Inside Aloe Online

In This Issue

Director's Message

On Feb. 6, the International Aloe Science Council (IASC) and its representatives met with the members of the Food and Drug Administration (FDA) for a discussion of *Aloe vera*, at the request of FDA's Center for Food Safety and Applied Nutrition (CFSAN). The meeting was motivated by rumors and concerns surrounding a study conducted by the Department of Health and Human Service's (HHS) National Toxicology Program (NTP) on the toxicity of *Aloe vera* for internal use.

As described in the Feb. 13 message to members, during the meeting several concerns were raised by FDA that the aloe industry must now address. While the concerns are serious, I am confident that we can effectively address these concerns and that IASC member companies can continue providing health-promoting internal-use *Aloe vera* products to consumers.

In the following article, IASC's goal is to clearly explain the situation presented before the organization, including FDA's concerns and the IASC's recommended actions. I encourage all members of IASC to become engaged in the efforts of the aloe industry to address FDA's concerns, and I also encourage all members of IASC to contact me with any comments, questions or concerns (dpowell@iasc.org; 301-588-2420).

Devon Powell
Executive Director

MEMBER ACTION NEEDED

IASC Requests Member Assistance in Addressing Regulatory Concerns Regarding Characterization, Labeling of Aloe Products

The Department of Health and Human Services' (HHS) National Toxicology Program (NTP) evaluates substances for a variety of health-related effects, generally using rodent models for study and protocols specifically designed to fully characterize the toxic potential. The substances evaluated by NTP are nominated by Federal and State agencies, national and international non-governmental organizations, academia, industry, the public and other stakeholders. These nominations undergo several levels of review before the agents are selected for study and toxicological studies are designed and implemented.

Aloe vera was nominated to the NTP in the late 1990's due to its widespread usage and was then selected for study by the program. The NTP has done several studies using *Aloe vera* since, but most notably and of concern to the International Aloe Science Council (IASC) is the recently completed 2-year bioassay (oral consumption) study currently under statistical review. This study was conducted after a 90-day study showed potential carcinogenic results. According to the lead researcher, Dr. Mary Boudreau, this study, and the 2-year assay, utilized a "whole leaf extract" ingredient in which the aloe latex was not removed.

At this time, neither the IASC nor the Food and Drug Administration (FDA) have a copy of the final report or the raw data; however, NTP has shared the initial finds with FDA. A serious concern exists that the results of the 2-year bioassay will be negative.

During the meeting, the two organizations discussed a mutual interest in proactively minimizing problems resulting from a negative finding. IASC representatives identified two areas of great concern to FDA (1) insufficient characterization of products on the market and (2) improper labeling of an ingredient as "whole leaf" when it does not literally contain the whole leaf.

Characterization

FDA has an interest in knowing, in advance, whether the article that was the subject of research is the same as any of the articles currently sold in commerce. FDA scientists will be characterizing the article that was used in the study. That means they are going to know exactly what was used, which the lead researcher on the study, Dr. Mary Boudreau, identified as "whole leaf extract" and defined in an email to the IASC Executive Director, Devon Powell, as: "The whole leaf extract was produced by grinding whole Aloe vera leaves and treating the slurry with cellulase (23 mg/L) to remove the rind components and to maximize yields. This product contained the inner leaf gel and the aloe latex."

It is important to note that during the meeting FDA representatives were told directly that the latex is not utilized in member products. An FDA representative responded that the agency understood this, but that there was no data to show it was only the latex in the test samples that may be the cause of any issues and the results of the NTP study.

