

# TAPS | therapeutic advertising pre-vetting service

<b>GUIDELINE 3</b> <b>NHPaDS</b>	<b>Risk Information for Consumers</b>
Last Updated	July 2016
What kind of product is this guideline for?	<b>Natural Health Products and Dietary Supplements</b>
What is the purpose of this guideline?	To provide background and guidance on the inclusion of appropriate risk information in advertisements for natural health products.

**BACKGROUND**

Natural Health Products and Dietary Supplements are generally regarded as lower risk products than those classified as medicines. However these products are not exempt from any risk. Labels for products where there is potential risk of an adverse reaction or interaction with medicines should include risk information so that the consumer can be informed at the time of purchase.

The Dietary Supplements Regulations 1985 has the following requirement for labels in section 5 (1);

*(i) a warning in any case where a danger exists if an overdose is taken:*

The ASA Therapeutic and Health Advertising Code (THAC) Principle 1, states;

*Advertisements must observe a high standard of social responsibility particularly as consumers often rely on such products, devices and services for their health and wellbeing.*

Based on this principle, it is appropriate to include warning statements for some ingredients for some natural health products in certain advertisements. This would help ensure that the consumer is well informed prior to purchase of the product. Whilst there is no legislated requirement to include risk information in advertisements and there is no specific code requirement to include risk information, in some situations the inclusion of risk information would be considered 'observing a high standard of social responsibility'.

## GUIDANCE

The ASA THAC Principle 1, Guideline 1 (a) has the following required statement for all advertisements for Natural Health Products and Dietary Supplements, regardless of the ingredients; *Always read the label. Use only as directed.*

Where a natural health product is likely to be taken when medical intervention would be important after a short time, the following statement should also be included; *If symptoms persist see your healthcare professional.*

It may also be important in some cases to have "do not exceed the recommended daily dose" or "incorrect use can be harmful" if there are risks for the consumer when the product is not taken strictly as directed. In some cases it may be necessary to include the statement "Do not take the entire bottle (or container)" if there are potential issues with over-dose.

In situations where consumers are already prescribed dietary supplements or natural health products by a health professional then the advertiser should not state that the consumer should go off these products and simply use the advertised product. Reference should be made to the advice and supervision of the health professional.

Below are some examples where inclusion of specific risk information in an advertisement would be considered as 'observing a high standard of social responsibility' as per the ASA TPAC;

- (1) An advertisement for a product that contains St John's Wort has information about the health benefits of this ingredient. The advertisement is placed in a consumer magazine directed toward the elderly. In this situation, a risk statement should be included.

*St. John's Wort affects the way many prescription medicines work, including oral contraceptives. Consult your Doctor.*

- (2) A product containing St John's Wort is advertised in a pharmacy flyer. Only the label and price is visible. In this case, a warning statement is not considered necessary.
- (3) A product containing Bee Venom is advertised on a website directed to the consumer. There is content that covers the health benefits of the ingredient. In this situation, a risk statement should be included.

*Contains bee venom. People allergic to bee stings should not use this product.*

- (4) A product containing Glucosamine derived from Crab Chitin is advertised in a brochure to consumers with specific joint health needs. The advertisement has content that covers the health benefits of glucosamine. In this situation, a risk statement should be included.

*Derived from Crab Chitin. People allergic to shellfish or seafood should not use this product*

- (5) An herbal product to support weight management appears in a strip-ad on a website. Only the product label is visible. No risk information is needed in this situation.

The following table contains a comprehensive list of ingredients with known risks and the recommended risk statement that could accompany advertisements for products that contain these ingredients and where it is considered appropriate to observe a high standard of social responsibility. It is not a complete list and if a product is advertised and that product contains an ingredient(s) with known risks then a responsible advertiser should include appropriate risk statements.

