Inside Aloe Online

In This Issue

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Director's Message

It is a time of great activity for the aloe vera industry...

In conversations I've had with some long-standing board members lately, comments have been made indicating this time period is something of a "perfect storm." Things have been getting busier and busier at the IASC as we move briskly through Spring and are building momentum into the Summer. In fact, things are heating up in a variety of areas - particularly in regards to regulatory issues with GMP's and further happenings in regards to the NTP study on aloe vera and the IASC efforts in response - the primary components of this "perfect storm." It is usually powerful conflict that drives change, and this "perfect storm" of regulatory and scientific challenges is indeed powerful. I thought a recap of some of the important items that have come about in the last few months would be in order.

On the good news front, a recent article in HerbalGram provided 2009 market sales data on supplements in the US, and likely no surprise to many, aloe vera was at the top of at least one of the lists. Based on what I've heard from many members, this trend seems to be continuing into 2010. The AHP monograph is also in the home stretch, going thru what we hope will be a few more "final reviews" prior to publication - certainly something for the industry to look forward to from a quality and compliance standpoint.

With regards to regulatory issues and in particular the dietary supplement Good Manufacturing Practices (GMP), in late March we saw an IASC member company receive a warning letter from the FDA based on inspections conducted in 2009. Though surely an unfortunate occurrence for the company involved, this does provide some very valuable information, insight and guidance into the FDA's possible thinking in regards to GMP compliance (and it should be noted that the IASC has been in contact and is providing what assistance we can to the company in question). The most immediate GMP issue we saw come out of this process was in regards to establishing identity.

Section 111.75 (a)(1)(i) of the GMP (21 CFR 111) states that prior to using any component that is intended to be a dietary ingredient at least one test or examination to establish the identity of the ingredient must be performed. The IASC has been working diligently on creating guidance for the industry in regards to the identification of suggested, appropriate tests or examinations that may be utilized for establishing identity, and hopes to have this document released in the coming weeks. This has been somewhat of a complicated process - in that we've heard in at least 2 different inspections, the FDA has indicated that NMR was "the" methodology to use - despite the fact that the regulations do not specify anything beyond the method must be scientifically valid or "fit for purpose" and provides a list of methodology examples.

With the June 25, 2010 deadline whereby ALL of the dietary supplement industry, regardless of size, will need to be in compliance is fast approaching, as I mentioned prior, we are aiming to have the aforementioned guidance released in the coming weeks which we believe will be assistive.

Where we currently stand with regards to the NTP study on the ingredient "aloe vera whole leaf extract (native)" has become a bit more complicated. I was informed that the NTP used as an ingredient an unfiltered aloe vera, which is an ingredient the vast majority of the industry does not sell/use in finished products for oral consumption. The organization has been diligently working with DBA Analytical, a toxicology group, on producing a risk assessment on aloe vera that will hopefully provide a safe use limit, or Lowest Observed Adverse Effect Level (LOAEL), for anthraquinones in aloe vera (a tele-conference meeting of the Characterization Working Group was held on May 14, 2010 to provide a complete update on this project. Interested members may join the working group - please contact me for details).

Mid-March, the NTP released the data tables from the study (this means the actual study was not completed/released - but per the NTP protocols, the majority of the data from the study is released for review by interested parties). Based on the information in the data tables, there is an increased likelihood the NTP will conclude that there is "clear evidence of carcinogenicity" in rats in regards to colon cancer and the ingredient used - whole leaf ale vera extract (native) - again, an unfiltered aloe vera ingredient we believe is not what the vast majority of the industry sells.

Aloe marketers need to be aware that as NTP is recognized as an "authoritative body" by the State of California, a report stating "clear evidence of carcinogenicity" could result in some kind of aloe vera ingredient listed on Proposition 65 (though we do not know exactly what the ingredient will be that is listed). This would certainly be a "worst case scenario" as the industry could be faced with both a regulatory and public relations problem.

We've been under the impression that there may be a way to sway the NTP via their Technical Review Committee's (TRC) review of the full study upon release, where we would be able to present data to encourage them to either derail the entire study and to not release their report, or to modify the report to clearly differentiate the ingredient used in the study from that used in finished products for oral consumption. What we now know is the TRC is a group of experts that reviews the study as it was conducted, and makes a determination as to the validity of the researchers' recommendations. Based on the lead DBA toxicologists input, we now understand that attempting to sway the TRC will be of no value - as that group will understand and make determinations only on the ingredient studied - not giving credence to its likeness or dissimilarity to products in commerce. However, we may have an alternate opportunity to urge NTP to do this...

