The Administration's Responses to the Issues Raised at the meeting of the Bills Committee on Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004 on 23 November 2004

(a) **To provide for an appeal channel against the decision made by the Director of Health to prohibit/restrict an advertisement for an orally consumed product, or alternatively to consider establishing a pre-approval system for advertising such claims.**

The Department of Health (DH) has put in place a warning mechanism, through which parties involved in the publication of a health claim, which are considered by DH to be potentially UMAO-infringing, are forewarned on the possible legal actions to be taken against them if the claim concerned continues to be published. The mechanism aims to prevent situations whereby parties are prosecuted for violating the Ordinance because they are unaware of or unclear about the provisions. The system has been working satisfactorily.

It should be noted that the mechanism is purely an administrative measure. The warning does not entail any legal consequence, and it is not a legal instrument to restrict/prohibit the parties concerned from continuing to publish the claims.

It should also be noted that the warning letter issued by DH is purely advisory. The ultimate decision on whether a claim is UMAO – infringing rests with the Court.

As for the proposal to set up a pre-approval system for advertising such claims, the Administration considers that the current Ordinance and the warning system provide clear guidance to parties concerned on whether a particular claim is potentially UMAO – infringing. The Administration considers the proposed pre-approval system will compromise DH's role as an enforcement agency of the Ordinance, and may provide an unintended avenue for people to circumvent the concerned provisions of the Ordinance.

(b) Evidence to support the claims made that the consumption of the so-called 'health food' products would result in improper self-medication or delayed proper treatment.

We understand from a number of experienced medical practitioners that they have come across many cases in their practice where their patients, who were suffering from certain diseases, took 'health food' products to mitigate their symptoms instead of consulting their doctors, but ended up with worsened conditions. Nonetheless, we do not have readily available figures in this regard.

(c) Overseas practice on the regulation of health claims from which the Administration has drawn reference in the formulation of the Undesirable Medical Advertisements (Amendment) (No. 2) Bill.

In the formulation of the Bill, the Administration has drawn reference to the practices in seven places, namely the Mainland (including Taiwan), Australia, Canada, Japan, the European Union and the United States, on the regulation of health foods and their claims. For the European Union and the United States, "health food" products are not subject to pre-marketing approval, but health claims for these products are regulated. Their practices are shown at **Appendix**.

Regulatory Frameworks on Health Food Products and Health Claims in the Mainland China

1. Definition of Health Food Products

Health food is defined as food that has specified health functions, suitable to be taken by specified group(s) of people, and for the regulation of the functional states of the human body and is not used for the treatment of diseases.

2. Types of Health Claims Permitted to be Carried by Health Food Products

A total of 27 categories of health functions claims are approved by State Food and Drug Administration as follows:

1.	增強免疫力	Enhancing immune function
2.	輔助降脂	Assisting blood lipids reduction
3.	輔助降糖	Assisting blood sugar reduction
4.	抗氧化	Antioxidation
5.	輔助收善記憶力	Assisting memory improvement
6.	緩解視疲勞	Improving tired eyesight
7.	促進排鉛	Facilitating lead excretion
8.	清咽功能	Moistening and cleaning throat
9.	輔助降血壓	Assisting blood pressure reduction
10.	改善睡眠	Improving sleep
11.	促進泌乳	Increasing milk secretion
12.	緩解體力疲勞	Stamina
13.	提高缺氧耐受力	Improving endurance during anoxia
14.	對輻射危害有輔助保護功能	Assisting protection against irradiation
15.	減肥	Controlling obesity
16.	改善生長發育	Improving growth and development
17.	增加骨密度	Increasing bone density
18.	改善營養性貧血	Improving nutritional anemia
19.	對化學性肝損傷有輔助保護	Assisting protection against chemical liver injury
20.	祛痤	Eliminating acne
21.	祛黃褐斑	Eliminating yellow-brown spot
22.	改善皮膚水分	Improving skin moisture
23.	改善皮膚油分	Improving skin oil content

24.	調節腸道菌群	Regulating intestinal microflora
25.	促進消化	Facilitating digestion
26.	通便功能	Improving constipation
27.	對胃粘膜損傷有輔助保護功能	Assisting protection against gastric mucosa damage

(The English translations of the claims are for reference only.)

3. Relevant Laws and Regulations

Regulation for the Control of Health Food

4. Law Enforcement Authorities

State Food and Drug Administration (SFDA) is responsible for the overall regulation and control of health foods in China.