As a result of the meeting with FDA and concerns identified during, the following items were requested directly by FDA of the IASC, or clearly need to be addressed:

- Constituents in Aloe vera - are these items identifiable and able to be characterized
- Polysaccharide chains/molecular weight distributions - how are these items

substantiated
- Aloin- methods of detection, allowable limits, etc.
- Description of processing (not generalized, but per manufacturer)
- Concentration information
- Dosage/consumption information - human vs. mice; recommended daily dosage (include info on concentration) - particularly on food usage

The following actions are being recommended, & requests of the membership are being made, by the IASC in response to the characterization concerns:

A working group of Science & Technical committee to characterize *Aloe vera* has been formed. The working group will be meeting weekly, every Thursday, via tele-conference, beginning **Thurs., Feb. 19**, until the project is completed. All active members in good standing are encouraged and welcome to participate in this meeting, and call-in information is below:

Characterization of Aloe Vera Working Group:
Dial-in Information: 1-888-632-5060
Passcode: 6387153

During the first meeting, the group will be responsible for identifying and outlining action items to address the concerns of the FDA and NTP study. Staff will continue to work on these projects in between meetings. The goal of the working group is to provide actions for the board to decide upon, to ultimately protect the industry. If you are interested in joining the working group, please email Devon Powell (dpowell@iasc.org).

REQUESTED INFORMATION FROM ALL MEMBERS REGARDING CHARACTERIZATION:

All members who manufacture or sell products labeled as a food or dietary supplement are requested to e-mail/submit all labels for such products to the IASC for database creation/ to address FDA dosage/consumption concerns. E-mail: dpowell@iasc.org ; Mail: 8630 Fenton St., Ste. 918 Silver Spring, MD 20910

All members are asked to submit any characterization testing of finished products (dietary supplements or food products) and raw materials to the IASC to compile and eventually provide to a reputable toxicology group for review and to provide background to utilize in defense against NTP study. Please email this information whenever possible.

All members are asked to submit any/all information on any/all studies or literature on *Aloe vera* to the IASC to develop a formal literature review. It is preferred to have these items delivered electronically, but mailed copies will be accepted.

Labeling

Bill Frankos, head of CFSAN's dietary supplement division, expressed regulatory concern regarding products labeled to contain "Whole leaf", that they do not in fact contain "the whole leaf" (quoting Bill Frankos - "It sounds like it has the entire contents of the whole leaf in the finished product"). Bill expressed dismay that a company that takes a whole leaf and then takes parts of it out is in fact not selling what the label says - and clearly indicated his opinion that such products are misbranded. There is also a concern that if a NTP study is released where the ingredient tested is "Whole leaf extract", any product labeled as "whole leaf" will be at risk, because the labels don't say "whole leaf without latex" or "whole leaf without A, B, C, etc.".

According to the FDA and as described above, they believe a product labeled "Whole leaf" means "includes everything in the leaf (including the aloe latex)" -- as there is no information presented to indicate otherwise on labels. Also of concern is that if the NTP study is released, those products labeled with "Whole leaf" may immediately find themselves with a target on their backs/Prop 65 lawsuits/etc.

The following actions are being recommended by the IASC in response to the labeling concerns:

A working group of the Regulatory Affairs committee to create labeling guidance has been formed. The working group will be meeting twice weekly, every Wednesday and Friday, via tele-conference, beginning with Wednesday, February 18, until the project is completed.All active members in good standing are encouraged and welcome to participate in this meeting, and call-in information is below:

Labeling Guidance Working Group:
Dial-in Information: 1-888-632-5060
Passcode: 6387153

During the first meeting, the group will be responsible for identifying and outlining action items to address the concerns of the FDA and NTP study. Staff will continue to work on these projects in-between meetings. The goal of the working group is to create labeling guidance by March 9, the date of the next board meeting. If you are interested in participating with this working group, please contact Devon Powell (dpowell@iasc.org).

Conclusion

It is imperative that all members understand that the entire aloe industry is threatened by this study, and the membership needs to mobilize and unite under the IASC banner in order to address these concerns and issues. The Council is asking all members to please review the recommended actions summarized below, and get involved and active as much as possible.

Information Needed:

- E-mail/submit all labels for food and dietary supplement products to the IASC for database creation/ to address FDA dosage/consumption concerns. E-mail: dpowell@iasc.org ; Mail: 8630 Fenton St., Ste. 918 Silver Spring, MD 20910

- Submit any characterization testing of finished products (dietary supplements or food products) and raw materials to the IASC to compile and eventually provide to a reputable toxicology group for review and to provide background to utilize in defense against NTP study. Please email this information whenever possible.

