IADSA NEWSFLASH
FEBRUARY 2013

CONTENTS

KEY EVENTS

IADSA

The International Alliance of Dietary /Food Supplements Associations was founded in 1998 to address the globalization of food supplement markets and increasing regulatory challenges. IADSA brings together more than 50 food supplement associations with the aim of building a sound legislative and political environment for the development of the food supplement market worldwide.

IADSA serves its worldwide network of associations and companies by:

- Providing a fast flow of regulatory and policy information on food 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 food supplement associations and supporting existing national associations.
- Organizing global and regional events to promote dialogue on the scientific and regulatory issues underpinning the food supplement market.

INTERNATIONAL DEVELOPMENTS

CODEX

CCFO DISCUSSES STANDARD FOR FISH OILS

The Codex Committee on Fats and Oils (CCFO) discussed this month in Malaysia the Proposed Draft Standard for Fish Oils at Step 4 of the Codex procedure.

At the start of the discussion, there was a proposal to limit the application of the standard to fish oils used in food. Although food supplements are regulated as foods in most of the countries in the world, IADSA intervened to request that it is explicitly mentioned in the standard that it applies to food and food supplements to avoid any potential confusion and barriers to trade. The IADSA intervention was supported by a significant number of countries at the meeting and the CCFO finally agreed to include wording to reflect that the standard applies to food and food supplements.

Then when addressing the section on named fish oils and unnamed fish oils, the CCFO agreed that the standard should focus on those that are traded internationally in significant volumes.

Finally, the IADSA concerns on the scientific validity of the fatty acid profiles, as presented in Table 1 of the proposed draft standard as an identifier for named fish oils, were overwhelmingly supported by a large number of countries at the meeting and the CCFO agreed that the values and ranges of the profiles in Table 1 for the named fish oils need to

be scientifically validated with robust data as recommended by IADSA.

An electronic working group was established by the CCFO, led by Switzerland, to redraft the proposed draft standard taking into account data on the trade volumes of fish oils, scientific data to set fatty acid profiles as an identification tool of named fish oils and the comments expressed during the meeting on the various sections on the draft standard.

It was also agreed that the working group would meet in person one or two days prior to the next CCFO meeting in 2015 to facilitate the discussion at the plenary.

For further information, contact: secretariat@iadsa.org

Source: IADSA

A CODEX COMMITTEE FOR SPICES AND AROMATIC HERBS?

Codex is currently considering the establishment of a Committee for Spices, Aromatic Herbs and their formulations.

The proposal to establish a specific Codex Committee in this area came from India, on the grounds that a significant amount of spices, aromatic herbs and their formulations are internationally traded and that the absence of harmonised standards makes the trading of these commodities complex. As India pointed out, spices could not come within the scope of the Codex Committee on Fresh Fruits and Vegetables (CCFFV) as most are dried before trading. Equally, they are outside the scope of the Codex Committee on Processed Fruits and Vegetables (CCPFV) because raw spices and herbs are processed and dried to develop and fix their flavour and aroma, as opposed to fruits and vegetables that are processed and dried to extend their shelf life.

This proposal for a specific Committee is now supported by the Codex Coordinating Committee for Asia, and it is expected that the Codex Alimentarius Commission, the highest decision-making body in Codex, will consider its establishment at its next meeting in July. If created, IADSA would wish to be involved with the new Committee's work as a significant number of spice extracts and botanicals perceived as spices and/or aromatic herbs are used in dietary/food supplements.

Source: IADSA

ASIA

JAPAN

CC PROPOSALS FOR SUPPLEMENT LABELS AND CLAIMS

The Japanese Consumer Commission (CC) has published their proposals for labelling and claims of dietary/food supplements to the relevant authorities, the Consumer Affairs Authority (CAA) and the Ministry of Health, Labour and Welfare (MHLW).

The four main proposals are:

- The strengthening of actions to ensure the appropriateness of both labelling and advertising on dietary/food supplements. Both CAA and MHLW should accumulate and review data on theses issues, based on the current laws like the Health Promotion Act. With regard to the actions of institutions in relation to the Act against Unjustifiable Premiums and the Misleading Representations and the Health Promotion Act, CAA should take actions for some issues.

- The promotion of measures to ensure the safety of dietary/food supplements.

