alliance for natural health
good science and good law

ANH INNOVATORS CLUB BULLETIN

Sept/Oct 2007

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URGENT: calls for action - please see page 10

CONTENTS:

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Key EU/US Regulatory Developments:

EU Nutrition and Health Claims Regulations (Reg No 1924/2006) Update

As discussed in the last bulletin, the NHCR came into force EU-wide on 1st July 2007. The opportunity to submit claims closed at the end of September, but the ANH submitted 77 generic, non-disease risk reduction claims before the closing date. Apart from the claims we submitted on behalf of three of our IC members, we submitted a number of general claims to protect nutrients vital to the natural health industry.

In our view, a significant proportion of the 659 claims Federation of Associations of Health Product Manufacturers (EHPM) / European Responsible Nutrition Alliance (ERNA) Article 13 claims list, had not been adequately substantiated to ensure approval by the European Food Safety Authority (EFSA). The requirement is for claims to be substantiated on the basis of "generally accepted scientific evidence", and be well understood by the average consumer. In our opinion, there were some key nutrient claims that were very likely to be rejected because a large body of the scientific evidence had not been included in the submission. In many instances we saw that only very limited evidence had been used as substantiation for the claim, when in fact there existed a much larger body of clinical trials and other evidence, eg RCTs, reviews, animal studies, etc.

Stakeholders were required to submit claims to the competent authorities in each Member State and the ANH has now received confirmation that the UK Food Standards Agency (FSA) is in receipt of our submission and are screening the claims. The screening process will involve, among others, a check to ensure that the claim is eligible under Article 13, and is supported by appropriate references that will enable an assessment by EFSA. In addition the FSA will check that the claim, food category, food or food component is non-medicinal. They will be screening claims in batches by type of claim and notify the ANH of the outcome once the process is complete. Their reply also included the caveat that due to the large number of claims received it may be some time before we receive further contact. Stakeholders will have the opportunity to review successful claims before their addition to the UK Article 13 list, prior to submission to EFSA in January 2008.

The ANH is aware that the FSA has received in excess of 2,000 claims and that this is reflective of an overall picture from the other Member States. EFSA have expressed concern at their ability to handle the amount of claims that have been submitted and it is likely that the panel of 11 'judges' will have to be significantly increased if the 2 year deadline for assessment and completion of the list is to be achieved.

Basil Mathioudakis, head of food law, nutrition and labelling at the Commission said: "*I am a little bit concerned by the numbers which have been circulating*". He goes on to say: *"There is screening for some of them which will, I expect, reduce the numbers submitted to EFSA. I think the time will come for commission and member states to sit down and do some work before the community lists."* We trust that, should this eventuate, full scientific protocol in line with EFSA standards will still be maintained.

The issue of ensuring that claims are comprehensible to the 'average consumer' has been mired in uncertainty since no guidelines have been issued by EFSA concerning how much or what type of scientific evidence is needed, and how the 'average consumer' is defined.

Consumer understanding is apparently not assessed by EFSA, but on the subject of whether consumers understand the health claim, Mathioudakis said the Commission will try and tackle how claims are interpreted – possibly a return of the famous black box tactics the EC frequently employs.

We expect to see EFSA guidelines for Article 14 disease risk reduction claims, e.g. lowers blood cholesterol *or* reduces blood pressure, published in the near future. The ANH will then be in a position to give estimates on potential costs for those who require assistance in their compilation. For clarification, Article 14 claims are product related and will likely require product-specific human RCTs for substantiation, whereas Article 13 claims are for a particular nutrient and are generic.

The Article 13 claims submitted by the ANH are available on request. Please email Meleni Aldridge at mel@anhcampaign.org if you would like electronic or paper copies.

EU Maximum Permitted Levels (MPLs)

The subject of Maximum Permitted Levels (MPLs) remains a hot topic in the EU following the release of the European Commission's (EC) Orientation Paper in August 2007 (attached). Dr Robert Verkerk has just produced an ANH Position Paper on MPLs (dated 19 October 2007) entitled "*Towards a scientifically valid and proportionate approach to the setting of MPLs*" and this will be launched in Ireland and will be supported by an Irish Member of Parliament (Greens Party) following a full briefing on the subject in Dublin on 24th October 2007.

Dr Verkerk's briefing is attached along with this Bulletin.

AAHF/ANH submission to FDA on Draft Guidance for Industry: Evidence-based Review System for Evaluation of Health Claims

The American Association for Health Freedom (AAHF) and the ANH submitted a joint consultation response to the FDA on 7th September 2007 in response to requests for stakeholder comments relating to the evaluation of health claims in the US.

