

IADSA NEWSFLASH

SEPTEMBER 2007

CONTENTS

INTERNATIONAL DEVELOPMENTS

CODEX: Questions on sweetener and colours
Agenda for nutrition committee meeting

AFRICA

SOUTH AFRICA: New food labelling laws proposed
Product recall for Damiana

EUROPE

EUROPEAN UNION: 'Orientation paper' on nutrient levels published
Health claims update
Report on consumer understanding of claims
Harmonised approaches to risk assessment
Emerging risks
Review of comments on EFSA fee proposals
EFSA meetings: Nutrient Profiling; Food Safety
Associations to meet EFSA top officials
Postponement of new fish oils rules agreed
Maximum levels for heavy metals update
EU rapid alerts for supplements
Botanical supplements update

GERMANY: ECJ advocate general overrules decision on garlic supplements

ITALY: Article 13 claims submission
Botanical re-approved for supplement use

SPAIN: ECJ ruling on failure to implement directive

SWEDEN: Guidance on article 13

UNITED KINGDOM: Tighter rules may affect supplement imports
FSA revises advice on colours
Safety of Pau Pereira questioned

NORTH AMERICA

CANADA: Import legislation to be reviewed

UNITED STATES: FDA to consider nutrition symbols
FDA advice on 'sugar free' claims
New FDA guidance on exports
FDA launches food safety measures
Association surveys supplement analytical methods
New reference standard for Gingko
Media to be responsible for misleading advertising?

Association urges FDA to provide guidance on pending AER requirements

SOUTH WEST PACIFIC

AUSTRALIA: Trans-Tasman harmonisation

INDEX OF ASSOCIATION CONTRIBUTORS

KEY EVENTS

IADSA

The International Alliance of Dietary /Food Supplements Associations was founded in 1998 to address the globalization of dietary supplement markets and increasing regulatory challenges. IADSA brings together 59 dietary supplement associations with the aim of building a sound legislative and political environment for the development of the dietary supplement market worldwide.

IADSA serves its worldwide network of associations and companies by:

- Providing a fast flow of regulatory and policy information on dietary supplements, ensuring that there is an awareness and understanding of new developments.
- Coordinating strategy and action on global regulatory issues, particularly in relation to Codex Alimentarius initiatives.
- Widening and deepening the network of associations around the world by helping the establishment of new dietary supplement associations and supporting existing national associations.
- Organizing global and regional events to promote dialogue on the scientific and regulatory issues underpinning the dietary supplement market.

INTERNATIONAL DEVELOPMENTS

◆ CODEX

QUESTIONS ON SWEETENER AND COLOURS

Following the adoption this year of a number of key sweeteners and miscellaneous additives, Codex continues the 'cleaning-up' exercise of the General Standard for Food Additives (GSFA) addressing now the last sweetener of the list of those used by the food supplement industry and a long list of colours. The electronic working group led by the US that has the task to provide recommendations to next year's meeting of the Codex Committee on Food Additives has started its work and a number of discussion papers have been made available to working group's members.

IADSA's technical advisors are currently evaluating the documents and will be seeking further information from IADSA members in order to prepare the comments that will be submitted to the working group to ensure that the sweetener, Aspartame-Acesulfame salt, and colours used by the food supplement industry are recommended to be included in the GSFA and if possible at the levels used by our industry.

For further information, contact the IADSA Secretariat at secretariat@iadsa.be

AGENDA FOR NUTRITION COMMITTEE MEETING

Several issues of high importance to IADSA member associations will be discussed at the November meeting of the Codex Nutrition Committee in Germany:

