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SUBMISSION ON PROPSAL P235
"REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS"

The directors of Health & Herbs International, [redacted], have not had time to carefully consider the whole of P235 in the time allowed.

In lieu of making a separate submission **we hereby endorse the submission put in by Citizens for Health Choices today.** We particularly want to emphasize the problems that would be created if FTDS and TTDS should be regulated under different regulatory bodies and Acts.

As we concur that FTDS and TTDS need to be regulated under the same scheme in New Zealand, we have also included below the submission made by **Health & Herbs International** on **"A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS".** There are many relevant sections in this submission.

As mentioned in the submission below, Health & Herbs International does not endorse a joint agency with Australia for the regulation of any dietary supplements.

COPY OF SUBMISSION MADE BY HEALTH & HERBS INTERNATIONAL on "A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS - JUNE 2002"

SUBMISSION ON DISCUSSION PAPER
"A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS - JUNE 2002"

Health & Herbs International Ltd is a thirteen year old New Zealand owned importing, wholesaling company and distribution centre specialising in dietary supplements and natural cosmetics. It currently imports over 400 dietary supplements, both ready packaged and in bulk from 14 American manufacturers. It also distributes products for New Zealand natural health companies.

The directors of the company have taken thousands of hours out of running the business to make numerous submissions, attend dozens of meetings (both industry and Medsafe) over the past ten years about new legislation to replace the Dietary Supplement Regulations 1985. It would appear that ALL constructive suggestions and agreed positions from those submissions and meetings have been ignored in the latest proposal. It has been made very clear over the past ten years that the Australian TGA system is not a viable system for dietary supplements in New Zealand due to excessive bureaucracy, red tape and costs.

We have major concerns about the economic impact of these proposals on our business. We have evaluated the present cost structure in Australia, translated it to our business and fees alone would cost over $750,000 the first year. This is without staff costs, unique labelling, consultants fees and the many other requirements indicated in this proposal. When all these

are added together the fees and costs would run into the millions. That means increased retail prices for all supplements.

The following points must be taken into account and require an explanation:

As the United States of America is probably the largest producer in the world of Dietary Supplements, around NZ$35 billion per year, we do not understand why their Dietary Supplement Health and Education Act of 1994 was not presented for evaluation and comparison with the Australian TGA model as basically proposed in the Discussion Paper. The majority of those American manufactured products are accepted around the world as being of the highest quality.

In Australia, the States are not harmonised under TGA law and sole traders are excluded in several states. It is reasonable under such a regime to expect New Zealand not to even consider harmonisation of dietary supplements with Australia.

It is impossible to make any knowledgeable submission when the second NZIER Economic Impact Report has still not been released and numerous documents requested under the Official Information Act have been withheld.

Major concerns are: governance arrangements, industry costs including red tape and fee structures, negative impact on business, negative impact on consumers, trade mark protection, non-harmonisation in Australia.

To the Australian Productivity Commission the CHC stated ' ***It is worth noting that there is no other complementary healthcare market in the world regulated in the same way as Australia and there is no international comparison*.'**

NOTE: The products in this submission are referred to as dietary supplements as that is their legal name in New Zealand. In Australia these products are referred to as complementary healthcare products. CHC is the Complementary Healthcare Council of Australia which is the peak complementary industry body in Australia.

INDUSTRY COSTS AND FEES

As a small business we are extremely concerned about the huge compliance burden this proposal will place on our company for NO ADDED BENEFITS. It is also at odds with the governments aim to reduce red tape and compliance costs for business.

We question the validity of a fee of $300 per product (as suggested by Medsafe) if the proposed system involves our company inputting all the information electronically. That means there is no work involved by Medsafe. However it does mean that we also have to pay a person to do this work. There must not be over prescriptive application forms, even if electronic, that require a consultant to figure out. All information gathering for listing products must be simple with little time required to perform the activities. Overt fees are only one area of cost for industry; compliance time and staff time are also costs.

The fees charged must be negligible and either one-off or a time span of say 5 years, before renewal is necessary. Annual renewal fees are considered unnecessary and unjustifiable on the basis of consumer safety.