The other efforts that have concurrently been taking place are the analysis of the NTP sample as well as aloe products for oral consumption for aloin content. The IASC funded the development of an HPLC method that has been used for this purpose. This information will be incorporated into the risk assessment, and a full report will be drafted demonstrating the difference between the NTP sample and marketplace products and delivered to the FDA and NTP, in an effort to get the latter organization specifically to clearly define and differentiate

in their Report on Carcinogens, in which this study will be published, between the ingredient tested and what the industry sells in products in commerce. What will also need to be considered are legal and possible PR efforts with California's OEHHA to work towards also ensuring that organization lists the ingredient favorably to the industry.

What these efforts do not cover is the wild cards - the media (potential backlash/negative reporting) and consumer perception. IASC staff and board will continue, however, to attempt to consider all of these factors in creating at the least an initial messaging campaign that will serve to provide a consistent and coherent voice for the industry.

Beyond these "major projects," several others actions have been ongoing, including the development and release of an aloe vera FAQ, the soon-to-be published (June 2010) chapter on aloe vera in the Office of Dietary Supplements Encyclopedia of Dietary Supplements, 2nd Ed., and the holding of the March board and membership meetings in Anaheim, California in conjunction with Natural Products Expo West. The new IASC corporate logo was also successfully rolled out, and we continue to see the certification program develop and grow, as well as take enforcement action against illegal users.

It is a time of great activity for the aloe vera industry...but working together I am confident we will weather the "perfect storm."

Devon Powell
Executive Director

Ullman Shapiro & Ullman INSIDE LAW

Washington Update

By Marc Ullman, Partner, Ullman, Shapiro & Ullman and IASC General Counsel

When Senator John McCain (R-AZ) introduced the so-called Dietary Supplement Safety Act of 2010 ("the DSSA"), industry reacted swiftly and surely to deliver a message that any such direct assault on the Dietary Supplement Health and Education Act of 1994 (DSHEA) would have severe consequences. After receiving thousands of emails and critical responses from groups as diverse as The John Birch Society and The Peace Team, Senator McCain was forced to seek help to extract himself from a potential political disaster. Coming to his rescue, long time industry champions Senators Tom Harkin (D-IA) and Orrin Hatch (R-UT) seem to have gotten Senator John McCain (R-AZ) to shift his focus from the draconian provisions of his S.3002 to working in a far more constructive manner with industry.

As a result, Senator McCain has announced that he no longer supports many of the provisions of his own proposal (product registration, unfettered recall authority for FDA, an "approved" dietary ingredient list) and has pledged to work with Senators Hatch and Harkin on constructive changes to pending Food Safety Legislation (S.510) as well as the DSHEA Full Implementation Act that is designed to direct FDA to finally give full force and effect to many long-neglected provisions of that law including providing industry with real guidance on New Dietary Ingredients and enforcement against rouge companies.

While this immediate crisis seems to be under control that does not mean that it is safe to turn our attention away from Washington. The DSSA continues to be pushed by the United States Anti-Doping Agency with backing from deep-pocket partners such as the National

Football League, Major League Baseball and other sports associations seeking to divert attention from the abuse of steroids and other performance enhancing substances by their athletes.

Moreover, several other issues with the potential to impact the dietary supplement industry in general and the Aloe trade in particular make it imperative that we not turn our attention away from Washington as the distractions of summer approach.

FTC

The first of these issues has to do with the Federal Trade Commission Reauthorization tucked away in H.R. 4173, the Wall Street Reform and Consumer Protection Act of 2009. Buried in this massive piece of legislation is a provision that would amend the Federal Trade Commission Act by removing existing procedural safeguards on the rulemaking and enforcement capabilities of the Federal Trade Commission ("FTC" or "Commission"). Make no mistake about it, this is a matter of serious concern that has the potential to severely restrict the way dietary supplements (and many other consumer goods and services) are marketed. Under H.R. 4173, the FTC would no longer be required to seek Congressional approval before undertaking formal rulemaking procedures.