5. Regulation of Health Food Products

a. Registration and Pre-marketing Assessment of Products

i. The standards and rules on evaluation on health foods are set by SFDA. The functional evaluation and testing on claimed health function, and the toxicological evaluation of the health foods shall be conducted by institutions appointed by SFDA.

ii. For health food which claim to have health functions manufactured in China, registration is required before marketing.

iii. No health foods shall be manufactured or marketed for sale without the approval by SFDA. A Health Food Certificate for the qualified and approved health food with a code number will be issued.

iv. All the labels, information leaflets and advertisements for the health foods shall fulfill the relevant standards and requirements of the SFDA and shall not claim to have any therapeutic effects.

b. Post-marketing Vigilance

SFDA may take samples of those approved health foods from the market for re-evaluation if necessary.

c. Substantiation of Health Claims

There shall be scientific substantiation on the formulation and the amount of ingredients used. Functional ingredients shall be identified. All the health function claims must be supported by scientific results of the necessary animal and/or human functional tests.

Regulatory Frameworks on Health Food Products and Health Claims in Taiwan, China

1. Definition of Health Food Products

In Taiwan, the term "health food" denotes food with specific nutrient or specific health care effects as specially labeled or advertised, but not food aimed at treating or remedying human diseases.

2. Types of Health Claims Permitted to be Carried by Health Food Products

i. The beneficial effects prescribed by the central competent authority are those regulating blood lipids, regulating the gastrointestinal tract, regulating the immune system, preventing osteoporosis, maintaining dental health, regulating blood sugar and protecting the liver (from chemical liver damage).

ii. The labeling and advertisement of the approved health food shall contain contents (which may include the beneficial effects) that have been approved.

3. Relevant Laws and Regulations

The "health food" in Taiwan are regulated by the Health Food Control Law which was enacted in 1999.

4. Law Enforcement Authorities

The Department of Health is responsible for the overall enforcement of the "health food".

5. Regulation of Health Food Products

a. Registration of Products

No food shall be labeled or advertised as health food unless it is registered as such. A product registration permit is issued when application for registration is approved.

b. Pre-marketing Assessment of Products

To become a health food, it has to contain chemical ingredients that promote health with reasonable consumption, as supported by scientific evidence, or if current technology is unable to provide evidence of beneficial effects, the ingredients with the relevant beneficial effects shall be listed and supporting literature should be submitted to the central competent authority for evaluation and identification to support the claim that the health food is harmless and effective.

c. Post-marketing vigilance

The central competent authority may re-evaluate approved health food during the validity of the health food permit for certain specified reasons.

d. Warning Statements

Only approved health care effects are allowed to be displayed on the containers and packaging, together with written instruction of the health food in Chinese, as well as the amount of intake and other necessary warnings.

Regulatory Frameworks on Health Food Products and Health Claims in Australia

1. Definition of "Health Food" products

In Australia, "health food" is classified under "**complementary medicines**". A complementary medicine means therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and:

(a) a traditional use; or

(b) any other use prescribed in the Therapeutic Goods Regulations.

2. Types of Health Claims Permitted to be Carried by Health Food Products

Indications or claims are catergorised as being "general", "medium" or "high" level:

(a) **General level claims** include:

- Health maintenance, including nutritional support
- Vitamin or mineral supplementation
- Relief of symptoms (not related to a named disease, disorder or condition)

(b) **Medium level claims** include:

- Health enhancement
- Reduction of risk of a disease/ disorder/ condition
- Reduction in frequency of a discrete event
- Assistance in the management of a named symptom/ disease/ disorder/ condition
- Relief of symptoms of a named disease, disorder or condition

(c) **High level claims** include:

- Treatment of any disease/ disorder/ condition
- Prevention of any disease, disorder or condition
- Treatment of specific named vitamin or mineral deficiency diseases

3. Relevant Laws and Regulations

All complementary medicines are governed by the **Therapeutic Goods Act** and **Therapeutic Goods Regulations**.

4. Law Enforcement Authorities

The Secretary of Department of Health and Ageing may authorize an officer to exercise powers under the provisions of the Therapeutic Goods Act. Provisions concerning complementary medicines are administered by the **Therapeutic Goods Administration (TGA)** of Department of Health and Ageing.

5. Regulation of Health Food Products

Registration and pre-market assessment
Complementary medicines may either registered or listed, depending on their ingredients and the claims made. Complementary medicines bearing high level claims are registered medicines. Most complementary medicines are listed medicines. All applications for registration and listing of complementary medicines are evaluated by the Complementary Medicines Evaluation Committee (CMEC).

Post-market vigilance
Any adverse events of therapeutic goods are required to be reported to the Department of Health and Ageing.

Substantiation of health claims
According to the "Guidelines for levels and kinds of evidence to support indications and claims", an applicant should hold general or medium level of evidence in order to make a general or medium level claim for complementary medicines. A list of TGA-approved literatures was issued as the source of evidence.

