accordance with CGMP regulations for food every day. Application of another standard is impossible to enforce or apply and a clearly undue burden on the manufacturer of such materials. Does the proposal require that if the food is to be used in the manufacture of a dietary supplement, that the ingredient manufacturer must now apply this new set of standards? What about cases where the food is sold to one company for distribution as a food product and used in the manufacture of a dietary supplement by another? The supplanting of current food CGMP is not within the realm of the stated purpose of either DSHEA or the industry's submission would not be appropriate.

There is no current mandate or explicit authorization for FDA to issue regulations on the manufacture of dietary ingredients. These products are not food additives, but are identified as foods and are inherently safe as noted previously. The only regulatory concern at present over the manufacture of dietary ingredients is in the confines of the ANPR. All of our

concerns expressed above with respect to the prematurity of this rulemaking and the lack of need applies more strongly if FDA was to attempt to propose regulations that apply not just to the manufacture of dietary supplements, but to the preliminary stages in the manufacture of dietary ingredients.

E. The CGMP Regulations Should be Confined to Manufacturing Procedures That Are "Current"

We emphasize that any CGMP regulations issued be confined to requiring practices that are indeed "current." Regulations should not attempt to impose standards that are not, in fact, part of the "current" good manufacturing practices now followed within the industry. Section 9 of DSHEA states that any CGMP regulations issued by FDA for dietary supplements "shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally-available analytical methodology." The current good manufacturing practice regulations for food are found at Title 21, Code of Federal Regulations, Part 110. Any novel provisions that go substantially beyond these regulations in an attempt to force new technology or new procedures would violate the statutory authorization and standard, in that it would not be "modeled after" the "current good manufacturing practice regulations for food."

F. Summary

The Summary of the Amway/Nutrilite comments contained in this section includes the fact that we strongly believe it is premature for FDA to initiate any rulemaking at this time to establish any CGMP regulations for dietary supplements. Instead, we believe the trade associations for the dietary supplement industry should work together to issue a common set of Uniform Guidelines for the Manufacture of Dietary Supplements. The trade associations should then work with the manufacturing companies to evaluate the appropriateness of those guidelines in the real world of manufacturing and revise and refine the guidelines as needed until the point of experienced consensus is reached before FDA considers proposing any regulations.

We also strongly believe that any guidelines or CGMP regulations for dietary supplements concern the following: 1. They should apply only to the manufacturing of finished dietary supplements and not the manufacture of dietary ingredients; 2. They should be "modeled after" the CGMP regulations for food, 21 CFR Part 110, as required by DSHEA and not contain concepts added from the drug CGMPs or other extraneous sources and; 3. They should be confined to articulating standards of good manufacturing practice that are in fact current in the basic food CGMP regulations, and not attempt improperly to force the evolution of new procedures that are not in fact now "current."

II. Responses to FDA's Nine Questions for Additional Comment

The Federal Register notice asks for comments on nine particular questions. The following are the views of Amway/Nutrilite with respect to each of these nine questions.

1. We believe that the issue of establishing DALs for dietary ingredients comes only remotely from the discussion of proposed CGMP. The establishment of a second set of DALs for dietary ingredients goes back to the need to distinguish between dietary supplements and dietary ingredients. Botanicals are specifically cited in this request for

comment. The request also supposes that use of botanicals in dietary supplements increases the exposure to a "much greater" level than as consumed as ordinary food. We are unaware of any data to indicate there is significant potential exposure increase. We do not know of any reason why there is any particular need for such establishment. If and when particular problems that might justify such action arise, FDA should provide public notice and invite public comment. There is no additional information in FDA's Federal Register document and no additional information of which we are aware that suggests that there is some public health need, at this time, for FDA to embark on this establishment and rulemaking exercise.

2. We do not believe that there is any need for FDA to develop "testing requirements to provide positive identification of dietary ingredients" used in dietary supplements. The request implies that only plant materials can cause serious harm. It is more likely that excess consumption of vitamin A as retinol would cause harm than the over ingestion of responsible botanical products. Botanical dietary ingredients are manufactured by companies such as ourselves and the other responsible members of this industry. There is obvious good in being able to assure the use of the correct material in the manufacture of any product whether it is a food or not. However, we disagree with the characterization of danger as "significant public health concern." In response to FDA's request for input we agree that the matter does come under section 402(g)(2) of the act concerning imposition of standards that are not technically feasible. There is certainly no current and generally-available analytical methodology to identify most dietary ingredients in dietary supplements extensively comprised of botanicals. Furthermore, to require such analytical testing would be inconsistent with the requirement of section 402 (g) (2) that CGMP regulations for dietary supplements "shall be modeled after current good manufacturing practice regulations for food." One does not analyze each batch of bread to verify it was made with flour. Such analysis is not part of food CGMP and thus has no place in CGMPs for dietary supplements. Such testing requirements would not be "modeled after" the food CGMP regulations. Issues such as these are part of the reason why establishment of uniform guidelines outside of regulations is the next important step. The evaluation would include the answers to the questions posed in this request through a complete, industry wide practice assessment.