This procedural safeguard was instituted in the early 1980s following FTC abuses of Administrative Procedures Act (the law that governs "notice and comment" rulemaking by Administrative Agencies like FDA) rulemaking procedures in the 1970s, when the Commission attempted to regulate children's advertising, lawyer's fees, advertising by physicians, ready-to-eat breakfast cereals, auto manufacturers, hearing aids, mobile homes and over-the-counter drugs. Removal of this protection would permit the FTC to promulgate regulations affecting many kind of advertising, including dietary supplements (like Aloe). This could easily lead to a major sea change in how the supplement industry is able to communicate with consumers. To illustrate:

Today when the FTC challenges advertising claims for a dietary supplement product on the basis that the advertiser does not have gold standard (long-term, randomized, placebo controlled, cross-over, multi-center) studies on the specific product in question, in order to prevail the Commission must first convince a Federal Judge that there is no basis for relying on ingredient based substantiation.

If H.R. 4173 is enacted into law without change, the FTC would simply be able to promulgate a regulation that requires any performance claim for any dietary supplement to be substantiated by two gold standard studies *on that specific product*. Supplement companies would not be able to rely on ingredient based substantiation.

H.R. 4173 has already passed the House of Representatives. Financial reform legislation is currently before the Senate. Representatives of the Natural Products Association (NPA), American Herbal Products Association (AHPA) and the Council for Responsible Nutrition (CRN) are already working with Senators Hatch and Harkin to address this concern; however, the possibility remains that Senator Jay Rockefeller (D-WV) may seek to include these expanded powers for FTC in the Senate's legislation. It is also important that your Senators hear from you on this issue. The Direct Marketing Association has set up an excellent webpage explaining the importance of ensuring that common sense restraints remain in place at the FTC and how to communicate with your elected officials on this important issue. (http://www.votervoice.net/Core.aspx?AID=1129&APP=GAC&IssueID=21410&SiteID=-1)

Food Safety

The second issue of immediate concern relates to the Food Safety Enhancement Act of 2009, H.R. 2749, which passed the House on July 30, 2009. This bill would impose a regime of Hazard Analysis & Critical Control Points (HACCP) on all food facilities in the United States. This change in existing law is ostensibly designed to upgrade weak Good Manufacturing

Practices (GMPs) in place for food producers. The problem is that H.R. 2749 does not recognize that as of this June, every dietary supplement manufacturer in the United States will be operating under the new, rigorous, dietary supplement GMPs. This creates the significant risk that FDA will determine that since dietary supplements are a subcategory of food, supplement manufacturers will have to scrap their newly implemented (at great cost) GMPs and adopt (at great cost) a HACCP program.
Fortunately, once again Senators Harkin and Hatch in conjunction with AHPA, CRN and NPA have stepped into the fray and ensured that the Senate version of this food safety legislation, S.510, specifies that the new HACCP requirements *do not apply* to dietary supplement manufacturers.

The challenge on this issue will now apparently take place when Senate and House negotiators get together to iron out the differences in the bills passed by each House. When this occurs, we will need a strong voice from the House of Representatives to speak for the supplement industry. Recently, AHPA President Michael McGuffin, Jon Benninger of Virgo Publishing (Natural Products Insider, Food Product Design, etc) and I hosted a fundraiser/reception for Representative Frank Pallone (D-NJ), one of the original sponsors of DSHEA and a long time champion of the supplement industry. Rep. Pallone assured us that he recognizes the importance of this issue and will work to ensure that the Supplement GMPs are not displaced. If you would like to discuss how you can show your appreciation and support for Congressman Pallone, please contact me.

GAO/IOM Reports

2010 has also seen the release of reports by the Government Accountability Office (GAO) and the Institute of Medicine (IOM) that have called for fundamental changes in the way FDA oversees the introduction of new food ingredients into the marketplace.