The two major weaknesses of this Regulation, in our view, are; a) over-reliance on randomised controlled trials (RCTs) for scientific evidence in relation to disease risk reduction claims (Article 14), and, b) a structure for approval which acts disproportionately against smaller food and dietary supplement manufacturers, suppliers and retailers, while these smaller businesses have been the pioneers of 'health foods'. We recognise the significant differences between the FDA's proposed approach and that of EFSA, and we recognise also that there are many details to be filled in with regard to finalisation of the FDA's proposed new procedures for SSA and qualified health claims. We strongly urge that full account is taken of the scientific complications associated with the evaluation of nutrients, given that intervention trials by their very nature cannot be controlled for in the same way as trials of pharmaceutical agents which are not components of a typical daily diet. We also urge that the FDA ensures that the final procedures in no way act disproportionately against small businesses and that the FDA remains true to its stated objective which aims to ensure, through the provision of adequate and truthful information on health claims, that "consumers can make a tangible difference in their own long-term health by lowering their risk of numerous chronic diseases".

In summary, the AAHF and the ANH requests that the FDA modify the guidelines to take into account ***all*** relevant scientific evidence from ***all*** research that has been done on foods or nutritional supplements. We request that special attention be paid to the extensive knowledge base in veterinary science and practices in formulating nutritional formulas and dietary supplements. We encourage the FDA to assemble an independent panel comprised of specialists from areas of dietary supplements, veterinary science, nutrition, biochemistry, and integrative medicine as well as consumers and academia.

Please find the full AAHF/ANH submission attached to this email.

US FDA publishes AER Draft Guidances

FDA has published separate draft guidances on adverse event reporting and recordkeeping for over-the-counter drugs and dietary supplements as required under the Dietary Supplement Nonprescription Drug Consumer Protection Act.

The guidances prepared by the Center for Drug Evaluation and Research and the Center for Food Safety and Applied Nutrition both say firms are not required to submit AERs to FDA when the persons making reports refuse to provide information on at least one way to contact them, although records of those reports should be maintained.

Neither draft addresses questions raised by the supplement industry, including whether firms must print some form of introductory language before contact information on their product

labels; whether labels must include a firm's street address as well as city and state information; and whether firms operating outside the U.S. can use U.S. addresses and phone numbers on their product labels but receive AER-related communications in their home countries.

Comments on the drafts will be due within 60 days of their publication in the Federal Register on Oct. 15.

Please follow the links for more detail, however the draft guidances are attached for your convenience.

Docket No. 2007D-0388, CFSAN 200741. Draft Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Record-keeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability. Pages 58313-58315 [FR Doc. 07-5074]

[TXT] http://www.fda.gov/OHRMS/DOCKETS/98fr/07-5074.htm
[PDF] http://www.fda.gov/OHRMS/DOCKETS/98fr/07-5074.pdf

Comments are due by December 14, 2007. Please email any comments or contributions you have to Meleni Aldridge at mel@anhcampaign.org. The ANH and its US affiliate, the American Association for Health Freedom (AAHF) will be making a submission and are very keen to collaborate with IC members.

International Developments

Codex Alimentarius

The next Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) meeting is in November in Germany, which will be attended by Dr Verkerk, as a scientific advisor to the National Health Federation, which as Observer status in Codex. Critical in influencing proceedings at the CCNFSDU is not only to have a clear position on various issues, in particular risk assessment, nutrient reference values and health claims, but also to have 'friendly' country delegations which can champion the cause.

We have been working, along with ANH/AAHF's new affiliate, the New Zealand Health Trust, to help bring the New Zealand government delegation up to speed on our concerns. Solid progress is being made, given the NZ Health Trust's effective campaign to help the government reject Trans-Tasman harmonisation of the Australian 'medicalised model' of natural health, which could have otherwise have had a potentially deleterious impact on New Zealand's vibrant and unique natural product market. It is hoped that New Zealand will replace South Africa which has stated its intention to be less outspoken against the general cut and thrust at Codex, possibly as a result of caving to sanctions that would have been imposed if it had maintained its stance against use of anti-retroviral drugs to combat HIV/AIDS.