- The consideration of functional claims for dietary/food supplements. Firstly, claims for additional nutrients for Foods with Nutrient Function Claims (FNFC) should be considered. Secondly, rules should be considered for creating criteria to evaluate the efficacy of Foods for Specified Health Uses (FOSHU).

- The promotion of consumer understanding of the characteristics and role of dietary/food supplements.

Both CAA and MHLW have been asked to report progress on these proposals by July 2013.

Source: AIFN

CAA SURVEY AND ACTION ON INTERNET ADVERTISING

The Consumer Affairs Authority (CAA) recently announced the status of their surveillance for false and fraudulent labelling of dietary/food supplements sold through the Internet. During the past one year survey (October 2011 - September 2012), 458 operators were requested to improve the labelling of 559 products. All requests for improvement were carried out. CAA will continue to survey this form of advertising, and take appropriate actions as necessary.

Source: AIFN

NEW RULES FOR INTERNET AND MAIL ORDER SALES OF OTC DRUGS?

As the result of an illegal judgement by the Japanese Supreme Court on the prohibition of internet and/or mail order sales of Over The Counter (OTC) drugs which are regulated under Pharmaceutical law managed by the Ministry of Health, Labour and Welfare, a Panel to create new rules for internet and/or mail order sales of OTC has been established.

The first meeting of this panel was held recently to consider the content and scope of any new rules. At present, stakeholders have both positive and negative comments, depending on their particular standpoints. For example, from the safety point of view, chain drug stores and pharmacist associations insist on face to face sales from a pharmacist for some OTC drugs with strong medicinal properties.

Source: AIFN

EUROPE

EUROPEAN UNION

HEALTH CLAIMS GUIDANCE PUBLISHED

On 25 January 2013, the European Commission's new guidelines regarding the use of food-related health claims ("Guidelines") were published in the EU's Official Journal. The Guidelines are intended to clarify ambiguities regarding the specific conditions for health claims laid down in Article 10 of the EU Health Claims Regulation (1924/2006).

Article 10 of the EU Health Claims Regulation imposes a general prohibition on non-compliant health claims, requires that health claims are accompanied by certain mandatory information, and bans general, non-specific health claims unless they are accompanied by a specific authorised health claim.

The Guidelines, adopted in the form of an Implementing Decision (2013/63/EU), provide clarifications on:

- How to include mandatory information on the labelling, or alternatively in the advertising or presentation, of the food for which a health claim is made, in particularly with respect to generic advertising, distance selling and non-prepacked foodstuffs.

- The information that the mandatory information must convey to consumers, in light of food business operators' general responsibility to market food which is safe and not harmful.

- The circumstances in which the use of general, non-specific statements relating to health or well-being benefits of foods is permitted, including the need for a relationship between the general, non-specific statement and the accompanying specific authorized health claim.

Source: ERNA

FEE PROPOSALS FOR EFSA ABANDONED

The European Commission (EC) has published its Impact Assessment (IA) on the possibility of establishing fees for the work carried out by the European Food Safety Authority.

The IA has concluded that none of the options proposing the introduction of fees would bring a clear benefit to anyone involved. As a result, the proposal had been abandoned and the current funding framework remains in place.

The reasoning behind this decision includes:

- The predominant system of generic authorisations in the food legislation (e.g. one applicant submits an authorisation dossier and pays a fee but all operators benefit from the authorisation);
- The limited number of dossiers liable for fees;
- The pre-existence of fees paid by industry for the same authorisation dossiers in some sectors;
- The difficulty of adequately meeting the needs of 19 different sectors;

- The fact that the introduction of fees could affect the perception of EFSA's independence.

Source: ERNA

OBSERVERS AT EFSA SCIENTIFIC MEETINGS

Under its commitment to openness and transparency, the European Food Safety Authority (EFSA) is giving access to some scientific plenary meetings either in total or in part in its 2012/2013 programme. However, because of the confidentiality of certain regulated product application dossiers and the need to respect proprietary data not all agenda items of all meetings will be discussed in the presence of observers.