Any fee structure would be a huge additional burden to this sector. For the majority of Dietary Supplements, the risk is less than for many foods. Suppliers of foods pay no fees for regulation. In order to be consistent, Dietary Supplements should have no fees that are collected from the industry for their regulation.

There have been moves in Australia to eliminate the "**low volume**" category that at present enjoys lower fees. It is imperative that there be lower fees for Dietary Supplements which have a low

volume turnover. A “low volume” in Australia could be a high volume in New Zealand given the vast difference in population base. Otherwise, very safe, high quality products could be effectively banned from being sold simply because it would be uneconomic to handle the product. Even a $70.00 fee (as currently charged in Australia) for a product sold only in New Zealand could effectively put the product off the market due to the retail price that would be required to be charged for the product due to the necessity to recover the fee.

The major brand we distribute has trademark protection in New Zealand but another unrelated company has the trademark in Australia. Therefore, there are no opportunities for us to sell the brand in both markets. This proposal does not take trademarks and distribution agreements into account.

The majority of the 15 American companies we import from are not on the Austarlian market. They all meet cGMP in America but are simply not prepared to pay for the huge Australian bureaucracy. This is supported by the Australian CHC’s comment to the Australian Productivity Commission “***CHC is aware of decisions taken by many companies not to enter the (Australian) market because of the high direct regulatory cost imposed by Government.”***

INTERNATIONAL FOOD SUPPLEMENT REGULATION

ANZFA proposal P235 has identified the situation with the international regulation of dietary supplements. In some countries regulation is effectively based on a 3 category system - dietary supplements (or another term), foods and medicines. The regulations pertaining to dietary supplements (or other) generally sit under a broader (2 category) legislative umbrella for either foods or medicines. For example the NZ Dietary Supplement Regulations places them under the Food Act while in Australia they are under therapeutic products (medicines) and the TGA. Countries with a 3 category approach include New Zealand, the United States, Canada (proposed system), Europe and Japan.

Countries using a 2-tier system include Australia and the United Kingdom (although their system is mixed).

It is obvious from this that New Zealand is similar to the majority of our trading partners and Australia is out of line and that this creates severe legislative problems.

There is a very strong case to be made for the retention of the New Zealand 3 category system which would create a more seamless regulation of products than the Australian 2 category system.

Many of these countries with a 3 category system allow some form of statement of purpose or claims, even though they classify dietary supplements under food.

GOVERNANCE ARRANGEMENTS

Despite the assurances from the Minister of Health that New Zealand will have equal authority and voice in the joint agency, this cannot be supported by the facts or statements made in the Discussion Paper.

The proposal gives too much authority to one person, the Managing Director, for setting fees and charges, and for setting the requirements that must be met before a product can be sold.

There is no structure for consumers or stakeholders to advise or influence the Managing Director or any other person in authority. In general, the governance arrangements as set out would be cumbersome and unworkable.

We strongly object to so much ultimate power being given to Australia. All five members of the board should be appointed with the agreement of both ministers. It is proposed that if there is no agreement, 2 of the 3 remaining board positions would be appointed by the Australian Minister and this does not protect New Zealand’s sovereignty. That the instruments of appointment would be signed by only the Australian Minister is also unacceptable and not sound business practice if it is an

equal partnership. They should be signed by both ministers. This would appear to indicate that the Australian Minister has ultimate power in the agency. Obviously this is not an equal partnership.

Managing Director

The Managing Director has ultimate and total power for running the agency. This is unacceptable as this person can make decisions on therapeutic product approvals and make technical orders, such as labeling requirements. There are no controls on any actions taken by this person. This person would have more authority than the New Zealand Minister of Health but is not accountable to either the bill payers or consumers. Who would make sure that this person did not make unreasonable requirements and/or decisions in these areas?

Stakeholder Input

The statement that the meetings would advise only in general rather than on particular regulatory decisions is an outrageous idea! Stakeholders must be able to question outcomes of all regulatory decisions.

There must be easy and inexpensive systems set up for stakeholders, including consumers, to question and challenge regulatory decisions.