US draft positions for CCNFSDU (21st September 2007)

Proposed Action- Nutrient Reference Values (#1.1-CCNFSDU; #1.5-CCFL). This proposal is to develop Nutrient Reference Values (NRVs) for labelling purposes for nutrients that are associated with both increased and decreased risk of non-communicable diseases. The United States recognises the importance of food label reference values as a means to help consumers determine the contribution of a food product to an overall healthful diet and as a basis for criteria for nutrition and health claims. The United States supports the ongoing work at the Codex Committee for Nutrition and Foods for Special Dietary Uses (CCNFSDU) to update and establish new NRVs for vitamins and minerals. In addition, the United States supports consideration of new work by CCNFSDU to develop NRVs for certain macronutrients associated with risk of non-communicable diseases. With both these efforts, we emphasize

the need for the NRVs to be based on sound science and on guiding principles. The United States recommends that Codex Committee on Food Labelling (CCFL) consider updating the list of mandatory nutrients for nutrition labelling (CCFL Proposed Action #1.3) as a priority. We further note the close relationship between these two action items, including consideration of nutrients that are of most public health significance globally, and recommend coordination between CCNFSDU and CCFL on both these items.

Please find the pdf of the US Draft Positions attached to this email.

Europe

Association of the European Self-Medication Industry (AESGP) conference

The AESGP conference was held on Wednesday 9th October 2007 and a summary of the main points follows:

- During the course of the conference, the possibility of the scope of the Traditional Herbal Medicinal Products Directive (THMPD) being expanded to encompass substances that are not herbal, such as vitamins and minerals, was mentioned by a number of speakers.

- In relation to the fact that, thus far, only 21 Member States have transposed the THMPD into their national legislation, Dagmar Roth-Behrendt, MEP, stated that there is the possibility of a court case if the directive is not transposed by all Member States.

- Discussing the nutrient dossiers that had been submitted under the provisions of the Food Supplements Directive, Basil Mathioudakis said that over 500 had been received, adding that: "*Many were very, very poor*." He went on to say some of the dossiers consisted of just a single page and that we are coming to a point where, unless further evidence is produced, the use of these nutrients will be curtailed. Hubertus Cranz, the Director General of AESGP, also made reference to this issue, saying that "*there doesn't seem to be scientific evidence*" for these substances.

  ANH Comment: In light of the comment above the ANH strongly advises companies once again, to consider making applications to the FSD Positive List for nutrients whose sale is currently protected by derogation dossiers (up until 31 December 2009).

- With reference to the report on other substances and nutrients in supplements (i.e. botanicals) that the Commission was required, under the provisions of the Food Supplements Directive, to submit to the European Parliament and the Council not later than 12 July 2007, Mathioudakis stated that the delay in producing this was because of a problem of resources. The Commission is working at a slower pace but is hoping that something will be completed early in the New Year, he said. Mathioudakis added that he did not see harmonisation of these substances coming very quickly in the Community.

  ANH Comment: It would appear that the initial information may take the form of an Orientation/Discussion paper. Innovators will be notified as soon as the ANH is aware of any release regarding how the EU EC is planning to handle substances other than vitamins and minerals.

- Fabio D'Atri (Policy Officer, Unit Food Law, Nutrition and Labelling, DG Health and Consumer Protection, European Commission) began his presentation by summarising the procedure by which the maximum amounts will be set. Essentially, this will be an implementing measure, he said, and will be done via the Regulatory Committee procedure. Apparently, the procedure begins with the preparation of a Commission proposal, which will be submitted to the Regulatory Committee for its Opinion. After "scrutiny" by the European Parliament (which, unlike the other steps, was merely shown in brackets on D'Atri's PowerPoint slide) the maximum amounts will be adopted by the Commission.

- Regarding the timescale for the setting of the maximum amounts, D'Atri pointed out that the Regulation on the Addition of Vitamins and Minerals to Foods states that "The Commission may, to this end, submit proposals for the maximum amounts by 19 January

2009." In doing so, D'Atri specifically stated that "it should not be forgotten that we are working on two categories of food." (i.e. Supplements and fortified foods). Given therefore that the methodology for setting the maximum amounts has been designed such that these two categories are very much intertwined, it would seem reasonable to assume, that this date may also prove to be applicable to supplements, at least in a general sense.

- D'Atri also ran through some of the issues that were raised in the Orientation Paper. From what he said, it was clear that one of the key difficulties that the Commission foresees concerns those vitamins and minerals for which, even at high levels of intakes, the risk of adverse effects appears to be extremely low or non-existent. D'Atri listed these low risk nutrients as being vitamin B1, vitamin B2, vitamin B12, biotin, pantothenic acid, vitamin K and chromium III. He also reiterated what had been outlined in the Orientation Paper on this issue, saying that maximum amounts should only be established on the basis of a risk-based analysis and that where there was no scientific basis for setting such levels they could be directly challengeable in front of a court. "Unfortunately," he went on "this position is not shared by the majority of Member States." He added that much of the concern is about vitamin K and chromium III and that the discussion is ongoing.