- Submit any/all information on any/all studies or literature on Aloe vera to the IASC to develop a formal literature review. It is preferred to have these items delivered electronically, but mailed copies will be accepted.

Working Groups Formed:

- Regulatory Affairs Committee working group to create labeling guidance: The working group will be meeting twice weekly, every Wednesday and Friday, via tele-conference, beginning with Wed., Feb.18, until the project is completed.

- Science & Technical Committee working group to characterize Aloe vera: The working group will be meeting weekly, every Thursday, via tele-conference, beginning Thurs., Feb. 19, until the project is completed.

Thank you for your attention to this matter and the positive response IASC has received thus far. The Council is confident the right steps are being taken to fully address FDA's concerns. And, again, please do not hesitate to contact IASC Executive Director Devon Powell with questions or concerns.

NEW THIS ISSUE...

Inside Aloe Online is excited to introduce "Inside Law," an exclusive column by IASC General Counsel Ullman, Shapiro and Ullman (New York, NY). The article below is the first in this new feature and focuses on trademark development and protection.

We hope our readers find this column useful and informative. If you have feedback on this new feature or any other aspect of **Inside Aloe: Online**, please send an email to the editor at info@iasc.org.

Ullman Shapiro & Ullman INSIDE LAW

Trademark Protection For Your Aloe Products

By Charles H. Knull, Esq.

Making a company's dietary supplement products seem different from the competition involves branding, and branding involves the use of trademarks to identify the source of products.

Trademarks began as signs on stores and primitive marks on products. One went to the Red Lion Tavern because one knew certain things about its level of cleanliness and strength of the tavern's beers. If another Red Lion Tavern appeared in the village, the first tavern could take action before the chancellor to make the second tavern change its name.

Eventually, consumer products came about, and a purchaser of champagne would want champagne from a certain winery, and the label on that champagne became its identifier to consumers. If someone else tried to sell another wine in a label that too closely resembled the champagne label, it could be sued for trademark infringement and unfair competition.

Trademark law is consumer protection law. Nobody really "owns" a trademark. The government says that a trademark is registered to a person or company that uses it to identify its products so that consumers can buy products with assurances that the quality, whether great or good, is what is expected in that product. The first user of a mark is the one who has the claim to protect it so long as it continues to be used. Under the current law, the Lanham Trademark Act, a first user who has registered its' mark can enforce that mark in federal court and obtain sanctions ranging from injunctive relief to the infringer's profits. If then infringement is willful, or with knowledge of the prior mark, it can also make the

infringer pay its legal costs and, perhaps, obtain treble damages. (Sticking one's head in the sand is not a defense.)

Adopting Trademarks

In the United States, trademark protection comes about from use of the trademark on the product. Use must be continuous over time. The longer one uses a trademark, the stronger it gets. Eventually, a trademark can become "famous" and the owner can keep others from using it even on unrelated products. (This is why one cannot use XEROX® or COCA-COLA® as a brand name for automobile tires.)

Trademarks also are stronger if they are more distinctive, coined terms like EXXON® or XEROX® or whimsical uses such as APPLE® for computers. ALOE would, for example, be a possible strong mark for window blinds, but not for products containing aloe.

The best trademarks are coined words, invented to cover a product. A lot of business people do not like coined words for trademarks because they must work hard and spend money to make such trademarks become associated with products. However, as a coined trademark can acquire the distinctiveness and renown that make up a famous mark in a short period of time, working to create coined marks or adding coined elements to marks is well worth consideration. For example, calling an aloe based lotion ZZAGGY would create a very strong trademark once consumers connected it to that product. But that connection is not, of course, going to happen overnight and will require substantial investment in marketing and advertising, since a consumer is not going to connect ZZAGGY with a lotion product automatically.

The worst sort of trademark to adopt and to enforce is one that is "descriptive". Such a mark describes the product or an aspect of the product, something like HEALTHY ALOE CREAM. There is another class of words that simply cannot be enforced at all-generic terms, which consist of the name of the product, e.g., ALOE DRINK.