Warning statements / health advice
There are detailed and specific requirements on advisory statement for medicine labels in Australia. For instance, if a complementary medicine containing greater than 2.5% but not more than 10% camphor as a natural component in essential oils, it should bear the statements "*Keep out of reach of children*" and "*Not to be taken*". All claims relating to symptoms must be accompanied by the advice "*If symptoms persist consult your healthcare practitioner*" or words to that effect.

Regulatory Frameworks on Health Food Products and Health Claims in Canada

1. Definition of "Health Food" products

In Canada, "health food" is defined as "**natural health products**" (NHP) and the definition of NHP has two components: **function and substance**.

The **function component** refers to the description of NHP in relation to those substances that are manufactured, sold or represented for use in:

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state or its symptoms in humans;
(b) restoring or correcting organic functions in humans; or
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The **substance component** refers to the medicinal ingredients in a NHP. The medicinal ingredients that natural health products may contain are specified under the law.

2. Types of Health Claims Permitted to be Carried by Health Food Products

All NHP must have health claims on their labels that link the product to a disease or health-related condition. The health claims must comply with the Food and Drugs Act and claims that refer to certain diseases or health-related conditions listed in listed in the law are not allowed.

Four types of health claims are allowed:

(a) **Therapeutic claims**, which relate to the diagnosis, treatment and mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans;

(b) **Risk reduction claims**, which describe the relationship between using a medicinal ingredient and reducing risk of developing a specific disease or abnormal physiological state;

(c) **Structure-function claims**, which describe the effect of a medicinal ingredient on a structure or physiological function in the human body, or a medicinal ingredient's support of an anatomical, physiological, or mental function;

(d) **Non-specific claims** (generally structure-function type) will also be considered only in cases where there is adequate evidence to demonstrate safety.

3. Relevant Laws and Regulations

NHPs are governed by the **Natural Health Products Regulations**, which are a set of new regulations under the Food and Drugs Act. The regulations came into force on 1.1.2004 and all NHPs must comply with the regulations.

4. Law Enforcement Authorities

The Natural Health Products Regulations are administered by the **Natural Health Products Directorate (NHPD)**, Health Products and Food Branch, Health Canada.

5. Regulation of Health Food Products

Registration and pre-market assessment
All NHPs are required to obtain a product licence before marketing. Applications should be submitted with supporting information and documents including complete formula, label, and information that support the safety and efficacy of the NHP when it is used in accordance with the recommended conditions of use. Upon approval, the Authority would assign a product number to each NHP.

Post-market vigilance
A licensee is required to provide the authority with a case report of each serious adverse reaction to the NHP within 15 days. An annual report should also be prepared by a licensee that contains a concise and critical analysis of all adverse reactions to the NHP.

If the authority is not satisfied, the licensee, manufacturer, importer and distributor may be directed to stop their sale of a NHP.

Substantiation of health claims
A guidance document was issued by the NHPD to help product licence applicants determine the evidence required to support the safety and efficacy of finished NHPs. In short, applicants who make a traditional use claim must provide at least 2 independent references from reputable sources.

Applicants who make a non-traditional use claim must provide evidence that supports the conditions of use based on scientific evidence.

Warning statements

The Food and Drug Regulations stipulates requirements on cautionary statements which are applied to NHP.

Regulatory Frameworks on Health Food Products and Health Claims in Japan

1. Definition of Health Food Products

In Japan, there is no definition for health food as such. Nevertheless, "Foods with Health Claims" are health foods that conform to the safety and efficacy standards set by the Minister of Health, Labor and Welfare. They consist of two categories:

i. "Foods with Nutrient Function Claims" (FNFC) - including 12 vitamins and 5 minerals
ii. "Foods for Specified Health Uses" (FOSHU)

2. Types of Health Claims Permitted to be Carried by Health Food Products

a. For FNFC, only the Approved Statements for Nutrient Function Claims for the 12 vitamins and 5 minerals are permitted.

b. For FOSHU, permitted health claims correspond to the Enhanced (or other) Function Claims of the Codex Alimentarius or Structure/Function Claims of the US. Permitted types of health claims are under eight categories, namely as follows:

i. Gastrointestinal conditions
ii. Serum cholesterol
iii. Blood glucose
iv. Blood pressure
v. Tooth health
vi. Blood neutral fat
vii. Absorb of minerals
viii. Bone health

3. Relevant Laws and Regulations

The "Health Foods" in Japan are regulated by several acts, including the Health Promotion Act, Food Sanitation Act and Pharmaceutical Affairs Act.

4. Law Enforcement Authorities

The Minister of Health, Labor and Welfare is responsible for the overall enforcement of the "Food with Health Claims".