For the ANH perspective on MPLs, please refer to the ANH Position Paper on Maximum Permitted Levels, attached.

Brussels rules OK

ANH Comment:: We have included this very thought provoking article that appeared in the print edition of The Economist on 20th September 2007, as it aptly explains why all eyes should be trained on Europe and the edicts emanating out of Brussels. The ANH has long been aware that the EU model is being exported around the world, via Codex and other mechanisms eg the signing of the cooperation agreement on food and food safety in July between the US FDA and EFSA. The EU '*precautionary principle*' and the principle that the burden of proof for safety remains with industry, rather than regulators having to prove harm, appears to be gaining ground. Additionally, consider that trade harmonisation means that it is not at all profitable for large corporations to be producing US only versions of global brands.

We feel that the writing is most definitely on the wall and this is not a time for heads in the sand or for companies to trust previously lax regimes eg the US. The death knell of DSHEA has been sounding for a while now and the recent FDA consultations on Health Claims, AER Reporting and CAM all bear witness to the fact.

How the European Union is becoming the world's chief regulator

Sep 20th 2007, From The Economist print edition

A VICTORY for consumers and the free market. That was how the European Commission presented this week's ruling by European judges in favour of its multi-million euro fine on Microsoft for bullying competitors. American observers had qualms. Would a French company have been pursued with such vigour? Explain again why a squabble among American high-technology firms ends up being decided in Brussels and Luxembourg (where Euro-judges sit)? One congressman muttered about sneaky protectionism and "zealous European Commission regulators". It certainly seemed zealous of the competition commissioner, Neelie Kroes, to say that a "significant drop" in the software giant's market share was "what we'd like to see".

More broadly, the ruling confirms that Brussels is becoming the world's regulatory capital. The European Union's drive to set standards has many causes-and a protectionist impulse within some governments (eg, France's) may be one. But though the EU is a big market, with almost half a billion consumers, neither size, nor zeal, nor sneaky protectionism explains why it is usurping America's role as a source of global standards. A better answer lies in transatlantic philosophical differences.

The American model turns on cost-benefit analysis, with regulators weighing the effects of new rules on jobs and growth, as well as testing the significance of any risks. Companies enjoy a presumption of innocence for their products: should this prove mistaken, punishment is provided by the market (and a barrage of lawsuits). The European model rests more on the

"precautionary principle", which underpins most environmental and health directives. This calls for pre-emptive action if scientists spot a credible hazard, even before the level of risk can be measured. Such a principle sparks many transatlantic disputes: over genetically modified organisms or climate change, for example.

In Europe corporate innocence is not assumed. Indeed, a vast slab of EU laws evaluating the safety of tens of thousands of chemicals, known as REACH, reverses the burden of proof, asking industry to demonstrate that substances are harmless. Some Eurocrats suggest that the philosophical gap reflects the American constitutional tradition that everything is allowed unless it is forbidden, against the Napoleonic tradition codifying what the state allows and banning everything else.

Yet the more proscriptive European vision may better suit consumer and industry demands for certainty. If you manufacture globally, it is simpler to be bound by the toughest regulatory system in your supply chain. Self-regulation is also a harder sell when it comes to global trade, which involves trusting a long line of unknown participants from far-flung places (talk to parents who buy Chinese-made toys).

A gripping new book* by an American, Mark Schapiro, captures the change. When he began his research, he found firms resisting the notion that the American market would follow EU standards for items like cosmetics, insisting that their American products were already safe. But as the book neared completion, firm after firm gave in and began applying EU standards worldwide, as third countries copied European rules on things like suspected carcinogens in lipstick. Even China is leaning to the European approach, one Procter & Gamble executive tells Mr Schapiro, adding wistfully: "And that's a pretty big country."

The book records similar American reactions to the spread of EU directives insisting that cars must be recycled, or banning toxins such as lead and mercury from electrical gadgets. Obey EU rules or watch your markets "evaporating", a computer industry lobbyist tells Mr Schapiro. "We've been hit by a tsunami," says a big wheel from General Motors. American multinationals that spend money adjusting to European rules may lose their taste for lighter domestic regulations that may serve only to offer a competitive advantage to rivals that do not export. Mr Schapiro is a campaigner for tougher regulation of American business. Yet you do not have to share his taste for banning chemicals to agree with his prediction that American industry will want stricter standards to create a level playing-field at home.

