FOOD SUPPLEMENTS: FRIEND OR FOE

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OUTLINE

• Use of supplements in the Philippines
• Definitions
• Current regulatory framework
• Evidence for safety and efficacy/benefit
• Recommendations
SALES OF NATURAL PRODUCTS*

• 5 BILLION PESOS – sales in 2007
Top 7 brands with 6 celebrity endorsers

• 3 BILLION PESOS – media expenditures

* Include herbal medicines; exclude vitamins and minerals, probiotics.
Reference: BFAD paper read during PHA Supplement Summit. May 2009
<table>
<thead>
<tr>
<th>Company</th>
<th>Sales (Pesos)</th>
<th>Product/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.6 b</td>
<td>SILYMARIN; carnitine-green tea; LUTEIN; garlic-ginkgo-ginseng-grape seed; TAHEEBO; glucosamine-chondroitin-methylsulfonyl methane-colllagen II</td>
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<tr>
<td>B</td>
<td>475 m</td>
<td>LAGUNDI; sambong; AMPALAYA</td>
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<td>C</td>
<td>469 m</td>
<td>Garlic-hawthorn-lemon balm-ginkgo</td>
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<tr>
<td>D</td>
<td>439 m</td>
<td>GLUCOSAMINE; coenzyme Q10; 16-ingredient product for kidney care</td>
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<tr>
<td>E</td>
<td>58 m</td>
<td>Bitter herbs combination; LAGUNDI; sambong</td>
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<tr>
<td>F</td>
<td>28 m</td>
<td>AMPALAYA</td>
</tr>
</tbody>
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POPULAR BRANDS

- Optein
- Heartvit, Vitaheart, Heartcare, Circulan, 4G
- Lungcare
- Liveraide
- Kidneycare, Cran-UTI, Releaf
- Arthricin, Arthro
- Memori Plus, Sleepasil
- Fitrum, Biofitrim, Biofit, Slenda
- Diabetrol, Charantia
- Enduranz, Tongkat Ali
- Vita Plus, Vita Veg, Red Juice
- Vcaps, Vitamin Beer, Fern C
- Nature’s Way, Herbalife, My Marvel
SCOPE OF SUPPLEMENTS

Considered as supplements are products which are not readily registrable as food, drug, or cosmetic

• **FOOD**. Consumed for its nutritive value, taste, or aroma

• **DRUG**. Used to prevent, diagnose, cure, mitigate, or treat disease; or to affect structure or function of the body

• **COSMETIC**. Applied to the body for cleansing, beautifying, or altering appearance
## SUPPLEMENTS ACCORDING TO SOURCE

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
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<tbody>
<tr>
<td><strong>PLANT PRODUCTS</strong></td>
<td>Ginkgo, ginseng, green tea, tongkat ali, noni, saw palmetto, echinacea, St Johns wort, garlic, ginger, Taheebo, policosanol, evening primrose, Malunggay, yacon, VCO, banaba, ampalaya, mangosteen, Silymarin, lutein, lycopene, caffeine, resveratrol</td>
</tr>
<tr>
<td><strong>ANIMAL PRODUCTS</strong></td>
<td>Glucosamine, chondroitin, colostrum, royal jelly, fish oil, omega 3, shark cartilage</td>
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<tr>
<td><strong>SINGLE COMPOUNDS</strong></td>
<td>Vit A, D, E, C, B1, B2, niacin, B6, Folic acid, B12, biotin, pantothenic acid, Glutathione, carnitine, taurine, melatonin, S-adenosyl methionine, choline, inositol, alpha-lipoic acid, Zinc, calcium, iron, chromium, selenium</td>
</tr>
<tr>
<td><strong>MISCELL</strong></td>
<td>Probiotics, prebiotics, Ganoderma, chlorella, spirulina, Ayurveda, homeopathy, Chinese traditional herbs</td>
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### VARIOUS TERMS USED

<table>
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<tr>
<th>FOOD</th>
<th>‘SUPPLEMENT’</th>
<th>DRUG</th>
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<td>Natural product</td>
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<td>Functional food</td>
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<tr>
<td>Function food</td>
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<tr>
<td>Health function food</td>
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<tr>
<td>Food with specific health use</td>
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<tr>
<td>Supplement</td>
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<tr>
<td>Dietary supplement</td>
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<tr>
<td>Food supplement</td>
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<tr>
<td>Nutritional supplement</td>
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<td>Health supplement</td>
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<tr>
<td>Complementary medicine</td>
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<tr>
<td>Traditional medicine</td>
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<tr>
<td>Traditionally-used herbal product</td>
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<tr>
<td>Herbal medicine</td>
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<tr>
<td>Nutraceutical</td>
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</table>
Varying criteria followed