The Discussion Paper states "…there may be separate regulatory units for…" There must be a separate regulatory unit for products currently regulated as complementary medicines in Australia and as dietary supplements in New Zealand. As in America under DSHEA 1994, people who make the decisions on their regulation must not be biased or prejudiced against this range of products.

PREFERRED PRODUCT TERMINOLOGY

Our preferred name is Dietary Supplements. That is the term currently used successfully in New Zealand, the USA and other countries. The term Dietary Supplement has been used in New Zealand since 1985 and New Zealand consumers understand it.

CURRENT UNITED STATES OF AMERICA DEFINITION OF DIETARY SUPPLEMENT FROM "DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994"

The term 'dietary supplement' means-
"(1) a product intended to supplements the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients:
(A) a vitamin, (B) a mineral, (C) an herb or other botanical, (D) an amino acid, (E) another dietary substance for use by man to supplement the diet by increasing the total dietary intake; (F) or a concentrate, metabolite, constituent, extract, or combination of any ingredient described (A), (B), (C), (D), (E), or (F);
(2) a product that-
(A)(i) is intended for ingestion in a form described (tablet, capsule, powder, softgel, gelcap or liquid form).
(ii) complies with
(B) is not represented for use as a conventional food or as a sole item of a meal or the diet and
(C) is labelled as a dietary supplement.

The term 'drug' does not include a dietary supplement

RISK BASED APPROACH

A risk based approach requires that a risk assessment is undertaken to determine actual risk -- that has never been done for dietary supplements in New Zealand.
While we agree that a risk based approach is appropriate, this Discussion Paper does not represent a risk based proposal for dietary supplements.

PRODUCT LICENSING & PROCEDURES

We do not support the concept of product licensing such as is currently in force in Australia and proposed in the Discussion Paper. Since 1998 we have supported a simple listing system for Dietary Supplements. In the Discussion Paper, the proposed system is virtually a copy of the present TGA system and is NOT a simple listing system. It is an expensive pre-evaluation system

We do not support the requirement that dietary supplements imported in "ready to sell" packaging be required to have retention samples retained in New Zealand, as long as such samples are kept by the manufacturer of the finished goods and would be available for assessment in the country of origin should there be any problems with the product. Retention samples are not required for foods. No other country that we are aware of requires retention samples for packaged dietary supplements be held in the importing country as well as the exporting country. For an imported supplement, any analysis required would be initiated through the originating manufacturer. This would also add huge costs to us as importers as we import products on a monthly or six-weekly basis to maintain good expiry dates.

EXPERT ADVISORY COMMITTEE

The function of these committees is dubious, as they appear to have no real power. It is essential that the makeup of the advisory committee, including the consumer member for dietary supplements have specific expertise and knowledge of their use. The present members of the Australian CEMEC are not supported by our association. Their knowledge of international movements in dietary supplements including best practice appear to be totally lacking.

We have grave concerns that the Managing Director appears to have sole and total authority to decide and recommend members of the Advisory Committees. As the makeup of the committees is not specified, it could well be that they are all Australians.

LABELLING

We have considerable concern that any unique labelling for the very, very, small New Zealand market will make the majority of our products non-viable. This will deprive New Zealanders of the products that have been on the New Zealand in many case for well over twenty years, without any problems reported by consumers. That in turn affects the whole company and the staff we employ.

Standard requirements for labels must not be so prescriptive that labels on products from countries other than Australia or New Zealand would not be accepted.

Many countries around the world accept American labelled dietary supplements as New Zealand has for well over twenty years.

As mentioned previously, the claim on the label must be voluntary not mandated and certainly not prescriptive. American labels are allowed to have structure and function claims and this should be allowed in New Zealand - generally it is less prescriptive than Asutralia. In Australia, we are aware that the TGA approves label claims for Australian complementary products using science borrowed from patented dietary supplements from Europe and America. This is official approval of false and misleading claims.

Standard names for Dietary Supplement must not be so prescriptive or unique to the system that they eliminate products from other countries and thus form a non-tariff trade barrier.