- Provisions on Dietary Fibre (where one of the main issues is the challenges of analysing fibre in foods - necessary if claims for the role of fibre in reducing cholesterol are to be made): IADSA comments submitted to the Nutrition Committee earlier this year support to continue working on the Codex draft definition of dietary fibre rather than taking as the starting point the rather limited definition by the World Health Organisation which was adopted last year.
- The Scientific Basis of Health Claims: draft comments prepared by the Scientific Group have been circulated to IADSA members and will be submitting to the Nutrition Committee very shortly.
- Application of Risk Analysis Principles: the Scientific Group is currently evaluating this text for potential comments that may deem necessary.
- Addition/Revision of Nutrient Reference Values: a working group led by Korea, and of which IADSA is a member, will soon finalise its discussions and a report should be circulated shortly.
- Amendment of the Codex Principles on the Addition of Essential Nutrients to Foods: a discussion paper for this work is expected by Canada. A key aspect of this proposal is the Canadian suggestion to address the addition of bioactive substances to foods.

For further information, contact the IADSA Secretariat at secretariat@iadsa.be

AFRICA

◆ SOUTH AFRICA

NEW FOOD LABELLING LAWS PROPOSED

New regulations for the labeling and advertising of foodstuffs have recently been gazetted. The Foodstuffs, Cosmetics and Disinfectants Act (54/174) aims to close loopholes and align more closely with international standards and guidelines regarding health claims on foodstuffs. Stakeholders have until 20 October to comment.

The South African Health Products Association (HPA) has set up a task team to examine the draft regulations and to make any necessary proposals, especially in relation to those health products which come under the scope of the new regulatory proposals – in particular, probiotics, beverages and energy bars.

Source: HPA

PRODUCT RECALL FOR DAMIANA

Several members of the South African Health Products Association (HPA) have been asked by the Department of Health Medicines Regulatory Authority (MRA) to remove products containing the herbal ingredient Damiana on the grounds that it is a banned substance in South Africa and could not be submitted as a complementary medicine.

The HPA has responded to suggest that Damiana has been incorrectly banned because it has a good safety profile, has Generally Recognised as Safe (GRAS) status in the United States and is included on the Australian Herbal TGA list as a 'Listable Active' which allows its inclusion as an excipient or active in listed or registered products. It has also been rated by the US Food and Drug Administration as appropriate for use as a flavouring in a number of products including frozen dairy deserts, candy, baked goods, puddings and gelatin as well as alcoholic and non-alcoholic beverages.

Source: HPA

EUROPE

◆ EUROPEAN UNION

'ORIENTATION PAPER' ON NUTRIENT LEVELS PUBLISHED

The European Commission has recently made available to interested parties its 'Orientation Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs', which takes into account 58 responses.

The paper does not give specific suggestions for levels, but recognises that:

- safety levels for micronutrients have been produced by the EVM & the US Institute of Medicine (as well as Scientific Committee for Food/European Food Safety Authority)
- a number of micronutrients had very high tolerable upper intake levels and may not need to have maximum permitted levels for supplements (MPLs) set for them – for instance, Vitamin B1, Vitamin B2, Vitamin B12, Biotin, Pantothenic acid
- it is necessary to look at intake data across Europe probably using the most recent, good quality national surveys.
- It is necessary to 'share' the potential total intake amongst food, fortified food & supplement sources
- a 'more cautious' approach could be taken on the vitamins & minerals where the safety margin is low.

Overall, the paper is generally regarded as a balanced document which clearly sets out the views received and the issues that arise - and it suggests some possible options that could enable levels to be set. It will now be discussed at a meeting of the '*Expert Group on food supplements and on the addition of vitamins and minerals and of certain other substances to foods*', that is being held today.

For more information on the Commission documents and responses to them, see:

http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

Source: EHPM

HEALTH CLAIMS UPDATE

Article 13 (generic) claims: Several associations belonging to the European Federation of Associations of Health Product Manufacturers (EHPM) have now submitted the industry list of 'generic' claims to their national food authorities, who then have the task of passing the list on to the European Food Safety Authority for approval. It is understood that some national authorities are carrying out quite detailed checks of the over 750 claims included on the list before passing it on to European Food Safety Authority (EFSA), whereas other are not.