3. There is no basis that we are aware of that suggests that there is any substantial public health problem, at the present time, with current dietary supplement industry manufacturing practices, in relying on suppliers to provide reasonable assurance that raw materials are satisfactory for use in food manufacturing. The requirements for filth and microbial contamination requirements already exist in food standards in this country. Application of these food standards is clearly the necessary step to take. The fact is that these ingredients are foods and not something else. They are classified as such owing to their long history of safe use among other factors and they are not ordinarily confused with pharmaceuticals. Concern over synthetic new dietary ingredients is already addressed in DSHEA. All that remains are the botanicals again. Botanicals conform either to international standards in many instances or to food standards in others. The certification of a supplier that the material is appropriate for use in the context of food

application continues to be appropriate as it is in CGMP for food. This too demonstrates the inappropriateness of proposing CGMP regulations at this time.

4. There is no evidence of any need and no statutory basis for FDA to expand the CGMP concept in regulations for dietary supplements to establish new recordkeeping requirements "to document that the procedures . . . are followed on a continuing or day-to-day basis." The CGMP regulations envisioned are to be "modeled after" the CGMP for foods. Since such a requirement for supervision is not found in 21 CFR Part 110, it is not from the CGMP for food. Further, the question here asserts requirements as they relate to enforcement not to CGMP and are not appropriate for inclusion in such a regulation.

5. We do not believe there is any basis known to us or in FDA's records that suggests that it "may be necessary that trained medical professionals rather than quality control or nonmedical scientific/regulatory personnel evaluate all reported adverse events associated with the use of a specific substance and advise responsible management of their findings." Once again, the FDA suggests that it might establish regulations that are not "modeled after" the CGMP regulations for foods, in violation of the criteria established by Section 402 (g) of the FDC Act for the issuance of CGMP regulations for the dietary supplement industry. Further, FDA's case is based on the premise that dietary supplements might include pharmacologically active substances. This could include vitamin E or vitamin C provided FDA had allowed health claims for these nutrients to stand. We submit that in order for a material to have a pharmacologically active effect (call it a health effect or health benefit) it must either be a drug or has successfully completed evaluation by FDA and has allowance to make such a claim. If FDA allows that some dietary ingredients are so active, they must either be drugs (which they are not) or have some health benefit allowed for use in labeling the product. FDA currently has authority to take action in instances where the public health is deemed to be at risk and has exercised this authority previously. There is no clear need to expand on this authority either under the guise of CGMP regulation or other regulation for dietary supplements.

6. The first request in this area is the same as it is for the one immediately prior. The difference is that FDA is asking about the provision of such information on dietary ingredients versus dietary supplements. The second request in this area is a request for comment as to whether or not FDA should establish a requirement that adequate scientific evaluation of dietary ingredients be performed prior to inclusion of a dietary ingredient in a dietary supplement. Whether a dietary supplement is safe for use is a matter that is handled under other sections of the law, not the provisions concerning CGMPs. DSHEA specifically establishes safety standards for dietary supplements, including procedures for notification of new dietary ingredients and standards for safety of those ingredients. To attempt to turn the CGMP regulations into an ingredient safety evaluation mechanism would go far beyond the intended scope of the regulations envisioned by DSHEA and again violates the principle in section 402 (g) of the FDC Act that the CGMP regulations for dietary supplements should be "modeled after" the CGMP regulations for foods. This approach is not within the confines of the law. Once more, if

FDA is allowing that some of these ingredients have pharmacological effect, the responsible manufacturer must be allowed to present this information to the public. If FDA has knowledge of such substances they should provide this information to industry as allowable health claims or identify the materials as drugs if this truly is the case. Lastly, establishing a regulatory definition of "adequacy" is extremely difficult, never clear and specific criteria are not provided. Any detailed discussion of what these evaluations should be is not meaningful in this context of establishment of CGMP.