On February 3, at the request of the Senate Health Education Labor and Pensions Committee and the House Committee on Appropriations Agriculture Subcommittee the GAO issued a report (http://www.gao.gov/new.items/d10246.pdf) assessing the status of FDA's knowledge of and control over new food ingredients into the American diet. While the Report goes on for over 70 pages, its salient finding is easily summarized: The self-GRAS (Generally Recognized as Safe) process for new food ingredients allows the entry of numerous new ingredients into the food supply without adequate review and understanding by FDA, and FDA has no idea as to exactly how many such ingredients are introduced annually. The GAO report's proposed remedy for this situation is to abolish the self-GRAS procedure and require the mandatory submission of safety data for review and comment by FDA prior to the introduction of and new ingredients for use in food. Coupled with comments regarding FDA's failure to adequately supervise New Dietary Ingredients for use in dietary supplements in GAO's 2009 report on Dietary Supplement Oversight (http://www.gao.gov/new.items/d09250.pdf), it appears that the Aloe industry may facing significant challenges in the near future on the manner in which it introduces new products into the supplement category as well as its new limitations on its ability to bring its products into the "food category."

In light of these two GAO reports, it is also worth watching developments in the Senate Special Committee on the Aging, where Senator Kohl (D-WI) has charged the GAO with investigating the status of new dietary ingredients in the market with the apparent intent of conducting hearings in the near future. It is fairly safe to assume that these hearings will not be designed to laud either FDA or the supplement industry.

Meanwhile, on May 14 a special committee of "experts" (including a senior advisor from FDA) committee of experts convened by the IOM (which is part of the National Academies of Science) issued a report (http://www.iom.edu/Reports/2010/Evaluation-of-Biomarkers-and-Surrogate-Endpoints-in-Chronic-Disease.aspx) calling on FDA to evaluate claims for foods and dietary supplements under the same standards that it applies to drugs. Specifically, the IOM called for FDA to require that companies making health benefit claims for supplements or food be able to identify specific biomarkers responsible for the product's claimed effects. This is

required of pharmaceutical companies during the New Drug Approval process, and the IOM report urges uniformity in applying this standard across all FDA regulated products. If this proposal is adopted by FDA (or FTC) Aloe marketers who wish to advise consumers of the health benefits of their products will be barred from doing so in the absence of a series of extensive and expensive clinical trials demonstrating the specific constituents of each of their products providing such benefits. Such a standard would be in clear contradiction of the intent of DSHEA, and close monitoring of potential regulatory action on this report is warranted.

NTP

While all of this is going on, we continue to await action by the National Toxicology Program (NTP) on its testing of so-called Aloe products. As IASC Executive Director Devon Powell clearly points out in the February 2010 issue of Inside Aloe Online, the NTP report has the potential to cause serious harm to the trade unless consumers are properly informed that the substance tested has nothing to do with the Aloe sold in the US market (http://www.iasc.org/InsideAloe/10_0218_IAO.pdf). An update on IASC's proactive measures in response to the pending publication of the NTP report is provided in this month's Director's Message.

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"Inside Law" is an "Inside Aloe: Online" exclusive column by IASC General Counsel Ullman, Shapiro and Ullman. Ullman, Shapiro and Ullman is a New York, NY-based law firm that specializes in legal issues in the dietary supplement and natural products industry (www.usulaw.com). The above article is based on a blog originally written for NPI Center (http://www.npicenter.com/) by Mr. Ullman.

PERSONAL CARE

NOP Responds to NOSB Recommendation for National Organic Personal Care Standard

By Katia Fowler

On April 23, the U.S. Department of Agriculture's National Organic Program (USDA/NOP) issued a memorandum from NOP Deputy Administrator Miles McEvoy indicating a willingness on the part of NOP to consider development of a single national organic standard for personal care products.

As described in the memorandum, the current NOP policy, based on two previous NOP policy

statements, "limits the scope of NOP authority to only those [personal care] products which bear the NOP seal." The first relevant statement supporting this policy is a 2005 NOP memo establishing that agricultural products may be certified as organic if they comply with the NOP regulations irrespective of end use - thus allowing for the certification of products such as personal care items and dietary supplements to the USDA organic standard. Three years later, NOP issued a second relevant document explicitly allowing personal care items to be certified and marketed to "other, private organic standards." NOP notes in the 2008 document it "does not regulate these labels at this time."

In November 2009, the National Organic Standards Board (NOSB) recommended NOP reconsider its 2008 policy and develop a "complete federal organic personal care program." NOSB made this recommendation due to a concern that, in McEvoy's summation, "the array of private standards obscured the requirements for organic claims for both manufacturers and consumers."