"**The Agency would adopt appropriate naming conventions for biological and herbal substances.**" **"…the Agency would adopt a system of standard terminology for herbal substances based on that currently in use in Australia."**

Our limited knowledge of this indicates that many herbs have unique Australian names that are not necessarily accepted internationally. The wording required on herbal remedies, as to the quantity of the herb in the product, currently in Australia is not recognized worldwide and is deceptive. It "cons"

the consumer by giving the impression that the product contains much more of an ingredient than it actually does. Internationally this is not acceptable and also in breach of New Zealand's Fair Trading laws.

Many of our herbal formulas are stated as a "proprietary blend". The names of all the herbs along with the total quantity of proprietary blend is stated on the label and should be all that is required – not the exact amount of each herb in this situation. This leniency is granted under law in the USA and is required to protect the manufacturer from others copying their blend.

We agree that sometimes a warning statement is necessary on a product. However, there must be clear scientific evidence that such a statement is required.

We would strongly recommend that it is not necessary to have a special product licence number printed on the label. This is the 2000's and we should be able to use the bar code which is a unique identifier. Special numbers are not required for food. It is 1980's technology to require printed numbers on labels.

MANUFACTURING PRINCIPLES AND GMP

All American companies we import from have current Amercan cGMP. Dietary Supplements must have a GMP requirement that is appropriate for the industry and recognizes the generally low risk nature of the products.

We also import product in bulk and pack in New Zealand. Again the GMP needs to be different than it is for those who actually manufacture the product.

Interpretive guidelines would not be sufficient guarantee that auditors would be able to use them correctly. The actual GMP needs to be less stringent.

Acceptance of overseas GMP standards, such as the FDA, European, Individual USA State GMP, or NNFA (USA) cGMP, must be acceptable.

REGULATION OF COMPLEMENTARY HEALTHCARE PRODUCTS

As the current legislation is so different in both countries, it makes common sense for New Zealand to "opt out" of any Trans Tasman regulation for dietary supplements /complementary healthcare products.

INTERNATIONAL TRENDS IN THE REGULATION OF DIETARY SUPPLEMENTS

It is indeed curious that the USA has been left out as an example of how dietary supplements are legislated internationally. The USA market, equivalent to NZ$ 35 Billion annually, is one of the biggest in the world, with a very good safety record. It has one of the most liberalised systems internationally for supplements, and it works! What could be the motive behind leaving this system out of this document?

To the Australian Productivity Commission, the CHC stated ***'US companies have indicated their interest in establishing an Australian presence as a stepping stone into the Asian market but have decided against it because of the associated difficulties and cost.'***

LISTING and APPROVAL SYSTEM

The negative listing system used in New Zealand has worked very well, indeed. There is no need for a positive listing system for ingredients in Dietary Supplements.

Any electronic lodgment system must be user-friendly, simple, only loosely prescriptive as to wording, and inexpensive. We understand that the current Australian ELF system is lengthy, overly prescriptive as to wording, and the TGA is certainly not helpful to applicants with getting the wording correct. If one word is incorrect, the whole submission is rejected, thus requiring a new application fee to be paid. This process in itself is unfair and overly expensive.

The requirement for clinical trials for new Class 1 ingredients is in most cases unnecessary and will be hugely expensive for products that cannot seek patent protection. If the ingredient has been approved in say the USA there is no reason why it should not be accepted in New Zealand.

This requirement would effectively stop new ingredients, accepted internationally, from being available to New Zealand consumers.

We are strongly opposed to a positive list, as such a system would unnecessarily restrict our ability to access and provide safe, new ingredients and products available internationally.

What mechanism(s) would you propose to enable sharing of the costs of evaluation of new substances? Give details.

This idea is bizarre! It is simply against all international business practice and would not be accepted by the international business community. New products of any sort are closely guarded as they are the life blood of industry. As there is very little risk with most Dietary Supplement ingredients, there should be so little cost to get them approved that this question is irrelevant! Any collusion by companies acting together is contrary to current New Zealand law and the Commerce Act. It has the potential to eliminate competitive advantages and thus increase prices.

The main problem is that natural products, in general, cannot be patented

Overseas approvals by reputable agencies must be accepted.