7. Standards for evaluation of the use of "computer controlled or assisted" manufacturing operations would be a positive step. These should first be established for the food industry generally as a part of the food CGMPs. It is a violation of the principle that the CGMP regulations for dietary supplements be "modeled after" the food CGMPs if FDA imposed new software requirements solely for the dietary supplement industry. Furthermore, insofar as FDA would attempt to impose new procedures that are not in fact "current," such action would violate the intention and authorization of DSHEA's enabling legislation. Application of industry sponsored uniform guidelines allows for the identification, evaluation and discussion of such systems as current. Thus evaluation would allow for a refined and appropriate set of guidelines for future rulemaking. To do as suggested in the request for comment reverses this position and mandates the evaluation while simultaneously progressing through rulemaking.

8. We are strongly opposed to any suggestion that Hazard Analysis and Critical Control Points (HAACP)--type regulations be initiated for the dietary supplement industry. Such regulations may be useful for seafood, where there are substantial reports of illness and injury resulting from microbiological contamination and toxins in the food that may need to be controlled by an unusually exquisite system of quality assurance. There is no evidence of similar problems related to quality control in manufacturing in the dietary supplement industry. Furthermore, to impose HAACP requirements directly violates the provision of section 402 (g) that CGMP regulations for dietary supplements "shall be modeled after current good manufacturing practice regulations for food." This also excludes FDA's HAACP regulations for seafood.

9. The request for segmentation of CGMP for the differing aspects of the manufacture of dietary supplements only reemphasizes the points in this commentary. There is still no wording within the body of the statute that suggests FDA approaches the manufacture of dietary ingredients or other raw materials used in dietary supplements. FDA appears to have neglected those companies with the capability and propensity to manufacture both dietary ingredients as well as dietary supplements, often within the same general facility. Application of a broad set of CGMP makes more sense both from an enforcement as well as from a feasibility perspective. This is clearly recognized in 21 CFR Part 110 since the CGMP for foods are broad and recognize the diversity of the processes governed. If there is greater detail or segmentation necessary, we strongly believe that the initial steps must include issuance of uniform guidelines by industry for application and evaluation. This shows why it is premature for FDA to propose any CGMP regulations for the dietary supplement industry at this time.

III Significant Differences from CGMPs for Food

As noted repeatedly in the confines of this document, the requirements of section 402 (g) of the act allow for issuance of CGMP for dietary supplements and that such CGMP if issued be modeled after food. The following lists several notable sections that differ significantly from 21 CFR Part 110 and thus are outside the scope of the CGMP for food and thus not in conformance with the stipulations of the act.

A. General Notations

The most objective evaluation of the proposal as published is that it attempts to apply too great a level of detail for effective application. Good regulations are structured in such a manner as to allow for changes in technique and technology without violation of regulatory requirement. The greater the level of detail contained in regulations the less innovative industry becomes while conforming absolutely to the letter of the regulation. Evaluation of the proposal via application of a set of Uniform Guidelines supported and enforced by industry would allow for identification of such refinements.

B. Areas of Major Difference Between the Proposal and CGMP for Foods

There are several areas where the differences between the CGMP for foods and the proposal are considered major these are listed as:

Requirements for written procedures for cleaning, testing, processing, label control and reprocessing

Requirements for records and documentation retention for product and batch records, yields and tests

Requirement for the existence of a Quality Control Unit with responsibilities for testing, accepting, rejecting and investigation

Requirement for complaint documentation and records of returned goods

Requirements for personnel qualifications, their training and documentation of same

Change in terminology common in the food industry from contamination to the pharmaceutical "adulteration"

C. Areas of Specific Difference Between the Proposal and CGMP for Foods

There are several critical differences that are specific in nature as they relate to the different between the proposal and the CGMP for foods.

1. DEFINITIONS -- The proposal defines words such as "Batch" or "Lot"; "Composition"; "Dietary Product"; "Lot number" ; "Manufacture"; "Quality Control Unit"; "Raw Material" and "Representative sample". These definitions as worded greatly expand the scope and application of the regulation beyond the direction given in DSHEA and the current CGMP for foods.

2. PERSONNEL – A new section (compared to the CGMP for foods) would add requirements for documentation of employee training. The section goes on to add requirements that Supervisory personnel be qualified with proper education, training and experience not just competent as specified in CGMP for foods.

3. PLANT AND GROUNDS – The differences are in the wording that requires plant design and space to prevent mix-ups implying that this could lead to "adulteration." Further is an additional requirement to control microorganism, dust, humidity and temperature that is not found in the CGMP for food.