Ingredient	Potential Risk	Recommended Warning Statement
St. John's Wort (Hypericum Perforatum)	Potential interactions with medicines e.g. AIDS medicines like indinavir, immunosuppressive medicines like cyclosporin, heart disease, depression, anticonvulsants, cancers, oral contraceptives. (Generally reduction in blood levels of the prescription medicine)	<i>St. John's Wort affects the way many prescription medicines work, including oral contraceptives. Consult your Doctor. Do not take if pregnant.</i>
Glucosamine Sulphate	To support healthy joints and cartilage. Derived from the sea from crab chitin. People allergic to shellfish and seafood should avoid use.	<i>Derived from Crab Chitin. People allergic to shellfish or seafood should not use this product</i>
Chondroitin	If derived from shark and not bovine sources, people allergic to shellfish and seafood should avoid use.	<i>Derived from Shark cartilage. People allergic to shellfish or seafood should not use this product</i>
Products of Shellfish Origin e.g. Chitosan, Green Lipped Muscle extract	These products should carry a warning for potential allergic reactions.	<i>People allergic to shellfish or seafood should not use this product.</i>
Guarana & Caffeine	Caffeine content could be additive to coffee and other drinks which contain caffeine.	<i>Contains caffeine [state quantity per dosage unit or per mL or per gram of product]. Caution for children and people who are sensitive to caffeine.</i>
Gingko Biloba	Support for brain function and circulation to the brain. Potential interaction with anticoagulants (blood thinning medicines). Altered bleeding times. Warning for patients prior to surgery.	<i>Gingko Biloba may affect the way prescription medicines work. Consult your Doctor. Avoid taking if you are on blood thinning medicines or before surgery.</i>
Glycyrrhiza Glabra [Whole Root Liquorice only]	Support for settling gut and stomach. Possible increase in blood pressure and fluid retention owing to effect on cortisol.  <u>Note: for DGL or deglycyrrhizinated liquorice this warning is not necessary as it does not have this side effect.</u>	<i>People on prescription medicines check with your doctor first. May increase blood pressure. Care required for people on blood pressure medicines.</i>
Kava Kava	Support for a calm and restful night sleep. Potential liver toxicity for people with liver disease. Caution for	<i>People on prescription medicines check with your doctor first. May potentiate the effect of hypnotic medicines. Care with driving and operating machinery.</i>

	people on hypnotic medicines and when driving or operating machinery.	<i>People with liver disease should not use this product.</i>
Valerian	Support for a restful night sleep. May interact with some prescription medicines and potentiate the effects of hypnotic medicines.	<i>People on prescription medicines check with your doctor first. May potentiate the effect of hypnotic medicines. Care with driving and operating machinery.</i>
Gymnema Sylvestre  Chromium  Momordica Charantia (Bitter Lemon)  Fenugreek Fibre  Silymarin from Milk Thistle	Herbs in Weight Products can alter the blood sugar levels and glucose metabolism.  These ingredients may lower blood sugar levels and could affect medication of diabetics, particularly as a number of diabetic patients could also be obese.	<i>People with diagnosed diabetes should check with their doctor as blood sugar levels could be altered when using this product.</i>
Olive Leaf Extract Astragalus  Ligusticum  Larch Aranogalactans  Echinacea  Berberine	Products which help support the immune response should not replace appropriate anti-infective treatment. Products with these ingredients should not be called alternative anti-virals or anti-infectives.	<i>Do not use in place of prescribed anti-virals or anti-infectives.</i>
Vitamin A	General warning for Pregnant Women. Vitamin A has potential teratogenic effects in large doses, so professional advice is recommended.	<i>Pregnant and breastfeeding women should not exceed 300 micrograms (1000 IUs) per day. If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist. Vitamin A can cause birth defects.</i>
Bee Venom Products	These products should have a clear warning for people who are allergic to bee stings.	<i>Contains bee venom. People allergic to bee stings should not use this product.</i>
Products for men's sexual performance	These products should have a warning for men with heart disease as men between 50-75 are likely to be users of these products.	<i>Men with heart disease and conditions like angina should check with their doctor before using this product.</i>

Selenium	Toxic in high doses.	<i>This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</i>
Fallopia multiflora & Fallopia japonica	May harm the liver in some people.	<i>Warning: Fallopia multiflora (or japonica) may harm the liver in some people. Use under the supervision of a healthcare professional.</i>
Black cohosh	In very rare cases, black cohosh has been associated with liver failure.	<i>Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.</i>
Phenylalanine	Warning for phenylketonurics.	<i>Phenylketonurics are warned that this product contains phenylalanine.</i>
Teucrium	May harm the liver in some people.	<i>WARNING: Teucrium may harm the liver in some people - use only under the supervision of a healthcare professional.</i>