To the Australian Productivity Commission the CHC stated '*CHC agrees with the finding that direct regulatory charges for generic products may give rise to first mover disadvantages; inhibiting the introduction of new products. Complementary healthcare products are based on substances which are not patentable; the cost of seeking approval for use of a new substance, and the 'free-rider' effect, is a major barrier to development of new products.'*

Tamper-evident packaging

All our products have tamper-evident packaging. We are agreed on tamper evident seals such as bottle lids where the seal is broken to gain entry. We are unaware of any problem of tampering with Dietary Supplements in New Zealand over the past 20 years. There does not appear to be any problem internationally with tampering of supplements. Many American supplements have an inner seal and an outer shrink wrap. However, it must be considered that these are major companies with huge turnovers who produce thousands of bottles of supplements daily for hundred of millions of people worldwide. What problem are we trying to solve?

ADVERTISING

Control of advertising must not be part of a joint Australia New Zealand agency in any way.

CONCLUSIONS

This proposal has nothing to do with enhancing health of New Zealanders in any way. It is all about creating a bureaucratic process and regime. There is no mention of improving the health of New Zealanders or encouraging them to take responsibility for their own health.

- In our opinion this proposal fails to meet the governments stated Code of Good Regulatory Practice. It also does not meet the government's aim of reducing business compliance costs and red tape, particularly for small business.
- Most of the comments made in this submission would apply to the future regulation of Dietary Supplements (including vitamins, minerals, homoeopathics, amino acids and other nutritional supplements) whether they are regulated under a joint agency with Australia or under a New Zealand only regime.
- Our company operates in the "top-end" of the quality dietary supplement market. We have no problem with the credibility of our products. Credibility is surely up to other companies to also

earn. Creating credibility for any industry is not the role of government or legislation. Also, there is no evidence that as a result of the Australian regime that Australian Complementary Healthcare industry enjoys any more credibility either locally or internationally, than do New Zealand products. In fact we have indications of the opposite.

- There is an element of public good in these regulations, otherwise why are they being considered. As food regulations and enforcement are funded from public funds, a major portion of costs for the regulation of Dietary Supplements should be paid for from public funds.
- The accountability channels are dangerously flawed in this system. With two ministers in two countries in charge, who would ultimately be responsible? The fact that, in any disagreement, the Australian minister would make most of the final decisions is unacceptable. Too much power, without proper safeguards, is given to the Agency's Managing director.
- There has not been sufficient evidence to show that a costly regime for the regulation of Dietary Supplements is necessary for the safety of or proof of the efficacy of these products in New Zealand. This proposal includes regulations that are inefficient, expensive, and effectively restrict the range of products by imposing inappropriate compliance costs, such as licensing fees, unique New Zealand only labelling, lengthy forms, appeals processes, and reams of red tape.
- Any regime must take into account that products with low volume sales must incur very low costs. Low volume sales must be appropriate for New Zealand's low population base. We distribute several hundred supplements. People in business understand the 80/20 principle and many of these products across our members have low volume sales The low volume products are maintained on the market as "service" products for consumers who rely on them. Fees, costs and special labeling would make them uneconomical and could force hundreds of them off the market.
- GMP and other standards of other countries must be recognized for products sold only in New Zealand, including labeling and packaging.
- A negative listing system is the most efficient and cost-effective. It works in New Zealand and many other countries, and has not been shown to compromise the safety of consumers.
- Given the volume of Dietary Supplements on the New Zealand market (estimated at 20 – 25 thousand), the problem of false claims being made is minute. There appears to be a lack of desire to enforce current laws in New Zealand. They can be regulated under existing laws that just need to be applied, eg the Medicines Act, the Fair Trading Act and/or the Commerce Act. Having said that, any truthful claims and non misleading statements need to be allowed.
- There is no safety justification for any sunscreens being classified as medicines. The proposed regime should apply only to ingestibles.
- The appeal and enforcement regime proposed is over-prescriptive, costly, and unnecessary for the low-risk nature of Dietary Supplements. All regulatory decisions must be open to review.
- In any regulatory environment, Dietary Supplements must have a separate regulatory unit.
- The fact that the states in Australia are not harmonised under the TGA, it is reasonable that New Zealand insist on that harmonisation occurring prior to any movement on a Joint Agency or harmonisation.