Children's claims – Article 14: The Commission has adopted and proposed two amendments setting a transition period for children's claims that have been used in compliance with national provisions before 19 January 2007:

- EU member states that have already evaluated and authorized these claims should present reports to the Commission showing the relevant scientific substantiation by January 31st 2008, after which they will go to EFSA.
- Claims not evaluated and authorized in a Member State can continue to be used, providing an application for authorization is made before 19 January 2008. In both cases, if the final decision from EFSA is negative, the claim must be phased out within six months.

Both these proposals must now be approved by the European Parliament and the Member States. The proposed amending Regulation is available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0368en01.pdf

EFSA Guidelines on Article 14 submissions: EFSA have now officially released *Scientific and Technical Guidance for the preparation and presentation of the application for authorization of a health claim* covering the requirements for submissions for reduction of disease risk claims and claims referring to children's development and health. Despite industry comment on the draft Guidelines, the data requirements for the application remain highly onerous and extremely challenging for most small and medium enterprises.

Source: EHPM

REPORT ON CONSUMER UNDERSTANDING OF CLAIMS

A Committee of the International Life Sciences Institute (ILSI), chaired by IADSA Scientific Group member Professor David Richardson, has recently produced a report entitled, '*Consumer Understanding of Nutrition and Health Claims; Sources of Evidence*', which is to be published in the British Journal of Nutrition in September.

The report has been issued in response to concerns expressed by industry in relation to the European Union Nutrition and Health Claims Regulation which lacks clear criteria by which to evaluate consumer understanding from a consumer science perspective.

The document focuses on the type of data and information that could be needed to provide evidence that the average consumer adequately understand a particular claim, and, after exploring several different methodologies, it proposes a case specific approach using a stepwise procedure for assessing consumer understanding of a claim.

The proposed ILSI methodology will now be presented to the European Commission. For further details, see: www.europe.ilsa.org/publications/Articles/consumersciencearticle.htm

Source: EHPM

HARMONISED APPROACHES TO RISK ASSESSMENT

A draft mandate for fostering harmonised risk assessment approaches in Member States was approved at the 25th Plenary meeting of the European Food Safety Authority (EFSA) Scientific Committee.

A report summarizing the existing guidelines, guidance and quality management documents in EFSA and in the Member States which have been developed for risk assessments, with advice on specific methodologies which require further harmonization will be prepared by December 2008.

Source: EHPM

EMERGING RISKS

The 25th Plenary meeting of European Food Safety Authority (EFSA) Scientific Committee has adopted a draft definition of emerging risk, prepared by the Committee's emerging risks Working Group: *'Having regard to Articles 23f and 34 of Regulation (EC) 178/2002, an emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard'*. The definition will now be published on the EFSA website:

www.efsa.europa.eu

A new EFSA Scientific Cooperation Working Group (ESCO) has now been set up to continue to work on this issue, together with additional experts from various European Union Member States and EFSA's scientific panels, and a new Unit on Emerging Risks is also to be set up to support the ESCO Working Group.

Source: EHPM

REVIEW OF COMMENTS ON EFSA FEE PROPOSALS

The European Food Safety Authority (EFSA) has now published a review of comments received in response to its public consultation on the advisability and feasibility of EFSA charging fees for processing authorization files. 51 response were received, 16 from European Union Member States.

The majority of Member States were not in principle opposed to a fee system, but were concerned about the feasibility of such a scheme, the need to safeguard EFSA's independence, and the creation of additional administrative and financial burdens for small and medium enterprises.

The majority of stakeholders were entirely opposed to the introduction of fees, or considered that they should only be charged where a market authorization is granted to a specific authorization holder.

The main difficulties foreseen by most respondents were:

- Authorization procedures for certain foods and substances are mainly aimed at giving general approvals for the benefit of all operators and provide little proprietary data protection
- As a consequence of the above, the complexity of establishing a fee system given the difficulty identifying those liable to pay fees.

The results of the review will now be fed into EFSA's reflection on the next steps to be taken.