EXAMPLE: GINKGO MAYBE VARIOUSLY REFERRED TO AS:

- Natural product [Canada]
- Food supplement [EU]
- Dietary supplement [US]
- Food with specific health use [Japan]
- Health function food [Korea]
- Function food [China]
- Complementary medicine [Australia]
- Traditional medicine [Malaysia]
- Food supplement or drug [Philippines]
Dietary supplement

• A product containing one or more of vitamin, mineral, herb or other botanical, amino acid, or a concentrate, metabolite, constituent, or extract or combination of any of those ingredients

• Intended to supplement the diet by increasing the total dietary intake

Dietary Supplement and Health Education Act, 1994
Dietary supplement

- A product taken by mouth marketed in dosage forms of tablets, capsules, powders, solutions or similar
- Intended to supplement the diet
- And is for a healthy person not a patient
Food supplement EU

- Foodstuff with ingredients including vitamins, minerals, amino acids, essential fatty acids, fiber, and various plants and herbal extracts
- Purpose: to supplement the normal diet
- Statement that food supplement should not be used as a substitute to a varied diet
Food for specified health uses (FOSHU) Japan

• Composed of functional ingredients that affect the structure/function of the body
• Used to maintain or regulate specified health conditions such as gastrointestinal condition, blood pressure, blood cholesterol level
• Health function claims allowed: Clinical tests required
• Ex. lactobacillus, fiber
Food for nutrition function claims

- 12 vitamins and 2 minerals [vit A, D, E, B1, B2, niacin, B6, Folic acid, B12, biotin, pantothenic acid, C, Ca, Fe]
- Nutrition function claim
Health function food

• Processed and manufactured goods in the form of tablet, capsule, powder, granule, liquid and pills
• That help enhance and preserve health of human body
• Using proteins, vitamin, minerals, fat, fiber, other functional ingredients
Function food China

- Immune regulation, blood lipid regulation, blood sugar regulation, delay of aging, memory improvement, vision improvement, blood pressure regulation, sleep improvement, promote lactation, anti-mutation, anti-fatigue, hypoxia tolerance, anti-radiation, osteoporosis improvement, anemia improvement, lead-expelling, throat moistening, slimming, face beautifying
Complementary medicines: collective term for

- Vitamins, minerals
- Amino acids
- Herbal medicines
- Homeopathic medicines
- Traditional medicines

Regulated as medicines

- Allows to make claims [vs most other countries where they are regulated as food]
PHILIPPINE REGULATIONS

Some administrative orders
• Food supplements
• Herbal products

Foreign models used in evaluation
• US FDA
• Codex Alimentarius
• EU
AO 62 series of 1968

- Food supplements defined as those used for supplementing or fortifying ordinary or usual diet of any vitamin, mineral or others with dietary property
MC 25 series of 1992

- October 15, 1992
- Additional labeling requirement for food supplement
- NO APPROVED THERAPEUTIC CLAIM
<table>
<thead>
<tr>
<th>AO 172</th>
<th>Guidelines on registration of herbal medicines</th>
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<td>AO 184</td>
<td>Guidelines on the registration of traditionally-used herbal products</td>
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<td>Draft AO</td>
<td>Guidelines on the registration of herbal food products</td>
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<td></td>
<td>Overtaken by ASEAN process on harmonization of evaluation of health supplements and traditional medicines</td>
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</tbody>
</table>
Health Supplement ASEAN

• Product that is used to supplement a diet, and to maintain, enhance, and improve the healthy functions of a human body

• Contains one or more or combination of
  
  A. Vitamins, minerals, amino acids, enzymes, fatty acids, probiotics, other bioactive substances
  
  B. Substances derived from natural sources, including animal, mineral, and botanical materials in the form of extract, isolate, concentrate, or metabolite [*Synthetic sources of ingredients mentioned in A) and B) may only be used where the safety of these has been proven.]