The evaluation by our company indicates that there are no benefits to our company in this proposal

or for New Zealanders in general and therefore we are rejecting the proposal.

NOTE: Below you will find a description of how Dietary supplements are regulated in the USA which provides insight into a way of achieving stated aims without the huge impact on industry and consumers.

[redacted]
Managing Director
Health & Herbs International Ltd

How Dietary Supplements are Regulated

Recognizing that dietary supplements play a valuable role in promoting improved health and well-being, in 1994 the Congress enacted a comprehensive new law changing the way in which vitamins, minerals, herbs and specialty supplements are regulated by the federal government. Called the Dietary Supplement Health and Education Act (DSHEA), this law gives considerable powers to the federal government to assure the safety of supplements and the accuracy of health claims. At the same time, DSHEA recognized the importance of funding additional scientific studies on the relationship between supplements and disease prevention and created the Office of Dietary Supplements within the National Institutes of Health to coordinate this research.

But because DSHEA set up a new framework for regulating dietary supplements, questions persist about how these products are regulated at the federal level. Accordingly, what follows is a review of the regulations now in place to ensure that only safe, beneficial, and quality supplements are marketed to the American public.

Dietary Supplements: Establishing a Formal Definition

In passing DSHEA, Congress recognized that consumers would benefit from having expanded and well-informed access to properly regulated vitamins, minerals, amino acids, herbs and other substances. For this reason, DSHEA defines a "dietary supplement" as a product that:

- Contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract or combination of these ingredients
- Is intended for ingestion in pill, capsule, tablet or liquid form, unless…
- It is not represented for use as a conventional food or as the sole item of a meal or diet
- It is labeled as a "dietary supplement"

An Emphasis on Safety

Before DSHEA, there was considerable confusion over how to regulate dietary supplements. Specifically, the U.S. Food and Drug Administration (FDA) regulated these products either as foods or as drugs, depending on their intended use, or sometimes as food additives like artificial colors. To resolve these inconsistencies, Congress determined that FDA should regulate supplements with the same safety requirements that the agency applies when regulating commonly used foods. This means that like most other foods, it is the manufacturer's responsibility to ensure that the company's products are safe and properly labeled prior to marketing.

Just as FDA doesn't require pre-market approval for foods with a very long history of safe use, the new law applies the same principle to dietary supplements that do not contain new dietary ingredients. For products containing a new ingredient (one not marketed in the U.S. before 1994), DSHEA requires manufacturers to submit data to the FDA demonstrating that the new ingredient does not present a safety risk under the conditions of use. Another option is for manufacturers to petition FDA, asking the agency to establish the conditions under which the new dietary ingredient would reasonably be expected to be safe.

In addition, FDA has considerable enforcement authority over dietary supplements that are on the market. Specifically, FDA has the power to:

- Stop any company from selling a dietary supplement that is "adulterated" or misbranded
- Stop the sale of a dietary supplement that makes false or unsubstantiated claims
- Take action against any dietary supplement that poses "a significant or unreasonable risk of illness or injury"
- Stop any company making a claim that a product cures or treats a disease
- Require dietary supplements to meet strict manufacturing standards, including potency, cleanliness and stability

Comprehensive Labeling Requirements

Like foods, dietary supplements are required to carry ingredient labeling. This information must include the name and the net quantity of contents on the principle display panel. The label must also list all ingredients that do not appear in the supplement facts information panel in the order of their amount in the product.

But unlike foods, the law spells out a number of labeling requirements for dietary supplements that are unique. Specifically, these rules call for:

- Inclusion of the term "dietary supplement" (or similar terms such as "herbal supplement") as part of the statement of identity
- Stating the quantity of each dietary ingredient or for combination products, the total quantity of all dietary ingredients in the blend

Most importantly for consumers, the new law requires that dietary supplements provide nutritional labeling. This labeling, called a "Supplement Facts" information panel, lists the amount of calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins, and minerals. The Supplement Facts panel must also include the quantity per serving for each dietary ingredient (or blend) and may describe the source of a dietary ingredient (for example, "calcium from Calcium gluconate").