Source: EHPM

ASSOCIATIONS TO MEET EFSA TOP OFFICIALS

Following a less than satisfactory meeting with the European Food Safety Authority (EFSA) in June of this year, the European Federation of Associations of Health Product Manufacturers (EHPM), together with the European Responsible Nutrition Alliance (ERNA) and the European Botanical Forum (EBF) have for some time been seeking a further meeting with EFSA's top officials, particularly to address the following issues:

- The Annexes to the Food Supplements Directive
- EFSA's approach to the list of claims proposed under Article 13 of the Nutrition and Health Claims on Foods Regulation
- The status of EFSA's project on botanicals.

Now, a response has been received from EFSA's Deputy Executive Director and Director of Science, offering a meeting with himself, EFSA's Executive Director, and technical experts. It is expected that a date for this important meeting will be announced shortly.

Source: ERNA

POSTPONMENT OF NEW FISH OILS RULES AGREED

Further to the report in the previous Newsflash, at a recent meeting the European Commission advised Member States of the problems Third Countries were experiencing in implementing the new rules on the production and export of fish oils for human consumption.

The Commission therefore put forward proposals to revise the rules by limiting the application of the legislation only to the refinement of fish oil, or by postponing the date of the entry into force of the Regulation from 31st October 2007 to the same date in 2008.

The decision of the Member States was to maintain current European Union rules, but to postpone the date of entry into force.

Source: EHPM

MAXIMUM LEVELS FOR HEAVY METALS UPDATE

Further to the report in the July/August edition of the Newsflash, a meeting has been held between top European Commission officials and representatives of the European Federation of Associations of Health Product Manufacturers (EHPM) to address the Commission's proposal for maximum levels for heavy metals in food supplements.

While it was clear that the Commission appreciated the problems potentially faced by industry (they reiterated that their goal is not to force products off the market), they confirmed that Member States wished to agree maximum levels for finished products, which in their view was the easiest option for control authorities to enforce.

The Commission also said that only when they have all available data will they be able to judge whether the various levels proposed are manageable for industry, and asked EHPM to submit as much data as possible by the end of September. The Commission will then review it prior to the next meeting of Member States at the end of October.

Source: EHPM

EU RAPID ALERTS FOR SUPPLEMENTS

A high number of alerts for food supplements is included in the 'Rapid Alerts' notified to the European Commission by European Union (EU) Member States for the past four months (weeks 17 – 32).

The main reasons for the notifications are irradiated herbal ingredients, heavy metal contamination, and unauthorized novel food ingredients. These problems have been found in most EU Member States, but particularly in Germany and the United Kingdom and in Norway, Malta and some eastern countries.

Source: EHPM

BOTANICAL SUPPLEMENTS UPDATE

The Minutes of the 25th Plenary meeting of the European Food Safety Authority (EFSA)'s Scientific Committee confirm that a guidance document, '*Safety assessment of botanicals and botanical preparations used in food as supplements*' prepared by the Botanicals Working Group was presented to the meeting. The document does not cover novel foods and Genetically Modified Organisms as they are subject to other specific regulations.

Two compendia were also presented:

- Compendium 1 lists botanicals and botanical preparations that have been considered for a food and/or food supplement use and that have been reported to contain toxic or psychotropic substances.

- Compendium 2 lists botanicals and botanical preparations that have been considered for food and/or food supplement use and have also been reported to have a medicinal use.

The documents will be updated according to comments made by the Committee members and the intention is then to submit the Guidance and the Compendia for possible adoption at the September plenary meeting of the Scientific Committee.

The Working Group has also identified the need to test the proposed guidance with a number of case studies, and this task is to be assigned to an EFSA Scientific Cooperation Working Group (ESCO), thereby involving further Member States.