➢ Presented in dosage forms in small unit doses such as capsule, tablet, powder, liquid

➢ Shall not include any sterile preparation such as injectable, or eye drop

*ASEAN harmonization of registration of traditional medicines and health supplements
Traditional medicine ASEAN

- Any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals)
- Used in the system of traditional practice.
- Should not include any sterile preparation, vaccines, any substance derived from human parts, any isolated and characterized chemical substances

*ASEAN harmonization of registration of traditional medicines and health supplements
EVALUATION OF EFFICACY AND SAFETY
HERBS THAT HARM: Kava
Piper methysticum

- Some evidence: maybe beneficial for anxiety
- Risk of liver damage
- Traditional use: ceremonial drink Pacific islands
- Use withdrawn by FDA
HERBS THAT HARM: Comfrey

• Panacea
• Hepatotoxic
• Pyrrolizidine
• Not recommended for systemic use
HERBS THAT HARM: Aristolochocha

- For weight reduction
- Nephropathy [interstitial fibrosis]
- Aristolochochic acid
- Use withdrawn in the Philippines
HERBS THAT HARM: Mahuang

- Ephedra
- For weight reduction: high doses
- Stroke
Anticoagulant effect may be increased by:

- GINKGO
- GARLIC
- GINSENG
- GRAPESEED EXTRACT
- GREEN TEA
- FISH OILS
- CHONDROITIN
- BROMELAIN
- S-ADENOSYL METHIONINE
- VITAMIN E [≥100 units daily]
EFFICACY EVALUATION

Based from RCT and meta-analysis studies

- COCHRANE NETWORK
- US NATIONAL INSTITUTES OF HEALTH
  (National Center for Complementary and Alternative Medicine, Office of Dietary Supplements, National Cancer Institute, etc)
- US AGENCY FOR HEALTHCARE RESEARCH AND QUALITY
Milk thistle  *Silybum marinum*

**Silymarin**

- Clinical studies done for various liver diseases [alcohol-related, toxin-induced, viral]; some promising results reported for amanita poisoning

**NO conclusive evidence to prove claims:**

- Small study population
- Poor study design
- Poor quality of reporting

**Ongoing studies by the NIH National Center for Complementary and Alternative Medicine [NCCAM] for:**

* Chronic hepatitis  C; non-alcoholic steatohepatitis; cancer prevention; complications in HIV patients

Evidence Report No 21. Agency for Healthcare Research and Quality
Ginkgo Ginkgo biloba

• Promising results for dementia, intermittent claudication, tinnitus but needed to be confirmed by large, well-designed studies Agency for Healthcare Research and Quality
• National Institute of Aging study on 200 adults: no improvement in memory JAMA 2002
• No convincing evidence Birks J. Ginkgo biloba for cognitive impairment and dementia. Cochrane library
• Known interaction with coumadin: increased risk of bleeding

Ongoing studies by the NIH National Center for Complementary and Alternative Medicine [NCCAM] for:
• Alzheimer’s; asthma; symptoms of multiple sclerosis; intermittent claudication; sexual dysfunction due to antidepressants; interactions with prescription drugs
Ginseng  Panax ginseng

• Many claims: well-being, immune, etc
• Some claims based on animal studies
• Some human studies: may lower blood glucose, or possible immune enhancement

NOT conclusive to prove claims

• Most studies small
• Flaws in study design
• Flaws in reporting

Agency for Healthcare Research and Quality

Ongoing studies by the NIH National Center for Complementary and Alternative Medicine [NCCAM] for:

• Drug interactions; chronic lung infection; impaired glucose tolerance; Alzheimer’s
Garlic  *Allium sativum*

- Some evidence that garlic can lower blood cholesterol for short-term use [1-3 months]
- Preliminary results: may slow development of atherosclerosis
- Mixed results on hypertension
- No effect on glucose or insulin sensitivity
- Decreased effect of saquinavir

Agency for Healthcare Research and Quality

**NCCAM studies**

- For lowering blood cholesterol; as anticoagulant; interactions with other drugs
Ginger *Zingiber officinale*

- Studies suggest short-term use can safely relieve pregnancy-related nausea and vomiting
- Mixed results for nausea caused by motion, chemotherapy, or surgery
- Unclear if effective for rheumatoid arthritis, osteoarthritis, muscle and joint pains

Agency for Healthcare Research and Quality

**NCCAM studies**
- For nausea in chemotherapy
- Drug interactions with immunosuppressants
- General safety
- Active components and effects on inflammation
Green tea Camellia sinensis