Regulating Health Benefit Claims

To help consumers make informed decisions about using dietary supplements, the law sets out very stringent requirements for when manufacturers can make claims about the health benefits of their products. Based upon DSHEA and specific food labeling laws, FDA has issued regulations that allow dietary supplement manufacturers to make three types of claims: 1) nutrient-content claims, 2) health claims, and 3) structure-function claims.

With nutrient-content claims, the regulations are straightforward: based on FDA's requirements, when a supplement contains a high enough level of a nutrient, the product can carry a claim such as "high in calcium" or "an excellent source of vitamin C." FDA also authorizes health-related claims for foods and dietary supplements when there is a documented link between a food/dietary supplement and a health-related condition. Here, FDA has by regulation established approved health-related claims based on a review of the scientific evidence for significant scientific agreement, or based upon an authoritative statement from a scientific body like the National Academy of Sciences. The following six claims apply to dietary supplements:

- Folic acid and a decreased risk of birth defects

- Calcium and a lower risk of osteoporosis
- Potassium and the reduced risk of high blood pressure and stroke
- Psyllium seed husk (as part of a diet low in cholesterol and saturated fat) and a reduced risk of coronary heart disease
- Soy protein and the reduced risk of coronary heart disease
- Plant sterol/stanol esters and the reduced risk of coronary heart disease

Finally, the law allows information describing the supplement's effect on the body's structure or function, such as Vitamin E supports a healthy heart, or fiber maintains bowel regularity. To use these claims, manufacturers must have scientific data to substantiate the statement and the product label must bear this notice: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." In addition, FDA requires marketers to inform the agency of the use of the claim no later than 30 days after the product is first marketed and to certify that they can substantiate the claim, if challenged. Knowingly filing a false certification is a crime.

While DSHEA permits manufacturers that qualify to make structure-function claims, the law specifically prohibits disease claims for dietary supplements. For this reason, FDA has developed regulations that distinguish between a structure-function claim and a disease claim. Under these regulations, for example, a product cannot carry the claim "cures cancer" or "treats arthritis" or make statements that the product is a substitute for an approved therapy.

Regulating Advertising

While FDA has primary responsibility for regulating the safety and labeling of dietary supplements, the Federal Trade Commission (FTC) has authority over claims in advertising, infomercials, catalogs, web sites, and direct marketing materials. Accordingly, FTC issued "Dietary Supplements: An Advertising Guide for Industry" in which the agency states that both strong scientific substantiation and a careful presentation of the facts are the criteria that FTC relies on in regulating the advertising and Internet marketing of dietary supplements.

When FTC determines that the claim is unfounded, the agency has the power to:

- Challenge and stop advertising that is not adequately substantiated
- Investigate complaints or questionable trade practices. Here, the agency has the power to require a company to produce documents, give testimony, and provide answers to written questions
- Negotiate a consent order or work through the administrative and/or federal courts to obtain a cease and desist order, which can be very broad in scope
- Seek preliminary or permanent injunctions to stop false advertisements or other marketing practices
- ?Seek civil penalties from violators

As this description makes clear, the dietary supplement industry is subject to extensive laws and regulations at the federal level, all of which are designed to ensure that safe, beneficial and quality supplements are available for health promotion and disease management. When viewed in this manner, the public can have confidence that the regulatory framework now in place gives consumers greater access to a wide range of dietary supplements while making sure that products that don't meet government requirements are removed from the market.

Updated: July 30, 2001

Myths & Facts About Dietary Supplements

Myth

Dietary supplements are virtually unregulated.

Fact

The Dietary Supplement Health and Education Act (DSHEA), enacted in 1994, gives considerable powers to the federal government to assure the safety of dietary supplements as well as the accuracy of their claims and labeling. Under DSHEA, the U.S. Food and Drug Administration has the same powers to regulate dietary supplements as the agency exercises over commonly used foods. This means that like most other foods, it is the manufacturer's responsibility to ensure that the company's products are safe and properly labeled prior to marketing.