Source: ERNA

◆ GERMANY

ECJ ADVOCATE GENERAL OVERRULES DECISION ON GARLIC SUPPLEMENTS

In the face of Germany's current practice to classify garlic supplements as medicines, the recent European Court of Justice Advocate General's opinion that the intended use of garlic supplements is not indicated or recommended for treating or preventing illnesses, and furthermore, it is not typically presented as a medicinal product, demonstrates support for the important principle of 'intended use' in distinguishing between medicinal products and food supplements.

The European Commission had taken Germany to court because it did not consider garlic supplements to be medicinal products. Instead it considered them as widely available foodstuffs whose sale should not be restricted, and that limitations proposed by the German authorities were a clear-cut example of national overregulation, creating unnecessary burdens for industry.

Source: BLL

◆ ITALY

ARTICLE 13 CLAIMS SUBMISSION

The Italian Ministry of Health has confirmed the deadline of end October to submit generic health claims to be included in the national list.

Claims submissions can also be made in English and the format proposed by CIAA/EHPM/ERNA can be used. The Ministry indicated that it will undertake a limited pre-screening, evaluating the relevance/seriousness of the provided claims substantiation references before inclusion of the claims on their

national list, although it has not specified the criteria. The selection task for the national list compilation will be undertaken by a claims expert group within the Ministry Consultative Commission on dietetics and nutrition.

The Ministry has not yet issued any official Article 13 claims submission guidelines nor indicated whether guidelines will be published.

Source: AIIPA / FEDERSALUS

BOTANICAL RE-APPROVED FOR SUPPLEMENT USE

The Italian Ministry of Health has recently re-approved for food supplement use of the plant *Desmodium adscendens*, a vine which grows wild in the Amazon rainforest of Peru and other South American countries and on the West Coast of Africa. It is also commonly known as 'Peruvian Royal', 'Amor Seco'/'Pega Pega' in Peru and 'Strong Back'/'Back relax' in Belize. The leaves and stems are the parts generally used in food supplements.

Following a safety re-evaluation (which included new scientific evidence), by the Ministry of Health Commission on dietetic foods and nutrition (CUDN, 'Commissione Unica di Dietetica') the botanical, which was previously included on the Italian negative list of herbs, has now been withdrawn from this list and re-approved for food supplement use

Source: AIIPA

◆ SPAIN

ECJ RULING ON FAILURE TO IMPLEMENT DIRECTIVE

Despite being advised by the Spanish government that the draft of a new Royal Decree was in process, the European Commission has initiated an action against Spain for being in breach of its obligations to implement Directive 2004/24/EC, the Traditional Herbal Medicinal Products Directive, by 30th October 2005.

As a result, the European Court of Justice (ECJ) has ruled against Spain stating that it has failed to fulfill its obligation of implementing the Directive.

Source: AFINUR

◆ SWEDEN

GUIDANCE ON ARTICLE 13 CLAIMS

The Swedish National Food Agency (NFA) has recently updated their homepage concerning health claims. Besides explaining the content of Regulation 1924/2006 on nutrition and health claims and presenting links to

other relevant homepages, NFA has also presented guidelines for stakeholders on how to compile an Article 13 list. Interestingly, these guidelines are based on explanatory notes made by trade organizations such as the Confederation of the Food and Drink Industries of the European Union (CIAA), the European Federation of Associations of Health Product Manufacturers (EHPM) and the European Responsible Nutrition Alliance (ERNA). Since NFA is using these explanatory notes as their own guidelines one would expect that the NFA will accept the format presented in the list prepared by CIAA, ERNA, EHPM and the European Botanical Forum.

For further information on the Swedish guidance for Article 13, please go to: http://www.slv.se/upload/dokument/livsmedelskontroll/narings_och_halsopast_aenden/livsmedelsverkets_vagledning_for_art_13%201.pdf

Source: FSE

◆ UNITED KINGDOM

TIGHTER RULES MAY AFFECT SUPPLEMENT IMPORTS

The UK Food Standards Agency (FSA) has recently issued for comment some proposed revisions to its Feed and Food Controls (England) Regulations 2006 which could result in delays in manufacturers receiving imported products.