EFSA has stated its intention *'to make efforts to ensure that Observers gain a better understanding of how scientific risk assessment works at EFSA*,' and that they will *'endeavour to provide new opportunities for interaction with EFSA's scientific experts.'*

Upcoming Plenary meetings open to Observers**:**

- Plenary meeting of the Panel on Dietetic Products, Nutrition and Allergies (NDA), 20 March 2013
- Plenary meeting of the Panel on Genetically Modified Organisms (GMO), 17-18 April 2013
- Plenary meeting of the Panel on Contaminants in the Food Chain (CONTAM), 15-17 May 2013
- Plenary meeting of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 18-20 June 2013
- Plenary meeting of the Panel on Food Additives and Nutrient Sources Added to Food (ANS), 2-4 July 2013

Registration for upcoming open Plenary meetings will be gradually opened at the latest month before the respective plenary meetings.

Source: ERNA

NEW SEARCH ENGINE FOR EFSA WEBSITE

EFSA's website now has a new search engine. The new tool allows users to execute full text searches of all EFSA's outputs regardless of format, and refine their search according to type (scientific opinion in the *EFSA Journal*, news story, topic, etc), date and scientific panel. It also contextualises search queries to suggest similar or related terms and corrects mistyped queries.

For further detail, see: www.efsa.europa.eu

Source: EBF

CORRECTED LIMITS FOR SILICATE AND SILICON DIOXIDE

The draft Regulation amending and correcting the limits for silicon dioxide and silicate in Food Supplements has now been adopted. The Regulation will aim at reverting the conditions of use for these additives to *Quatum satis* as set in the original Directive. (The limit of 10000 ppm defined in Annex II of Regulation (EC) No 1333/2008 was an error that occurred in the transposition of the data for the additives in question).

The revised Regulation will be applicable from June 13.

Source: ERNA

GUIDANCE ON SUBSTANTIAL EQUIVALENCE

Novel foods are normally placed on the market after submission of a novel food application. Products which are substantially equivalent to a product already on the market can be placed on the market through a simplified notification procedure which in practice can be difficult to use.

Products that undergo this procedure must be shown to be 'substantially equivalent ' to an existing food or food ingredient as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substance. Now, the European Commission has developed for further discussion a guidance on the data that should be submitted when a request for an opinion on substantial equivalence is submitted. Requirements include:

- Administrative information. Name and contact details of the applicant.
- Compositional information. Detailed characterisation and specifications of the novel product that should be compared with only one existing food product. Analyses should be provided for a number of representative batches.
- Nutritional value and metabolism. Information on the bioavailability should be considered.
- Intended use. e.g. in food supplements or other specific food categories; levels of use should be specified. Requests for new uses, particularly if they are likely to result in consumption of the product by a wider range of the population or at higher levels when compared with the existing product, are not permitted under the simplified procedure.
- Level of undesirable substances. Presence and level of undesirable substances originating from environmental circumstances; processing and other contaminants, allergens, naturally occurring toxins and anti-nutrients, and undesirable microorganisms. Analytical proof on several batches.
- Other relevant data. Reports of safety studies; a proposal for labelling to demonstrate that consumers will be adequately informed of the nature of the novel ingredient, its intended use and any restrictions that may need to be respected; details of any monitoring that will be undertaken to provide ongoing assurance that the product is of appropriate quality with regard to its composition and the presence of undesirable substances.

The guidance will be published in the coming weeks on the Novel Food website of DG SANCO.

Source: ERNA

EFSA INITIATES FURTHER WORK ON CAFFEINE

The European Food Safety Agency (EFSA) has published a request to undertake further work on caffeine. In particular EFSA intends to initiate an extensive literature search and review of the retrieved literature in order to determinate the intake level of caffeine which would pose no safety concerns for the population.

This follows the decision of the Standing Committee of December during which several Member States had raised concerns in relation to:

- The potential health risks of caffeine consumption for people performing exercise.
- The validity of the safe daily intake proposed in the conditions of use for caffeine claims.

The requisition is not a self-mandate but a procurement (internal mandate) initiated by the NDA panel who can outsource some projects.

For further information, see: http://www.efsa.europa.eu/en/calls/procurement.htm

Source: EBF

SYNTHETIC ZEAXANTHIN AUTHORISED FOR SUPPLEMENT USE

Synthetic zeaxanthin has now been approved for use in the European Union (EU), which means that it can now be used in food supplements marketed in the EU.