- Laboratory studies: may help protect from or slow growth of certain cancers
- Human studies: mixed results
- Some evidence to improve mental alertness [caffeine]
- Not enough reliable data for weight loss, decreasing cholesterol

Agency for Healthcare Research and Quality

NCCAM studies
- Cancer
- Diabetes
- Heart disease
St John’s wort  Hypericum perforatum

- 23 European studies: maybe useful for mild to moderate depression  BMJ 1996
- Pfizer study: not effective for major depression  JAMA 2001
- NCCAM study: not effective for major depression  JAMA 2002
- Decreased effects of indinavir, cyclosporin, irinotecan

NCCAM studies
- Minor depression
- Social phobia
- Obsessive-compulsive disorder
- Interactions with narcotic analgesics, oral contraceptives
Saw palmetto  Serenoa repens

- Earlier small studies: *maybe effective* for BPH symptoms
- Large study [225 men]: no improvement in moderate to severe BPH  
  *NEJM* 2006;354:557-66
- NOT enough evidence to support use for reducing size of BPH
- Side effects: tender breast, decline in sexual desire
Cranberry  Vaccinium macrocarpon

- Inconclusive results for UTI

NCCAM studies for

- Prevention of UTI
- Prevention of formation of dental plaque
Echinacea Echinacea purpurea, E pallida, E angustifolia

- 2 NCCAM studies have not proven that echinacea shortens the course of colds or flu. 

- Other studies show beneficial effects. 
  Seminars in Integrative Medicine 2003;1:106-11

- Results not consistent. 
  Linde K. Echinacea for preventing and treating the common cold. Cochrane Library
Lycopene

Insufficient scientific agreement from clinical trials to conclude an effect on any disease (cardiovascular disease and prostate cancer)

US FDA, Health Claims that Meet Significant Scientific Agreement
Soy

- Research suggests that daily intake of soy protein may slightly lower levels of LDL ("bad") cholesterol.
- Some studies suggest that soy isoflavone supplements may reduce hot flashes in women after menopause. However, the results have been inconsistent.
- There is not enough scientific evidence to determine whether soy supplements are effective for any other health uses.
- NCCAM studies: effects on women's arteries and bones after menopause.
Vitamin C

- Scant evidence that these combinations of antioxidant supplements (Vit C and E) have any cardiovascular health benefits.

Office of Dietary Supplements
Heart Protection Study
Vitamin E

- Two large primary prevention trials on lipids reported clinically insignificant (but statistically significant) changes.

- No evidence that vitamin E alone or in combination has a clinically and statistically significant favorable or unfavorable effect on lipids. (after at least 8 weeks and no more than 24 weeks supplementation with vitamin E alone and in combinations in doses ranging from 100 IU to 1,200 IU)

Office of Dietary Supplements
Beta-carotene, Vitamin A, vitamin E

- Cochrane methodology
- Treatment with betacarotene, Vitamin A or Vitamin E may increase all-cause mortality
- Further studies needed for Vitamin C and selenium

Bjelakovic G et al. Mortality in randomized trials for primary and secondary prevention. JAMA 2007;287:842857
The value of coenzyme Q10 supplementation in patients with CVD is still an open question, with neither convincing evidence supporting nor refuting evidence of benefit or harm.

Office of Dietary Supplements
Carnitine

• Often promoted as an aid for weight loss, to improve exercise performance, and to enhance a sense of well-being
• Healthy children and adults do not need to consume carnitine from supplements, as the liver and kidneys produce sufficient amounts from the amino acids lysine and methionine to meet daily needs
• Not an essential nutrient


NIH Office of Dietary Supplements
Omega 3 fatty acids

Alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic (DHA)

• Anti-inflammatory and anti-clotting effects, based on RCTs
• Raise blood levels of DHA, and slow down the progression of abnormal thickening of artery walls due to fatty deposits
• Lower incidence of irregular heartbeats
• Help lower blood levels of triglycerides and cholesterol among patients with diabetes and metabolic syndrome
Omega 3 fatty acids