Under the new proposals, revenue and customs official would have the legal right to withhold consignments of non-animal origin pending inspection by local or port health authorities, and there would be a prohibition on the imports of feeds and foods that do not meet EU law. (Similar regulations already exist for products of animal origin).

Source: HFMA

FSA REVISES ADVICE ON COLOURS

Research commissioned by the Food Standards Agency (FSA) and carried out by Southampton University has suggested that eating or drinking certain mixes of certain artificial food colours together with the preservative sodium benzoate could have negative effect on children's behaviour. As a result, FSA is advising parents of children showing signs of hyperactivity that cutting these colours from their diets might have a beneficial effect.

The colours in question are Sunset yellow (E110), Quinoline yellow (E104), Carmoisine (E122), Allura red (E129), Tartrazine (E102), Ponceau 4R (E124) and Sodium benzonate (E211).

Initial meetings with the food industry have been held and the report has been forwarded to the European Food Safety Authority (EFSA) for consideration. EFSA has since confirmed that the study will be taken into consideration by its

AFC Panel on additives, flavourings, processing aids and materials in contact with food, as part of its current safety review.

Source: CRN

SAFETY OF PAU PEREIRA QUESTIONED

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has recently written to companies with interests in herbal products following an information request from Belgium concerning the use of herbal products containing Pau Pereira.

The Belgian concerns are:

- Botanical confusion between plants/species with the same common name: 'Pau (ou Pao) Pereira'. These include certain Apocynaceae, some of which are toxic due to their alkaloidic compounds that can intercalate into the DNA chains and induce mutagenic and teratogenic effects.
- The risk to the general public, including pregnant women, considering the current claims, e.g. 'Enhancing the body's natural defences'.

The MHRA are aware that there are no UK licensed medicines containing 'Pau Pereira', but seek information as to whether unlicensed products may be available.

Source: HFMA

NORTH AMERICA

◆ CANADA

IMPORT LEGISLATION TO BE REVIEWED

As a result of concerns about the quality of imported products, most recently, toothpastes with unacceptable levels of diethylene glycol, the Canadian government is carrying out a review of its import legislation. Its intention is then to amend the Hazardous Products Act so as to ensure that Canadian consumers are protected from counterfeit or dangerous imported products.

Source: CHFA

◆ UNITED STATES

FDA TO CONSIDER NUTRITION SYMBOLS

In advance of a public hearing in September, the US Food and Drug Administration (FDA) has been inviting comment on the use of nutrition symbols on food products. This practice is increasingly used by manufacturers to provide consumers with easily understandable nutrition information, but there are many different symbol programmes with different nutrient requirements.

Issues on which FDA seek information include the usefulness of such symbols, the consistency of the standards they are based on, and the costs involved in their use.

The FDA is also interested in consumer research, including consumer understanding of symbols, attitudes towards products carrying symbols compared with those that do not, and whether symbols are effective in promoting purchase.

Source: NPA

FDA ADVICE ON 'SUGAR FREE' CLAIMS

The US Food and Drug Administration (FDA) has issued a letter to manufacturers expressing its concerns about the number of products that contain claims regarding the absence of sugar (such as 'sugar free'), but fail to bear the required disclaimer that the foods are not 'low' or 'or 'reduced' in calories, or do not place it appropriately or make it sufficient conspicuous.

The FDA has advised that it is highlighting accurate claims as a regulatory priority, and that it will take appropriate action against products that fail to meet the requirements of the regulation that defines 'sugar free'.

Source: NPA

NEW FDA GUIDANCE ON EXPORTS

The US Food and Drug Administration (FDA) has recently issued new '*Guidance for Industry on Exports under the Food and Drug Administration Export Reform and Enhancement Act*'.

The main thrust of the Guidance is that any FDA-regulated product made in the United States for export to a foreign country must be in compliance with that country's laws and regulations.