As specified in the Annexe to Decision 2014/49/EU, zeaxanthin is permitted for use in food supplements at levels of intake up to 2 mg per day. The ingredient should be designated on the labelling as 'synthetic zeaxanthin'.

Source: ERNA

FRANCE

COMMITTEE DISCUSSES DRAFT BOTANICALS DECREE

As reported in the previous edition of the Newsflash, in December of last year the French authorities notified under the procedure of Article 19 of Directive 2000/13/EC and of Article 12 of Regulation (EC) No1925/2006 a draft Decree laying down the list of plants, other than mushrooms authorised in food supplements and their conditions of use. The draft measure provides *inter alia* for a positive list of plants and plant preparations which are allowed to be used in food supplements, and establishes conditions of use such as the maximum permitted level of certain metabolites and warning statements for some of them.

The draft was discussed at the February meeting of the European Union Standing Committee on the Food Chain and Animal Health (SCFCAH), where all the Member States of the EU are represented. Some delegations sought clarifications concerning the

authorisation procedure for a food business operator to follow so as to include substances in the positive list, and also whether the draft measure could interact with other legislation such as that for medicinal products. The Commission asked for further clarification on the justifications for the warning statements required for certain plants.

It was explained that the list may be updated regularly on the basis of applications for authorisation presented by operators according to the procedure laid down in the French Decree No 2006-352 on food supplements or on the basis of the mutual recognition clause. Established case law on the classification of a product as a medicinal or a food will be taken into account when permitting a product to be placed on the market as a food supplement. The French authorities also clarified that the warning statements required for specific groups of the population mainly come from the existing provisions of other Member States, and some result from different tests and evaluations carried out at national and/or European level.

Some Member States underlined the need to harmonise the various European national lists (such as the Belgian and Italian lists) of plants and plant preparations which can be used in food supplements, and it was noted that the Commission is still reflecting internally on the feasibility of harmonised rules for plants and their preparations used in food in the discussions on health claims on these substances.

The Commission will now express its opinion on the French draft Decree, taking into account the SCFCAH'S views.

Source: EBF

IRELAND

NEW CHAIRMAN FOR THE FSAI

The Food Safety Authority of Ireland (FSAI) has welcomed the appointment of Prof. Michael Gibney as its new Chairman. Prof. Gibney, who is Professor of Food and Health at University College, Dublin's (UCD) Institute of Food and Health, has a long and distinguished career as a world-leading expert in food science and nutrition.

According to Prof. Alan Reilly, Chief Executive, FSAI: "*Prof. Gibney will be a tremendous asset to our Board's cumulative deliberations. His appointment reaffirms our science-based ethos which underpins all the decisions, policies and actions of our organisation. He has an impeccable global reputation for research on food and nutrition and has served on a number of high-level advisory committees in this area, both nationally and at EU level.*"

Source: IHTA

UNITED KINGDOM

AGENCY PUBLISHES PRIORITIES FOR SCIENCE AND EVIDENCE

The Food Standards Agency has published its Forward Evidence Plan for 2013. The plan outlines priority science and evidence activities for the coming year, including potential areas for research funding and workshops that will help develop the Agency's evidence base.

For further details, see: food.gov.uk.

Source: CRN UK

NEW SUGGESTED LABEL MESSAGES FOR UK VITAMIN D SUPPLEMENTS

Last year the Chief Medical Officers in England, Scotland, Wales and Northern Ireland wrote to healthcare professionals to increase awareness of risk vitamin D deficiency. They recommended the use of vitamin D supplements for at risk groups such as pregnant women, infants and young children.

Now, to promote these recommendations and having consulted the main trade associations for food supplements, the UK Department of Health has produced some voluntary statements and is encouraging businesses to use them on their labels for products containing between 5 and 10 micrograms of vitamin D.

The recommended wording and conditions of use can be seen at: https://www.wp.dh.gov.uk/publications/files/2013/02/Wording-and-conditions-of-use-CMO-Vitamin-D-statement-05%E2%80%A6.pdf

Source: HFMA

TOLERANCES AND THE PRACTICAL APPLICATION OF EC GUIDANCE

Further to the report in last month's Newsflash on the European Commission's Guidance document on Tolerances for Nutrient Values, the UK Department of Health has advised stakeholders (both business and enforcement officials) that the guidance *'…represents a compromise between existing Member States practice',* and that they intend to take advantage of the time to the end of the transition period in December 2014 '…*to test the practicability of this guidance.*'

In particular they warn business against setting manufacturing processes to consistently run close to the upper tolerance for nutrients such as fats, salt and sugar or the lower tolerance for vitamins and minerals. They also set out a wide list of issues to be considered by enforcement officials when a sample is found that is outside the tolerance range prescribed in the guidance.