- **Recommendations:** 2 servings (about 8 ounces) of fish per week *(American Heart Association)*
- Up to 12 ounces per week for pregnant, nursing mothers, and young children *(Environmental Protection Agency)* of fish low in mercury like catfish, tuna
- **Supplements may be considered under medical supervision;** individuals with high blood triglycerides may consider up to 2-4 grams of EPA and DHA per day provided as capsules.
- More definitive clinical trials are needed before relatively high intakes (1-2 grams/day) of omega-3 fatty acids for either primary or secondary prevention are recommended.
<table>
<thead>
<tr>
<th>EFFECTIVE</th>
<th>FISH OIL, NIACIN</th>
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<tr>
<td>LIKELY EFFECTIVE</td>
<td>OAT BRAN, PLANT STEROLS AND STANOLS, PSYLLIUM, RED YEAST RICE</td>
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<td>POSSIBLY EFFECTIVE</td>
<td>SOY, ARTICHOKE, BARLEY INOSITOL</td>
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<tr>
<td>INSUFFICIENT EVIDENCE</td>
<td>POLICOSANOL</td>
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<td>POSSIBLY INEFFECTIVE</td>
<td>GARLIC GUGGULIPID</td>
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### ‘SUPPLEMENTS’ USED FOR DIABETES

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<tr>
<td>PSYLLIUM, GUAR GUM, OAT BRAN, SOY, GINSENG, CHROMIUM, PRICKLY PEAR CACTUS, ALPHA-LIPOIC ACID</td>
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<td>CASSIA CINNAMON, BANABA, BITTER MELON, FENUGREEK, GYMNEMA, STEVIA</td>
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<td>SELENIUM</td>
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‘SUPPLEMENTS’ USED FOR OBESITY

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<td>BEAN POD, CHITOSAN, GLUCOMANNAN, GUGGUL</td>
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<td>HOODIA</td>
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<td>BITTER ORANGE, ARISTOLOCHIA</td>
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<td>GARCINIA, INULIN</td>
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CONCERNS ON USE OF SUPPLEMENTS

People perceive products from natural sources as safe.

SOME HERBS ARE HARMFUL
- Mahuang
- Aristolochia

SOME HERBS INTERACT WITH DRUGS
- Ginkgo
- Garlic
CONCERNS ON USE OF SUPPLEMENTS

People use ‘supplements’ as medicines. Regard supplements as alternative to mainstream medicines.

REGISTRATION OF SUPPLEMENTS DOES NOT ENTAIL THE EFFICACY EVALUATION

• ‘No approved therapeutic claims’
CONCERNS ON USE OF SUPPLEMENTS

People easily succumb to word-of-mouth and aggressive marketing.

‘PANACEAS’ COME AND GO

- Comfrey, noni, bee pollen, honey
- Mahogany, narra, VCO
- Pitupito

CLAIMS IN DIRECT MARKETING BASED ON

- Traditional use
- Theory
- Testimony
RECOMMENDATION

Congruence in the evaluation and registration of products

- INTRINSIC PROPERTY OF PRODUCT
- TERMINOLOGY FOR CLASSIFICATION
- APPROPRIATE INDICATION
- APPROPRIATE CLAIM
GENERAL TERMINOLOGY FOR CLASSIFICATION OF PRODUCTS

- FOOD
- HEALTH SUPPLEMENT
- TRADITIONAL MEDICINE
- MEDICINE
RECOMMENDATION:
Some objective sources of information

<table>
<thead>
<tr>
<th>Source</th>
<th>Website</th>
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<tr>
<td>Cochrane Collaboration</td>
<td><a href="http://www.cochrane.org">www.cochrane.org</a></td>
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<td>European Union Food Safety</td>
<td><a href="http://www.europa.eu">www.europa.eu</a></td>
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<tr>
<td>Natural Standards</td>
<td><a href="http://www.naturalstandards.com">www.naturalstandards.com</a></td>
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<td>National Drug Information Center</td>
<td><a href="mailto:ndic@druginfo.ph">ndic@druginfo.ph</a></td>
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RECOMMENDATION

For practitioners

• Rationally use ‘supplements’ with proven efficacy and safety: VIT A, IODINE, ZINC, IRON, FOLIC ACID, FISH OIL / OMEGA 3, PROBIOTICS

• Discourage use of ‘supplements’ which have been proven to be harmful: KAVA

• Always ask use of ‘supplements’ in medical history taking: GINKGO
RECOMMENDATION

Counsel patient on wholistic approach to health

• Feed your body right
• Exercise
• Do not smoke
• Drink moderately, if you must
• Manage stress
• Feed your soul
Thank you!