Source: CRN USA

FDA LAUNCHES FOOD SAFETY MEASURES

The US Food and Drug Administration (FDA) has launched a national programme, the '*Manufactured Food Regulatory Programme Standards*', aimed at the adoption of more uniform, equivalent and high quality regulatory programmes by the state agencies responsible for regulating facilities that manufacture, process, pack or hold food under FDA's jurisdiction. Currently activity in these areas can vary from state to state, leading to potential food safety problems.

The new standards define best practices for the critical elements of state regulatory programmes, and include staff training, inspection, quality assurance, food defence preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management.

Source: UNPA

ASSOCIATION SURVEYS SUPPLEMENT ANALYTICAL METHODS

The American Herbal Products Association (AHPA) is surveying the members of its Analytical Laboratories Committee to determine the methods they use to analyse the vitamin and mineral content of supplement products.

The results of the survey, which is carried out on the understanding that many of the methods in use may not be suitable for all individual supplement products, may then be presented at the forthcoming Office of Dietary Supplement Analytical Methods and Reference Materials Programme Stakeholders Meeting to help determine whether the National Institute of Health should invest in developing analytical methods for quantifying vitamins and minerals in dietary supplements.

Source: AHPA

NEW REFERENCE STANDARD FOR GINKGO

The US National Institute of Standards and Technology (NIST) has issued a group of Standard Reference Materials for the herbal supplement, *Ginkgo biloba*. Their purpose is to help researchers validate the accuracy of analytical methods for flavonoids and terpene lactones (constituents which are associated with the perceived efficacy of Ginkgo), as well as toxic trace elements in the herb, including arsenic, cadmium, lead and mercury.

Source: AHPA

MEDIA TO BE RESPONSIBLE FOR MISLEADING ADVERTISING?

In a major policy shift, the US Federal Trade Commission (FTC) may soon hold media companies liable for preparing and running allegedly deceptive advertisements for someone else's products or services. In a recent letter

closing an investigation of a national radio network that ran purportedly deceptive diet-supplement ads, the FTC likened media companies to advertising agencies, which have historically been liable for deceptive advertisement in cases where an agency was actively involved in developing and producing the advertising campaign.

To require media companies to substantiate advertising claims would increase cost, preclude or severely limit advertising by many smaller advertisers and raise significant issues with regard to commercial speech.

Source: AHPA

ASSOCIATION URGES FDA TO PROVIDE GUIDANCE ON PENDING AER REQUIREMENTS

With the December effective date drawing closer on a new serious adverse event report (AER) law for dietary supplements and over-the-counter medicines, the American Herbal Products Association (AHPA) has made several suggestions and requests to help industry comply.

AHPA wrote the US Food and Drug Administration (FDA) in August about the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which goes into effect on December 22, 2007. That new law requires that information on serious AERs be submitted to FDA, but the details of the law require FDA guidance.

AHPA stated that it was necessary that FDA implements the law and provides reasonable guidance so that all the large and small companies in this industry can comply with.

In its letter, AHPA suggests:

- That domestic addresses on labels may be a street address, city, State, and ZIP code; except the street address may be omitted if it is shown in a current city directory or telephone directory as provided for by current law.
- That companies importing products to the US may provide either a domestic address or a domestic telephone number that can be reached by mailing or by dialling from within the United States, whether or not the mail is responded to or the telephone is answered by someone within the US.
- That the language specifically referring to AER reporting on labels is not required by the law, and may be confusing to consumers.

AHPA requests that FDA:

- Revise the MedWatch form to create a form for AERs associated with dietary supplements, based on stakeholder input.
- Issue a Small Business Compliance Guide to provide information and examples for small businesses, including a decision tree, for evaluating

- whether an adverse event associated with a dietary supplement is a serious adverse event that is required to be reported to FDA.
- Clearly communicate that the compliance date for any label changes that may be necessary to meet requirements of the new law is December 22, 2008, as stated in the Senate Report accompanying the legislation.