Feedback from industry and enforcement officials will be sought in 2014. Further details of the Guidance can be found on: http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

Source: HFMA

NOVEL FOOD APPLICATIONS

The Food Standards Agency (FSA) has received applications for novel food clearance from two novel foods and is now requesting comments from interested parties. One application requests an opinion on the 'equivalence' of a refined edible oil, derived from the seeds of the herbaceous plant *Buglossoides arvensis*. The oil is rich in omega-3 and omega-6 polyunsaturates.

The other is for sporopollenin shells where, according to the FSA, a company intend to fill the empty shells with ingredients such as fish oil and vitamin D.

For further information see:

- http://www.food.gov.uk/news-updates/news/2013/jan/novel-oil#.UQfop3bscng
- http://www.food.gov.uk/news-updates/news/2013/jan/novel-shells#.UQfo5Xbscng

Source: HFMA

LATIN AMERICA

CHILE

PROPOSAL TO BAN FOOD SUPPLEMENTS IN SCHOOLS

The draft regulation that amends the Chilean Food Sanitary Code, allowing the implementation of the Law 20.606 on Nutritional Composition and Advertising, was published in January by the Ministry of Health.

It includes the following restrictions concerning the use of food supplements and foods for sportsmen:

- Article 8: hereby added to Article 534, the following new final paragraph: "Food supplements may not be sold, marketed, promoted or advertised in nursery, primary or secondary schools."

- Article 9: hereby added to Article 539, the following new final paragraph: "Foods for sportsmen may not be sold, marketed, promoted or advertised in nursery, primary or secondary schools."

The draft regulation is available for download at the website of the Ministry of Health and the period for submitting comments has been recently extended until 16th March.

For further information, contact: secretariat@alanur.org

Source: ALANUR

NORTH AMERICA

CANADA

NEW RULES FOR NHPs AND 'FOOD-LIKE' SUPPLEMENTS

Temporary Exemption Numbers (ENs) for natural health products (NHPs) and 'food-like' supplements were granted while the Natural Health Product Directorate (NHPD) cleared its backlog of product assessments ceased as of February 2013. A nine-month transition period, ending in December 2013, will be granted to manufacturers, importers, etc. to clear stock of existing products without market authorisations.

After 1 December 2013, retailers and distributors will receive an additional nine months - until 1 September 2014 - to finish selling their stock of unauthorised products. After this time Health Canada's Compliance and Enforcement Policy will come into effect and no product without an NPN will be allowed in the marketplace.

Thus the only legal licence to sell an NHP on the Canadian marketplace is now a Natural Product Number, granted by the NHPD to signify a complete assessment for safety, efficacy and quality. This procedure should take no more than 180 days for products with unique claims or ingredients and 60 days for products that mirror existing monographs However, 'food-like' NHPs – products which are more like fortified foods, such as energy drinks, beverages, bars, etc. – will fall under a different system. This is because Health Canada considers that such products are being marketed as foods and thus consumed as foods and should consequently be regulated as such, away from the NHP regulations.

Marketers of 'food-like' products are now required to apply for a Temporary Market Authorisation (TMA) from the Food Directorate to sell their product. TMAs temporarily allow sale of the product, according to specific conditions, while Health Canada collects market and safety data and makes the necessary amendments to the Food and Drug Regulations.

Applying for a TMA is less demanding than applying for an NPN and a site license for importation is not required. However, the time for the government to respond to requests and grant a TMA is uncertain, and reformulations may be required.

Source: IADSA

UNITED STATES

ALOE VERA MONOGRAPH PUBLISHED

The American Herbal Pharmacopoeia (AHP) has released a monograph on the botanical materials aloe vera leaf, aloe vera leaf juice, and aloe vera inner leaf juice. Aloe Vera Leaf Juice and Aloe Vera Inner Leaf Juice is the first monograph of this kind on aloe vera (*Aloe vera* (L.) Burm. f., or *Aloe barbadensis* Mill.), which is one of the oldest and most widespread botanicals in the world.