Myth

The passage of DSHEA has weakened FDA's enforcement powers over the dietary supplement industry.

Fact

The passage of DSHEA actually maintained and increased FDA's enforcement powers over dietary supplements by establishing new labeling and potency standards and by making violations of these standards a crime. Following DSHEA, FDA has the power to:

- Refer for criminal action any company that sells a dietary supplement that is toxic or unsanitary
- Seize dietary supplements that pose "an unreasonable or significant risk of illness or injury"
- Stop a new dietary ingredient from being marketed if the FDA does not receive enough safety data in advance
- Stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard
- Require manufacturers to certify and substantiate their claims
- Require dietary supplements to meet strict manufacturing guidelines including potency, cleanliness and stability

Myth

The FDA has limited authority over the ingredients used in dietary supplements.

Fact

Under law, if a manufacturer wants to market a product containing an ingredient that was not used in commerce prior to the passage of the DSHEA, the FDA must be notified in advance and provided with safety data. At any time, FDA may even request a court order to require a recall of a product if the agency believes it presents a health risk.

Myth

Dietary supplement makers don't have to follow the same strict good manufacturing practices as do other consumer products.

Fact

This is absolutely false. The dietary supplement industry follows the same guidelines that are in effect for the food industry to ensure that controlled, sanitary manufacturing practices are in place and that the resulting products contain what is on the label. Failure to do so is a violation of the law and could even lead to criminal prosecution. While operating under these food GMP regulations, the industry is currently working with FDA to establish GMP regulations specifically for supplements. At the same time, a number of industry groups and trade associations have adopted voluntary programs to ensure that quality standards are being followed.

Myth There is not enough control over dietary supplement claims.

Fact Under current law, makers of dietary supplements are limited to the types of claims they can make about their products. Statements of nutritional support, commonly referred to as "structure-function" claims, are restricted to explaining how a particular product or ingredient affects the structure or function of the body. As a result, manufacturers are prohibited from making claims that their products are intended to diagnose, treat, cure or prevent a disease. In fact, manufacturers are required to put this disclaimer on the labels of their products whenever making a tructure/function claim. Further, manufacturers must have substantiation that the statement is truthful and not misleading and must notify FDA within 30 days after first using the claim in the marketplace.

Myth The advertising of dietary supplements is not adequately regulated at the federal level.

Fact The Federal Trade Commission has enforcement authority over claims about dietary supplements in advertising, infomercials, web sites and direct marketing materials. When the FTC determines that a claim is unfounded, the agency has the power to:

- Challenge and stop advertising that is not adequately substantiated
- Investigate complaints or questionable trade practices. Here, the agency has the power to require a company to produce documents, give testimony, and provide answers to written questions
- Negotiate a consent order or work through the courts to obtain an order from an administrative or federal court requiring a company to cease and desist making unsubstantiated claims. These orders can be very broad in scope
- Seek preliminary or permanent injunctions to stop false advertisements or other marketing practices
- Seek civil penalties from violators

To further ensure that manufacturers stay within the confines of the law when marketing their products, the FTC published advertising guidelines for the dietary supplement industry in 1998.

Myth

There is not enough scientific data to support the safety and efficacy of most dietary supplements

Fact

Adding to the large body of scientific evidence supporting the health benefits of dietary supplements, each year, numerous studies are published in major medical journals that document new findings about how dietary supplements can be used to address specific conditions, reduce the risk of diseases or to enhance general nutrition. Such studies can be found in *The Journal of the American Medical Association*, *New England Journal of Medicine*, *American Journal of Cardiology*, *American Journal of Clinical Nutrition and the Journal of the National Cancer Institute*.

Besides newly published research studies on the benefits of dietary supplements from such leading institutions as Johns Hopkins University and the American Heart Association, the Dietary Supplement Health and Education Act created the Office of Dietary Supplements within the National Institutes of Health to focus specifically on advancing the study of dietary supplements in this country. Since starting operations in November 1995, ODS has held symposia and has sponsored numerous studies to study the effectiveness of commonly used supplements.

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