The April 23 memorandum responds to the NOSB recommendation. In the document, NOP states it will do the following:

> 1. "Collaborate with the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) to understand issues associated with the use of the term "organic" in personal care products. The objective of this collaboration is to have a comprehensive approach that aligns with each respective agencies missions and regulations.
>
> 2. Begin gathering information regarding the organic labeling of personal care products in the marketplace. The exact methods for obtaining this information have not been finalized yet, but NOP will engage with the public at large. Methods to collect this information might include a public survey and/or Advanced Notice of Proposed Rulemaking.
>
> 3. Consider the recommendations of the NOSB on rulemaking and take them under advisement for future incorporation."

NOP has already begun "gathering information regarding the organic labeling of personal care products in the marketplace." NOP's March report notes members of the Compliance Enforcement Division of NOP attended Natural Products Expo West to fulfill several objectives, including: "analyze the current landscape of regulated and unregulated organic personal care product industries by surveying products personal care products containing organic claims" and "attend trade show education sessions regarding the use of organic claims in personal care products." The report states:

> Staff visited and reviewed over 250 booths in conducting investigative activities and also systematically reviewed health and beauty product organic claims displayed on the trade floor. NOP will conduct follow-up investigative activities concerning several new regulatory violations it noted while managing open compliance cases as well as apply its observations concerning personal care organic claims in prospective NOP policy development.

In the April 23 memorandum, NOP reports the following product claim observations among 26 personal care exhibitors at the show: "6 products were USDA certified by an accredited certifying agent, 21 products were not USDA certified and 14 of these products included the term 'organic' in the company trade name or a general claim on the principal display panel that the product was organic."

As McEvoy states in the memorandum's opening sentence, organic labeling on personal care items has long been a "divisive issue" in the organic food industry and the cosmetic industry. The central point of disagreement is whether personal care products fall within the scope of the Organic Foods Production Act of 1990 (OFPA) and the National Organic Program (NOP).

Those who argue personal care products do not fit within the scope of the OFPA and NOP tend to favor the development of private organic standards by industry and the certification and marketing of personal care products to these standards. Those who argue personal care products fit within the scope of the OFPA and NOP tend to favor a national standard and certification and marketing of personal care products exclusively to the USDA organic standard.

In the past, McEvoy and others at NOP have identified personal care as a low-priority issue. However, as evident in the discussion section of the memorandum, activity surrounding the issue of organic labeling on personal care products has recently increased. McEvoy notes that Consumers Union (the publisher's of *Consumer Reports*) in March joined with the Organic Consumers Association (OCA) in filing a petition with the Federal Trade Commission (FTC) urging action on organic personal care claims. The petition argues such action is in-line with the commission's increasing interest in "green" claims and asserts that USDA has declined to take enforcement action against companies making organic claims that are not USDA-certified.

NOP also cites in the discussion section a Q&A on "Organic" Cosmetics that FDA posted on its website in March. NOP writes that FDA stated in the document "that organic labeling of personal care products must comply with NOP organic standards." NOP makes this conclusion based on the following question and answer:

> *If a cosmetic is labeled "organic" according to the USDA, is it still subject to the laws and regulations enforced by FDA?*
>
> Yes. The USDA requirements for the use of the term "organic" are separate from the laws and regulations that FDA enforces for cosmetics. Cosmetic products labeled with organic claims must comply with both USDA regulations for the organic claim and FDA regulations for labeling and safety requirements for cosmetics. Information on FDA's regulation of cosmetics5 is available on our Cosmetics6 Web site.

The April 23 memorandum appears to represent an attitude change at NOP with regards to oversight of personal care products. In an April 6 *Washington Post* article, USDA Deputy Secretary Kathleen Merrigan declared this an "age of enforcement" for NOP. It appears this "age of enforcement" may expand into the personal care arena.

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Katia Fowler is Director of Communications for the American Herbal Products Association (AHPA).

IASC NEWS

IASC Logo

IASC Unveils New Association Logo

At its most recent meeting, the Board of Directors of the International Aloe Science Council (IASC) voted to adopt a new logo for the trade association.

"IASC's new logo offers a cleaner, more modern image for the association that better suits IASC's dynamic and the Council's commitment to cutting-edge science," said Executive Director Devon Powell.