The AHP monograph, which was supported by the International Aloe Science Council (IASC), establishes independent standards for the identity, analysis, and quality control of aloe vera juices. These standards include limiting the concentration of potentially carcinogenic phenolic compounds (aloins), while ensuring a minimum requirement of polysaccharides, the putative beneficial constituents of the juice products. The monograph also contains detailed analytical testing methods for the detection of adulterants that may appear in commercial aloe vera leaf and inner leaf juice products.

The monograph is available for purchase from the AHP website.

Source: AHPA

CALL FOR CANDIDATES FOR SUPPLEMENT ADULTERATION PANEL

In recent months, the Food and Drug Administration (FDA) has alerted consumers to more

than 180 cases of adulterated products, often with deceptive labelling information and containing active pharmaceutical ingredients (APIs) that may result in harm for to consumers. Categories most frequently adulterated are products marketed for sexual enhancement, weight loss and bodybuilding.

The United States Pharmacopoeia (USP) is now inviting qualified candidates to serve on the USP Intentional Adulteration of Dietary Supplements with Drugs Expert Panel. Members of this Expert Panel will develop screening methods for drugs as adulterants for dietary supplements based on the claimed benefits and similar drug effects of such adulterants. The methods, mostly based on chromatographic and spectroscopic techniques, will be developed to detect adulterants in suspected dietary supplements. Selected methods should have the merit of high specificity and wide applicability with sensitivity appropriate for the claimed effect. The ultimate goal of the Expert Panel is to draft a new general chapter containing written analytical procedures for the detection of intentional adulteration of dietary supplements with drugs.

USP is particularly seeking individuals with expertise in the areas of chromatographic and spectroscopic techniques with specific knowledge in natural products and dietary supplements.

Source: AHPA

FDA ISSUES FINAL RULE ON FOOD DETENTION

The Food and Drug Administration (FDA) has issued a final regulation that adopts, without change, the interim final rule (IFR) entitled "Criteria used to order administrative detention of food for human or animal consumption" that was published in the Federal Register on 5 May 2011 (the 2011 IFR).

This final rule affirms the IFR's change to the criteria for ordering administrative detention of human or animal food as required by the FDA Food Safety Modernization Act (FSMA). Under the new criteria, FDA can order an administrative detention if there is reason to believe that an article of food is adulterated or misbranded.

Source: CRN US

COMPANY SHUT DOWN FOR NON-COMPLIANCE WITH REGULATIONS

A federal judge has ordered a California company and its owner to stop manufacturing and distributing drugs and dietary supplements in domestic commerce until their manufacturing operations comply with the Federal Food, Drug and Cosmetic Act (the Act). The order was entered in response to a complaint filed by the U.S. Department of Justice, on behalf of the FDA.

The court found that the company and its owner violated the Act by failing to follow current Good Manufacturing Practice for drugs (Drug cGMP) and for dietary supplements (Dietary Supplement cGMP). The court also found that the defendants violated federal law by distributing unapproved new drugs in violation of the Act. Prior to entry of the court's order, the company manufactured and domestically distributed a variety of drugs and dietary supplements.

"The FDA continues to take strong enforcement actions against companies that fail to comply with federal drug and dietary supplement manufacturing regulations," said acting Associate Commissioner for Regulatory Affairs Melinda K. Plaisier*. "The actions we are taking are necessary to make sure that the drugs and dietary supplements consumers purchase have been manufactured in compliance with cGMP."*

Source: AHPA

TAINTED SUPPLEMENTS SEIZED

U.S. Marshals, acting on behalf of the U.S. Food and Drug Administration (FDA), have seized tainted dietary supplements from Florida-based company. The products may be unsafe because they contain an undisclosed active pharmaceutical ingredient.

Several of the seized products were found to contain sibutramine hydrochloride (sibutramine), the active ingredient in an obesity drug which was withdrawn from the U.S. market after clinical data demonstrated that it increased the risk of heart attack and stroke. The company markets its products with claims that its products can lower blood pressure and cholesterol, among others. Under the Federal Food, Drug and Cosmetic Act, products offered for such use are considered to be drugs, since they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Thus the company's products are drugs that have not been approved by the FDA for their claimed uses.