The better trademarks to enforce, if one does not want to reach for the coined mark, is a mark that is "suggestive." Such a trademark might be MARATHON or LIFETIME for an aloe based ointment (suggesting that they will have long lasting effects).

Trade Dress. A trademark can be derived from use of trade dress. Trade dress describes the packaging of products. The best trade dress incorporates a design which, like a coined trademark, has grown itself to be an identifier of the product, such as the NIKE® "Swoosh" design. While trade dress generally is more difficult to protect than trademarks, a retailer who too closely adopts the trade dress of a name brand product can be liable for infringement. Thus, it is best if a manufacturer adopts a trade dress different from the colors and designs already used in their marketplace. A manufacturer who packages its product line in bottles which resemble another well known brand is asking to be sued for trademark/trade dress infringement and unfair competition.

The House Mark. A "House Mark" is a trademark that is used to identify the source of a line of products rather than a single product. Retailers and manufacturers often adopt House Marks for their lines of products. A manufacturer who wants to adopt a House Mark must be concerned with trademark law. While imitation may be a form of flattery, too closely imitating the trademark and trade dress of a name brand may lead to a complaint for trademark infringement.

A House Mark offers immense advantages if it is based on a trademark which has been in long use, such as a mark based on the retailer's existing store name. Trademark protection grows in strength over time through use of the trademark on a service or product. The longer one

uses the trademark, the stronger it gets.

Thus, the best and strongest House Mark is one which is already a famous trademark or service mark, and if a company is fortunate to have such a mark available, it is sold gold. An example of this is the Vicks mark which is strong or famous on VICKS VAPORUB® and is now being extended to use on vaporizers, thermometers, tissues and other "cold related" products. If a company does not have a strong and long used name, it should look for a trademark that is a "coined" or an invented word. For example, a manufacturer with the House Mark QUALITY ALOE PRODUCTS (a "weak" mark until it has been used for years) might concoct a new mark such as QUAPRO, which has no immediate meaning. If invented terms are not to the retailer's liking then adopting a House Mark which is "suggestive" of the products on which it will be used is the next best approach. For example, a maker could use the mark HIGHT HEALTH for aloe based lotions and creams, citing a suggested benefit of the products. The worst type of mark to adopt, especially as a House Mark, would be a "descriptive" mark.

Whether a trademark for a specific product or a house mark, it is enforceable when it is used. But the real clout results from registration of the mark at the U.S. Patent and Trademark Office. Trademark registration takes about a year and is best handled by attorneys and paralegals specializing in such applications. With registration comes the right to use the ® (and other notations) with the trademark. Only a registered mark can carry the ®.

The Trademark Search Report. Selection of a trademark is the last place to take an "ignorance is bliss"approach. A company that adopts and uses a trademark without checking it out can be held to be a "willful infringer" if a similar mark is already in use on related or competing product.

The best defense to willful infringement is not only to do a thorough search but also to have a trademark lawyer review the search report and provide an opinion letter on the potential use and registration of the mark. Normally, a company planning to use a trademark will search for other's uses of the mark, and similar marks, on related goods. If the search report shows a clear mark, then an application can be filed well before the product is much more than an idea for a product, under the intention to use provisions of the trademark law. If the mark is already in use, an in-use application is usually filed.

EXAMPLE A: Company X conceives of a soothing aloe based lotion for post exercise, calling it WORK-OUT SMOOTHE. A search report is conducted, and its counsel notes in the report that the closest mark found was for a similar lotion called SLEEK WORK OUT, but provides a sound, reasoned legal opinion that the two marks are not likely to cause confusion. Nonetheless, the owner of SLEEK WORK OUT sues X for using WORK-OUT SMOOTHE and Company X is found in a questionable decision to be an infringer. However, the court does not find willfulness because Company X did the proper thing and obtained advice of counsel before adopting the mark. Although the owner of SLEEK WORK OUT stops WORK-OUT SMOOTHE's use, it must pay its own attorney fees.