The new logo does not affect the IASC certification seal in any way. The IASC website,

documents and other materials will be transitioning to the new logo in the coming weeks. The new logo will also be adapted shortly and available to IASC members to identify their organizations as "Proud Members of the IASC". Members interested in obtaining this logo should contact Devon Powell at the IASC office.

IASC and ALOE IN THE NEWS

Seeking Aloe Vera Everywhere - Natural Products Insider, April 5, 2010
By Devon Powell, Executive Director, IASC

The promising future of aloe vera - PremiumBeautyNews.com, March 2, 2010
A report on the Aloe vera Symposium featuring Executive Director Devon Powell

Everything about Aloe Vera! - Times of India, April 14, 2010

Aloe vera to find a home in arid Bundlekhand - IndiaExpress.com, April 12, 2010

IASC NEWS

IASC Announces Results of Board of Directors Elections

The IASC is please to announce he following individuals now comprise the IASC Board of Directors:

Tom Brown - Florida Food Products
Chris Clarke - Winning Solutions/Miracle of Aloe
Chris Hardy - Aloe Vera of America
Jesper Hummeluhr - Aloe Vera Group ApS
Qi Jia - Unigen
Ken Jones - Aloecorp
Walt Jones
Sabine Larsen - LR Health & Beauty Systems
Don Lovelace - Lily of the Desert
Wenwen Ma - Unigen
Charlie Metcalfe - Custom Analytics
Bahn Phan - Aloe Vera of America
Bill Pine - Improve USA
Roger Poore - Aloe Vera of America
John Price - RBC Life Sciences
Santiago Rodriguez - Lorand Laboratories
Don Smothers - Naturetech
K.S. Yoon - Aloecorp

"The IASC continues to be represented by an active and highly dedicated group of individuals," said IASC Executive Director Devon Powell. The Board Officers election was also completed, and is now comprised of the following:

Ken Jones, Chairman
Chris Hardy, President

Santiago Rodriguez, President-Elect
Chris Clarke, Secretary
Tom Brown, Treasurer
Walt Jones, Executive Committee at-large member
Bill Pine, Executive Committee at-large member

ALOE SALES

Aloe Vera is 2009's Top Selling Supplement in Health Food Channel

According to SPINS data reported in the current issue of *Herbalgram*, Aloe vera was the top-selling dietary supplement in the natural and health food channel last year. Market data firm SPINS records a 6.27 percent year-over-year increase in sales of Aloe vera in health food stores, with total sales approaching $22 million for the 52 weeks ending Dec. 26, 2009.

Aloe vera's 6.2 percent growth rate is a step ahead of year-over-year sales growth for all herbal supplements combined. SPINS shows sales of herbal supplements growing 4.48 percent year-over-year, reaching nearly $250 million in total 2009 sales in the health food channel.

Coming in a close second to Aloe vera, flaxseed and/or flaxseed oil sales approached $21 million in 2009 despite a 6.9 percent decrease in sales over the prior year. Together Aloe vera and flaxseed supplements accounted for 17 percent of all dietary supplement sales in the health food channel.

The remaining top five dietary supplements in the natural and health food channel were wheat or barley grass, açai, and turmeric. Açai and turmeric both showed impressive growth in 2009, up133.06 percent and 22.7 percent, respectively.

IRI data finds Aloe vera among the top 20 selling dietary supplement in the food, drug and mass market channel. In 19th place, sales of Aloe vera in the FDM channel (excluding Wal-Mart, Sam's Club, other large warehouse buying clubs, and convenience stores, which are not captured in IRI data) totaled roughly $646,000, representing a 4.8 decrease in sales compared to 2008. IRI lists cranberry, soy, saw palmetto, garlic and echinacea as the top five selling supplements in the FDM channel.

Sales of Aloe vera in important channels such as multi-level marketing are not reported in the *Herbalgram article*; however, the *Nutrition Business Journal*, which collaborated with the American Botanical Council on the article, estimates combined sales of herbal supplements rose in all channels in 2009.

"IRI data indicates that Aloe vera is an important dietary supplement to many health-focused consumers and a crucial contributor to dietary supplement sales in natural and health food stores," commented International Aloe Science Council Executive Director Devon Powell.

The complete article is available online at http://cms.herbalgram.org/herbalgram/issue86/article3530.html?Issue=86.