"Companies that distribute products containing undisclosed drugs are not only breaking the law, they are putting consumers at risk," said Howard Sklamberg, Director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research*. "With these kinds of hidden dangers, consumers cannot make informed decisions about the products they are taking."*

Source: AHPA

JUDGE GIVES FAVOURABLE RULING ON PROPOSITION 65

An important decision was recently made by a California Superior Court judge, when he ruled in favour of the defendants in a trial that involved Proposition 65 complaints that questioned whether products marketed as dietary supplements are "food" under California's Proposition 65's rule on exposures to "naturally occurring chemicals in a food."

The complaints, brought against three supplement manufacturing companies alleged that certain of the defendants' supplement products contained lead and challenged the long-established understanding that naturally occurring chemicals in dietary supplement products do not present exposures to these chemicals for purposes of Proposition 65. Under Proposition 65, consumer goods sold in the state must generally provide a "clear and reasonable warning" if chemicals listed by the state as carcinogens or reproductive toxicants are present above specified limits. For food products, the limits that trigger a warning requirement are those that are present in excess of any naturally occurring amount, including presence "as a result of absorption or accumulation of the chemical, which is naturally present in the environment" so long as the chemical "did not result from any known human activity."

In his decision, the judge ruled that the intent of the California Health and Welfare Agency was to adopt the same definition of "food" for Proposition 65 under California's Sherman

Food Drug and Cosmetic Law as was defined in federal law under the Food, Drug, and Cosmetic Act of 1938. Therefore, each of the products at issue is a dietary supplement and is classified as a "food."

Source: AHPA

SUPPLEMENT/DRUG INTERACTION REPORT PUBLISHED

The National Centre for Complementary and Alternative Medicine has recently released an 18-page summary of its March 2012 roundtable meeting to discuss dietary supplement-drug interactions. The roundtable meeting brought together researchers and other experts on dietary supplements (including herbs, botanicals, and other supplements) and drugs to discuss outcomes, methodologies, the state of the research, and prioritisation of a research agenda.

For further information see:
http://nccam.nih.gov/sites/nccam.nih.gov/files/HerbDrugInteractionsWorkshopSummary.pdf

Source: UNPA

FTC FINAL ORDER CONFIRMS REQUIREMENT FOR TWO RCTs

The Federal Trade Commission (FTC) has upheld a trial judge's decision, reported in last month's Newsflash, that a company deceptively advertised its pomegranate juice and supplement products.

FTC's final order bars the company from making any claim that a food, drug, or dietary supplement is "*effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease,"* unless the claim is supported by two randomized, well-controlled, human clinical trials (RCT).

This is a controversial move because the two RCT requirements for such disease claims mirrors FDA's basic requirement of at least two such trials to support the approval of most new drugs. It is expected that the company will appeal the judgement.

Source: UNPA

SOUTH WEST PACIFIC

AUSTRALIA & NEW ZEALAND

CONSULTATION ON ANZTPA THERAPEUTIC GOODS REGULATION

The Australian Therapeutic Goods Authority (TGA) and the New Zealand authority, Medsafe, are seeking comment and input from stakeholders on their discussion paper, which sets out the high level features of a possible framework for regulation of therapeutic products within the Australia New Zealand Therapeutic Products Agency (ANZTPA) as part of a joint scheme to regulate therapeutic products in Australia and New Zealand.

The Australian and New Zealand Governments announced their agreement to proceed with a joint scheme for regulation of therapeutic products in June 2011, along with the proposal that it be administered and overseen by the ANZTPA.

The discussion paper puts forward for comment the following issues:

- Medicines covered and Standards applied
- Manufacturing principles and licensing products
- Exemptions
- Post-market monitoring and compliance
- Spontaneous adverse event reporting and risk management
- Surveillance and testing
- Recalls & public notification
- Therapeutic products' seizure and promotion
- Provision of expert advice
- Fees and charges, and
- Review of decisions, approvals, classifications, statutory timeframes, conditions and data protection
- Obtaining information

Source: CHC

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KEY EVENTS 2013

Date	Conference	Place
March 06 - 07	Nutracon http://www.nutraconference.com/nutracon13/public/enter.aspx	Anaheim, CA, United States