Winning the regulatory race

One American official says flatly that the EU is "winning" the regulatory race, adding: "And there is a sense that that is their precise intent." He cites a speech by the trade commissioner, Peter Mandelson, claiming that the export of "our rules and standards around the world" was one source of European power. Noting that EU regulations are often written with the help of European incumbents, the official also claims that precaution can cloak "plain old-fashioned protectionism in disguise".

Europe had no idea the rest of the world was going to copy its standards, retorts a Eurocrat sweetly. "It's a very pleasant side-effect, but we set out to create the legislation we thought that Europe needed." At all events, America's strategy has changed. Frontal attempts to block new EU regulations are giving way to efforts to persuade Brussels to adopt a more American approach to cost-benefit analysis. That would placate students of rigour, who accuse some European governments of ignoring scientific data and pandering to consumer panic (as shown by European campaigns against "Frankenstein foods").

But rigour can quickly look like rigidity when it involves resisting competition. There is a genuine competition to set global regulatory standards, as Europe and America have discovered. There are also rising protectionist pressures. Perhaps zealous EU regulators may be what jumpy consumers need if they are to keep faith with free trade and globalisation. Viewed in such a light, even Microsoft's champions might hope that this week's verdict will help global competition in future.

* "Exposed: The Toxic Chemistry of Everyday Products and What's at Stake for American Power", by Mark Schapiro. Chelsea Green Publishing.

USA

Using Dietary Supplements in Patient Care Congressional Briefing

On Wednesday, September 26, 2007, several well-respected practitioners brought together by the AAHF, briefed Congress and the public on the use of dietary supplements in treating patients in the United States. Whether it's using dietary supplements as an alternative to drugs or surgery, finding relief when there is no other option, or saving the patient or taxpayer money, dietary supplements are a misunderstood, but vital component of the healthcare system.

Interestingly, according to the 129-page annual report of the American Association of Poison Control Centers, published in the journal Clinical Toxicology (Feb 2007), the National Poisoning and Exposure Database showed that there was not even one death caused by vitamins in 2005, yet dietary supplements are increasingly attacked and scrutinized.

Special Guest Speakers

"***Dietary Supplements – an Integral Component of Medical Care***" - Robban Sica, M.D., Practitioner of Integrative Medicine

"***Assisting Academic Medical Centers to Help Physicians Learn How Integrative Medicine and Dietary Supplements Can Improve Health Care Outcomes***" Woodson C. Merrell, MD, Sc.D.(hc), Chairman, Dept of Integrative Medicine, Beth Israel Medical Center, NYC

"***Mitigating Side Effects of Drugs with Dietary Supplements***" by James B. LaValle, R. Ph., C.C.N., M.S., Author of *Drug-Induced Nutrient Depletion Handbook* and *The Nutritional Cost of Prescription Drugs and Natural Therapeutics Pocket Guide*.

The briefing was moderated by Health Freedom Foundation board member, Sherri Tenpenny, D.O. and was very well received.

Programme:

Wednesday, September 26th

Senate Breakfast: 8:30-9:30a.m. Place: S-120, US Capitol and sponsored by Dr. Tom Coburn (R-OK)

House Lunch: 12noon-1:15pm: Place: 2247 Rayburn HOB and sponsored by Rep. Diane Watson (D-CA)

The briefing is open to the general public and to the media.

If you would like more information on the activities of our US affiliate the AAHF we would ask you to log on to www.healthfreedom.net and sign up for their news blasts. Alternatively, you can contact Brenna Hill, Executive Director, on (703) 294 6244. They are based in Washington, EST.

Significant Advances in Dietary Supplement Research Highlighted in 2006 Annual Bibliography (NIH report)

Studying the risks and benefits of dietary supplements has always posed unique challenges to researchers. To potentially support conclusive recommendations, these studies must enrol thousands of people and follow them for years. Additionally, as dietary supplements are regulated as foods, products can be sold without demonstrating efficacy. These factors can result in exaggerated research findings and conflicting health messages to consumers. To help advance the field and better inform the public, the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) has published the 2006 Annual Bibliography of

significant Advances in Dietary Supplement Research, highlighting 25 of the most significant dietary supplement research advances of the past year.