LEGISLATIVE NEWS

CAM, Supplement Provisions Survive in Health Care Reform Bill

The health care reform bill signed into law March 23 by President Barack Obama, the Patient Protection and Affordable Care Act, includes several provisions that address complementary

and alternative medicine (CAM), and one focused on certain dietary supplements.

Among the provisions included in the final law, section 4206 would have a direct effect on those dietary supplements for which there are FDA-approved health claims by setting up a pilot program for "wellness plans," which can now include those few supplements with "health claims approved by the Secretary." Currently approved health claims include, for example, claims for calcium and osteoporosis; soluble fiber and coronary heart disease; and folic acid and neural tube birth defects. The full list can be found on the Food and Drug Association (FDA) Web site.

Another notable provision in the health care reform bill is section 2706, which prohibits "discrimination" against any health care provider licensed in a state; more specifically:"A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law.

"Other sections of the new law will also promote more inclusion for CAM practitioners. These include section 5101, that establishes a National Healthcare Workforce Commission to work with the U.S. Department of Health and Human Services; and section 3502, which creates "community health teams," defined to include, among others, "licensed complementary and alternative medicine practitioners."

"The new health care law is a starting point for a broader inclusion of CAM within the U.S. healthcare system," said International Aloe Science Council (IASC) Executive Director Devon Powell. "If managed properly, greater inclusion of alternative practitioners in health care should open a pathway for increased acceptance of the dietary supplement products they provide."

For more information on the provisions, see a Jan. 13, 2010 open letter from American Herbal Products Association (AHPA) President Michael McGuffin.

THE SCIENCE OF ALOE - Recently Published Studies

- In vivo evidence of the immunomodulatory activity of orally administered Aloe vera gel.
- Implications for degenerative disorders: Antioxidative activity, total phenols, flavonoids, ascorbic acid, beta-carotene and beta-tocopherol in Aloe vera.
- Aloe vera as a functional ingredient in foods.
- Therapeutic approach by Aloe vera in experimental model of multiple sclerosis.
- Aloe-induced toxic hepatitis.
- [Protective effects of Aloe vera extract on mitochondria of neuronal cells and rat

brain]

- Heavy metal bioaccumulation in selected medicinal plants collected from Khetri copper mines and comparison with those collected from fertile soil in Haridwar, India.

- [Effects of enhanced UV-B radiation on leaf anthraquinones content and cell ultrastructure of Aloe vera L]

REGULATORY NEWS

Treated Wooden Pallets Cause of Massive Odor-Related Recall

McNeil Consumer Healthcare has traced the source of a musty odor on certain over-the-counter products back to wooden pallets treated with a halogenated phenolic preservative called 2,4,6-tribromophenol (TBP). Because pallets are used in the dietary supplement industry, the International Aloe Science Council (IASC) is bringing this issue to members' attention.

While rarely used in many parts of the world, including the U.S., TBP treatment of wood continues in some regions that supply wood to the US and other countries. Certain fungi can convert TBP to the halogenated anisole compound 2, 4, 6-tribromoanisole (TBA). This compound produces a strong musty odor and is prone to volatilize and adsorb onto articles stored near the TBA source.

According to a question and answer document recently released by the Food and Drug Administration (FDA), because of their volatility, it appears that even minute levels of halogenated anisole compounds can adversely affect a large quantity of product in a single contamination incident. According to FDA, currently available data indicate that serious adverse health effects have not resulted from ingestion of drugs or foods contaminated with halogenated anisole compounds at the levels of contamination that have been reported.

In the Q&A document, FDA recommends that manufacturers and distributors take precautions to prevent the use of wood products treated with or exposed to a halogenated phenolic preservative anywhere in supply chain. This includes all facilities that manufacture, hold, or distribute drug products, components, or packaging materials. FDA recommends that manufacturers not store drug products, components, or packaging materials near wood or wood-derived storage materials unless there is assurance that the wood material has not been treated with a halogenated phenolic preservative.

FDA further recommends that manufacturers establish agreements and request certification from suppliers to provide assurance that halogenated phenolic preservatives are not present. Manufacturers should also be vigilant to the characteristic odor of the offending compounds so they can intervene before product is contaminated or further distributed.

For more information, see questions five through ten in the "Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance Buildings and Facilities": http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm192869.htm#7.

More information is also available in McNeil's Feb. 5 response to the FDA Warning Letter: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm192869.htm.

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