Date	Conference	Place
March 06 - 10	SupplyExpo http://www.supplyexpo.com/engredea13/public/enter.aspx	Anaheim, CA, United States
March 06 - 10	Engredea Ingredients and Innovation Exposition http://www.engredea.com/engredea13/public/enter.aspx	Anaheim, CA, United States
March 06 - 10	Natural Products Expo West http://www.expowest.com/ew13/public/mainhall.aspx	Anaheim, CA, United States
March 07 - 11	Cosmoprof / Cosmopack www.cosmoprof.com	Bologna, Italy
March 18 - 22	Codex Committee on Food Additives http://www.codexalimentarius.org/meetings-reports/en/	Beijing, China
March 26 - 27	Vitafoods South America www.vitafoodsouthamerica.com	Sao Paulo, Brazil
April 03 - 05	WorldFood Uzbekistan http://www.ite-uzbekistan.uz/vis/worldfood/eng/index.php	Tashkent, Uzbekistan
April 08 - 12	Codex Committee on Contaminants in Foods http://www.codexalimentarius.org/meetings-reports/en/	The Hague, Netherlands
April 19 - 21	Cosmofarma Exhibition 2013 http://www.cosmofarma.com/index.asp	Bologna, Italy
April 30 - May 02	Supply Side MarketPlace http://www.supplysideshow.com/2012/marketplace/home.html	New York, United States
May 07 - 09	Food Ingredients Istanbul 2013 http://fi-istanbul.ingredientsnetwork.com	Istanbul, Turkey

Date	Conference	Place
May 14 - 16	Vitafoods Europe www.vitafoods.eu.com	Geneva, Switzerland
May 15 - 17	Codex Committee on Food Labelling http://www.codexalimentarius.org/meetings-reports/en/	Canada
June 25 – 27	Natural Products Association MarketPlace http://www.naturalmarketplaceshow.com/nm12/Public/enter.aspx	Las Vegas, NV, United States
June 25 - 28	Executive Committee of the Codex Alimentarius Commission http://www.codexalimentarius.org/meetings-reports/en/	Rome, Italy
June 26 - 28	Natural Ingredients / Health Ingredients China 2013 http://fiasiachina.ingredientsnetwork.com/home	Shanghai, China
June 26 - 28	Health Ingredients Philippines 2013 http://fiphilippines.ingredientsnetwork.com/	Manila, Philippines
July 01 - 05	Codex Alimentarius Commission http://www.codexalimentarius.org/meetings-reports/en/	Rome, Italy
July 14 - 16	Cosmoprof North America 2012 www.cosmoprofnorthamerica.com/	Las Vegas, NV, United States
August 06 - 08	Food Ingredients South America http://fi-southamerica.ingredientsnetwork.com/home	Sao Paulo, Brazil
August 26 - 29	13th International Nutrition & Diagnostics Conference http://www.indc.cz/en/	Olomouc, Czech Republic
August 29 - 31	Natural Products Expo Asia 2013 http://www.naturalproductsasia.com/ea13/public/enter.aspx	Hong Kong, China

Date	Conference	Place
September 07 - 10	25th SANA 2013 http://www.sana.it/en/	Bologna, Italy
September 11 - 13	Food Ingredients Asia - Thailand http://fiasia-thailand.ingredientsnetwork.com/	Bangkok, Germany
September 25 - 28	Natural Products Expo East http://www.expoeast.com/expoeast2013/public/enter.aspx	Baltimore, MD, United States
October 03 - 05	Food Ingredients India http://fiindia.ingredientsnetwork.com/	Mumbai, India
October 09 - 11	Health Ingredients Japan http://www.hijapan.info/eng/	Tokyo, Japan
October 30 - November 01	Worldfood Ukraine 2013 http://www.worldfood.com.ua/en/exhibition/about/	Kyiv, Ukraine
November 04 - 08	Codex Committee on Nutrition and Foods for Special Dietary Uses http://www.codexalimentarius.org/meetings-reports/en/	Germany
November 13 - 15	Cosmoprof Asia 2013 http://www.cosmoprof-asia.com/	Hong Kong, China
November 19 - 21	Food Ingredients Europe & Natural Ingredients http://fieurope.ingredientsnetwork.com/home	Frankfurt, Germany

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