"When we initiated this project in 1999, our objective was to give researchers credit for raising the bar on supplement research and encourage others to follow their lead," said Paul M. Coates, Ph.D., director of ODS. "However, even the highlighted studies should be viewed as clues, not verdicts. Just because a study points to a compound having an interesting effect doesn't mean we are ready to make a broad public health recommendation." The Annual Bibliography is part of ODS' commitment to improve the quality of dietary supplement research and subsequent health messages.

The 2006 Annual Bibliography highlights emerging findings from a diverse array of laboratory and human studies. These include the potentially favorable effects of black cohosh in bone remodeling, ginkgo and omega-3 fatty acids in cognitive health and slowing the progression of Alzheimer's disease, resveratrol as an anti-inflammatory compound, and vitamin D in reducing prostate cancer risk.

"If these preliminary findings are substantiated in more rigorous studies, they could lay the foundation for some exciting health milestones – but only time will tell," said Rebecca B. Costello, Ph.D., editor of the Annual Bibliography.

Since its inception, ODS has used the Annual Bibliography to track emerging areas of dietary supplement research, identify needs, and make recommendations to the research community. The 2005 Annual Bibliography noted that study materials were not described sufficiently to enable other researchers to confirm the findings. "It is encouraging to see that many leading journals are now requiring authors to make their research more transparent by providing specifics about their study design," said Leila Saldanha, Ph.D., R.D., co-editor of the Annual Bibliography.

Now in its eighth issue, the Annual Bibliography included the top 25 papers based on the rankings of recognized experts in the fields of nutrition, botanical sciences, and public health. These were selected from about 300 papers that appeared in more than 45 peer-reviewed scientific journals. Over 50 percent of the studies that appear in the 2006 Annual Bibliography received funding from the NIH.

Copies of the Annual Bibliography of Significant Advances in Dietary Supplement Research 2006 may be downloaded from the ODS Web site at http://ods.od.nih.gov/Research/Annual_Bibliographies.aspx. Copies may also be requested by e-mail (ods@nih.gov), or by writing to the Office of Dietary Supplements at 6100 Executive Blvd., Rm. 3B01, MSC 7517, Bethesda, Md. 20892-7517, USA. This year's issue was released September 29, 2007 at the Food & Nutrition Conference & Expo of the American Dietetic Association (Philadelphia, Pa.) and American College of Nutrition Annual Meeting (Orlando, Fl.).

The Office of the Director, the central office at NIH, is responsible for setting policy for NIH, which includes 27 Institutes and Centers. This involves planning, managing, and coordinating the programs and activities of all NIH components. The Office of the Director also includes program offices which are responsible for stimulating specific areas of research throughout NIH. Additional information is available at http://www.nih.gov/icd/od/.

The mission of the NIH Office of Dietary Supplements (ODS) is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population. For additional information about ODS, visit http://ods.od.nih.gov.

The National Institutes of Health (NIH) – The Nation's Medical Research Agency – includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

http://www.nih.gov/news/pr/oct2007/od-01.htm

URGENT: calls for action
Company response required!

1. **Applications to Positive List of EU FSD called for**: Comments from the European Commission and AESGP at the AESGP conference in October 2007 highlight the risk to companies relying on derogation dossiers for product sales. The ANH strongly advises companies once again, to consider making applications to the FSD Positive List for nutrients whose sale is currently protected by derogation dossiers. The ANH can provide support through the IC membership for Gold and Silver members and through the ANH Consultancy Ltd if necessary. Key action point for 2008.

2. **Comments required for AAHF/ANH submission to FDA on AER Reporting**. The deadline for submission is 14th December 2007 and we would appreciate feedback from IC members on the Draft Guidances (attached). Please email comments to Meleni Aldridge at mel@anhcampaign.org and we will liaise with the AAHF.

3. **US Innovators:** Charitable tax deductible donations (for US individuals and companies) can be made to the ANH via our US affiliate the American Association for Health Freedom/Health Freedom Foundation. Donations should be sent to The Health Freedom Foundation clearly marked that the gift is in support of European or global work.

   The Health Freedom Foundation
   4620 Lee Highway, Suite 210
   Arlington, VA 22207
   Phone: 1800 230 2762 or 703 294 6244 or Fax: 703 624 6380

   Note to US companies: We would be extremely grateful if you could publicise this method of making charitable tax deductible donations to the ANH from within the US to your customers in any marketing literature you are about to send out.

For further information about the ANH, the ANH Innovators Club or ANH Consultancy Ltd, please contact:

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