4. SANITATION OF BUILDING AND FACILITIES – This section would require that rodenticides, insecticides and fungicides be registered in accordance with other regulation. Beyond the differences relative to CGMP for foods this appears to be redundant with other regulations. The section also uses the term "potable water" and specifies any water contacting in-process or finished product must meet EPA Primary Drinking Water Regulations (40 CFR Part 141) which is clearly outside the scope of requirements for CGMP for foods. The section also adds qualification requirements of supervision of sanitation to be documented as qualified by education, experience and training.

5. EQUIPMENT AND UTENSILS – This section requires that "insofar as necessary, equipment will be taken apart for through cleaning". It also requires written cleaning procedures and documentation of the cleaning in individual equipment logs. This goes far beyond the scope of the CGMP for foods.

6. QUALITY CONTROL – An entire section adds a requirement for a "Quality Control Unit" and outlines responsibilities for approving and rejecting specifications, procedures, raw materials, finished products and evaluation of errors. All procedures must now be in writing. The scope of the function as well as the existence of the function goes well beyond the CGMP for foods.

7. EXPIRATION DATING – These requirements and stability testing requirements as mandated in the proposal are completely outside the requirements from the CGMP for foods. In many instances due to technological unfeasibility, such establishment of stability data may not exist and thus runs counter to the same section of the act as the requirement that these CGMP be "modeled after" the CGMP for foods.

8. PRODUCTION AND PROCESS CONTROLS – Sections of the proposal require extensive Master Production and control records, documentation and record keeping . These requirements do not come from the CGMP for foods but exist specifically in the CGMP for pharmaceuticals 21 CFR Part 210. The requirements for extensive batch production and control records including yields; label control records; written procedures for raw material controls and; testing, approval, etc. and distinctive lot numbering come not from the CGMP for foods but from the CGMP for drug products. This clearly does not meet the requirements of DSHEA. The proposal also requires raw material identity tests; Certificate of Analysis/specification tests; stock rotation; re-testing after storage times and a quarantine system. Again these are from the CGMP for drug products not

the CGMP for foods. Written procedures for reprocessing would now be required. Written procedures for label testing, storage, usage and destruction. Lot number required on package and labels and lot numbers checked. None of these items come from the CGMP for foods but come from the CGMP for drug products.

9. WAREHOUSE DISTRIBUTION AND POST-DISTRIBUTION RECORDS – The requirements for record retention as outlined for distribution, product batches and raw materials, batch records complaint files and laboratory records exceed the scope of the CGMP for foods by a wide margin. Additionally, a returned product procedure and reserve samples are also required. Product salvaging procedure requirements are also specified. The excerption and minor modification of these requirements from the CGMP for drug products as opposed to the CGMP for foods clearly do not meet the design or intent of the law.

D. Summary

Regardless of the point of emanation of the proposal published in the Federal Register notice, the law is clear concerning the design of CGMPs for dietary supplements.

IV Conclusion

Amway/Nutrilite represents a superb perspective on the ANPR for dietary supplement CGMPs. This perspective is one of a responsible manufacturer of both dietary ingredients as well as dietary supplements using these dietary ingredients. We are also active members of multiple trade associations reflecting the breadth of our product line and involvement while showing concern for the continued responsibility in the industry. This perspective allows us one of the greatest and most educated view of any individual manufacturer of dietary supplements.

Our views are outlined in this commentary and succinctly are that it is premature to enter into rulemaking for the purpose of issuing CGMP for dietary supplements. There are multiple facets to this view documented in the material preceding. Further, we provide response to each of the nine additional requests for comment contained in the ANPR. We strongly believe that these additional inquiries also support the contention that the issuance of CGMP regulations is a premature activity. We trust these comments are helpful.

Sincerely,

James C. Lassiter /dr

James C. Lassiter
Senior Manager, Quality Control/Technical and Regulatory Affairs

cc: Robert J. Moore, Ph.D. (HFS-456)
Office of Special Nutritionals
Center for Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street S.W.
Washington, D.C. 20204

Byron Johnson
Amway Corporation, Nutrilite Division

Ray Jaglowski
Amway Corporation

cc Dick Bednarz
Amway Corporation

Annette Dickinson, Ph.D.
Council for Responsible Nutrition

Jeff Morrison
American Herbal Products Association

Patrice Wright, Ph.D.
Nonprescription Drug Manufacturers Association