AHPA's letter to FDA is available on the association's website at http://www.ahpa.org/Portals/0/pdfs/07_0813_AHPA_SAERequests.pdf.

Source: AHPA

SOUTH WEST PACIFIC

◆ AUSTRALIA

TRANS-TASMAN HARMONISATION

Further to the report in the July/August Newsflash, the industry group the Complementary Healthcare Council of Australia (CHC) has now expressed its disappointment at the New Zealand government's decision not to currently proceed with the establishment of a joint agency with Australia to regulate therapeutic products.

CHC's Executive Director, Dr. Tony Lewis, is quoted as saying that '*The majority of CHC members both here and in New Zealand are supportive of a joint agency and we have been actively involved in assisting with the development of a model that supports the continued delivery of safety, high quality and cost effective complementary healthcare products in both the Australian and New Zealand Communities.*'

It is understood that CHC intends to continue to work closely with the governments of both Australia and New Zealand on the development of a joint regulatory model.

Source: CHC

INDEX OF ASSOCIATION CONTRIBUTORS

- AFINUR (Spanish Association of Phytotherapy and Responsible Nutrition): afinur@afinur.net
- AHPA (American Herbal Products Association): ahpa@ahpa.org
- AIIPA (Associazione Italiana Industrie Prodotti Alimentari): a.paonessa@aiipa.it
- BLL (German Federation for Food Law and Food Science): srams@bll.de
- CHC (Complementary Healthcare Council of Australia): chc@chc.org.au
- CHFA (Canadian Health Food Association): awilkie@chfa.ca
- CRN (UK) (Council for Responsible Nutrition): juliehcrn@aol.com
- CRN (US) (Council for Responsible Nutrition): webmaster@crnusa.org
- EHPM (European Federation of Associations of Health Product Manufacturers): secretariat@ehpm.be
- ERNA (European Responsible Nutrition Alliance): secretariat@erna.be
- Federsalus (Italy): federsalus@federsalus.it
- FSE (Sweden) (Föreningen Svensk Egenvård): info@svenskegenvard.se
- HFMA (UK) (Health Food Manufacturers' Association): hfma@hfma.co.uk
- HPA (Health Product Association of Southern Africa): bruce@vhf.co.za
- NPA (US) (Natural Products Association): natural@naturalproductsassoc.org
- UNPA (US) (United Natural Products Alliance): loren@unpa.us

KEY EVENTS: OCTOBER - DECEMBER

Date	Conference	Place
October 10 - 12	Natural Products Expo Japan 2007 www.naturalproductsjapan.com	Tokyo, Japan
October 30 - November 01	Food Ingredients Europe http://europe2007.fi-events.com/	London, United Kingdom
October 30 - November 01	Natural Ingredients - Exhibition & Conference www.ni-events.com	London, United Kingdom

November 06 - 08	Supply Side West - International Trade Show and Conference www.supplysideshow.com/west/	Las Vegas, NV, United States
November 12 - 16	Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) www.codexalimentarius.net	Bad Neuenahr, Germany
November 14 - 16	Cosmoprof Asia - Where beauty meets trends and Business www.cosmoprof-asia.com	Hong Kong, China
November 20 - 22	Health Ingredients Japan 2007 www.hijapan.info/en/	Tokyo, Japan
December 04 - 06	Executive Committee of the Codex Alimentarius www.codexalimentarius.net	Geneva, Switzerland

Prepared by the
INTERNATIONAL ALLIANCE
OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS
rue de l' Association 50
B-1000 Brussels
Tel: (00) (32) (2) 209 11 55; Fax: (00) (32) (2) 223 30 64,
E-mail: secretariat@iadsa.be - Website: www.iadsa.org

IADSA endeavours to check the veracity of information covered in the Newsflash, but cannot be held responsible for any inaccuracies in the articles published. Where available, IADSA provides links to other World Wide Web sites as a convenience to users, but cannot be held responsible for the content or availability of these sites