5. Regulation of Health Food Products

a. Registration of Products

i. Approval from Ministry of Health is not needed for FNFC before they are marketed.

ii. In order to market a product as a FOSHU, the manufacturer has to submit two documents to the Office of Health Policy on Newly Developed Foods, the Ministry of Health, Labor, and Welfare, namely "Application for Labeling Approval" under the Health Promotion Act and "Application for Judgment on the Safety and Effectiveness of the Food" under the Regulatory Standards for Foods, Food Additives, etc (Ministerial Ordinance).

b. Pre-marketing Assessment of Products

i. For FNFC, no pre-marketing assessment is necessary. A total of 12 vitamins and 5 minerals were standardized as "FNFC" as of March 2004.

ii. For FOSHU, upon the examination of the Food Safety Commission and the Pharmaceutical Affairs and Food Sanitation Council, the Minister of Health, Labor, and Welfare gives approval on a case by case basis to allow the manufacturer to attach certain claim and mark it on the product.

c. Substantiation of Health Claims

The statements of FOSHU must be based on current relevant scientific substantiation.

d. Warning Statements

i. For FNFC, it is a mandatory requirement for these products to be attached with specified warning statements, depending on their ingredients.

ii. For FOSHU, it is also a mandatory requirement for these products to be attached with suitable warning statements, which depend on structure/function health claim or enhanced health claim approved.

Regulatory Frameworks on Health Food Products and Health Claims in European Union

1. Definition of "Health Food" products

In Europe, "health food" is known as "**food supplements**" which means foodstuffs with the purpose of *supplementing the normal diet* and which are *concentrated sources of nutrients, i.e. vitamins or minerals, or other substances* with a nutritional or physiological effect, alone or in combination, *marketed in dose form*, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

2. Types of Health Claims Permitted to be Carried by Health Food Products

The existing EC Directives on the labeling, presentation and advertising of foods and food supplements prohibit the attribution of preventing, treating and curing a human disease. Some Member States interpreted the Directives as banning all health claims relating to human diseases.

3. Relevant Laws and Regulations

Currently, food supplements are controlled by Directive 2000/13/EC on the approximation of the "Laws of the Member States relating to the labeling, presentation and advertising of foodstuffs" and Directive 2002/46/EC on the approximation of the "Laws of the Member States relating to food supplements".

4. Law Enforcement Authorities

The enforcement of EC Directives relies on the national health authorities of each Member States.

5. Regulation of Health Food Products

Registration and pre-market assessment
No registration is required for food supplements before marketing.

Post-market vigilance

"Regulation EC/178/2002" has defined the scope and procedures of a food safety monitoring system. The Regulation requires food business operators to inform the national authorities for any adverse events.

Warning statements

According to Directive 2002/46/EC (laws relating to food supplements), the label of a food supplement should bear the following warning and cautionary statements:

(a) Not to exceed the stated recommended daily dose;
(b) Statement to the effect that food supplements should not be used as a substitute for a varied diet;
(c) Statement to the effect that the products should be stored out of the reach of young children.

Regulatory Frameworks on Health Food Products and Health Claims in USA

1. Definition of "Health Food" products

In USA, "Health Food" is defined as "**dietary supplement**" and it means:

(a) a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
- A vitamin;
- A mineral;
- An herb or other botanical;
- An amino acid;
- A dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- A concentrate, metabolite, constituent, extract, or combination of the above

(b) a product that:
- Is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form;
- Is not represented for use as a conventional food or as a sole item of a meal or the diet; and
- Is labeled as a dietary supplement

Except for purposes of a drug as defined in the Federal Food, Drug, and Cosmetic Act, a dietary supplement shall be deemed to be a food within the meaning of the Act.

2. Types of Health Claims Permitted to be Carried by Health Food Products

(a) Health claims

Health claims describe the relationship between a dietary supplement ingredient and reducing risk of a disease or health-related condition.

(b) Nutrient Content claims

Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high* and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced* and *lite*.

(c) Structure-function claims

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans.

3. Relevant Laws and Regulations

In USA, dietary supplements are controlled under **Dietary Supplement Health and Education Act of 1994** and **Federal Food, Drug, and Cosmetic Act**.

Moreover, the 1990 Nutrition Labeling and Education Act, 1997 Food and Drug Administration Modernization Act and 2003 FDA Consumer Health Information for Better Nutrition Initiative are relevant to the labelling requirements of dietary supplement.

4. Law Enforcement Authorities

Relevant regulations concerning dietary supplement are administered by the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA.

5. Regulation of Health Food Products

Registration and pre-market assessment
Dietary supplements are not required to be registered before marketing. However, if the manufacturer of a dietary supplement proposes to make a structure/function claim in the labeling of the dietary supplement, the manufacturer has to notify FDA no later than 30 days after the first marketing.

Post-market vigilance
A post-marketing surveillance system is established in FDA to collect and evaluate any adverse events of food, drugs and dietary supplements.

Substantiation of health claims
The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-approved by FDA but must be truthful and not misleading.