EXAMPLE B. Company XX puts out the same product called WORK OUT SMOOTHE. The owner of SLEEK WORK OUT sues and Company XX, offering no evidence that it cleared the name, is held to be a willful infringer, owing SLEEK WORK OUT's owner all its legal fees.

The Rights and Duties of the Trademark Registrant. Once registration is obtained, the trademark registrant has the right to keep others from registering confusingly similar trademarks and the right to sue infringers to obtain an injunction against the infringer's uses plus any profits made, and, in outrageous situations where the infringement is found to be willful, to obtain attorneys fees and treble damages.

The registrant can also present its trademark to U.S. Customs and block entry of infringing goods into the U.S. After five years, the registrant can increase the power of the trademark by filing a Declaration of Incontestibility, which removes many defenses to infringement from play in an infringement suit. After the same five years, and at ten-year intervals, the registrant must pay fees to renew and maintain the registration.

Conclusion

Makers of nutritional and health products invest in marketing and advertising in order to set their products apart from other products. It is penny wise and pound foolish not to reinforce this investment by taking the necessary steps to protect the valuable trademarks that are the by-product of such marketing and advertising. Much of the clout in the trademark law comes from early filing and registration.

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Charles H. Knull is Trademark Counsel to Ullman, Shapiro and Ullman, a New York, NY-based law firm that specializes in legal issues in the dietary supplement and natural products industry.

Aloe Monograph Corrected

NMCD Revises Monograph for Aloe Vera Following IASC Input

The IASC became aware of the Natural Medicines Comprehensive Database (NMCD) monograph for *Aloe vera* through a review of the Japanese Ministry of Health's use of the NMCD aloe monograph. The IASC was concerned by a lack of adequate discrimination in the monograph between aloe gel and aloe latex.

IASC Executive Director Devon Powell contacted the NMCD with a proposed revision of the monograph, and noted that the distinction between aloe gel and aloe latex is a very important due to the distinct safety profiles. The NMCD was receptive to IASC's request and indicated there had originally been two separate monographs, but these two monographs had been combined. In the process of combining the two monographs, some of the distinguishing

language was lost. The editor of the NMCD promptly made changes to the monograph to distinguish between gel and latex and these changes are now reflected in the database.

"The accuracy of monographs used by regulatory agencies is critical, and IASC must be vigilant in reviewing such monographs," said Powell. "We appreciate NMCD's concern for accuracy and gracious response to our request."

THE SCIENCE OF ALOE - Recently Published Studies

- Protective effect of a mixture of Aloe vera and Silybum marianum against carbon tetrachloride-induced acute hepatotoxicity and liver fibrosis.
- Novel botanical ingredients for beverages.
- The efficacy of Aloe vera, tea tree oil and saliva as first aid treatment for partial thickness burn injuries.
- Caco-2 cell methodology and inhibition of the P-glycoprotein transport of digoxin by Aloe vera juice.

GUEST ARTICLE

Truvia, PureVia Get GRAS Nod From FDA: What Does It Mean For Stevia Products?

By Anthony Young, Esq.

In letters dated Dec. 17, 2008, the Food and Drug Administration (FDA) advised Cargill and Whole Earth Sweeteners - a wholly-owned subsidiary of Equal®-marketer Merisant Company - that FDA has "no questions" with respect to their Generally Recognized as Safe (GRAS) notifications for the use of their stevia extracts in certain foods. Truvia™ rebiana (Cargill) and PureVia™ (Whole Earth Sweetners) are two distinct "highly purified" forms of Rebaudioside A, one of several steviol glucosides found in the stevia plant. FDA's allowance of their use in beverages, foods and tabletop sweetners is a landmark event in the history of FDA's regulation of stevia, and it has drawn much attention from the natural products industry. A clear explanation of the event's broader impact; however, has been lacking. A question pressing in the minds of many in the industry: what is the impact of FDA's no objection letter on other companies with stevia products?

As with all matters regulatory, the devil is in the details.

Say It Ain't Sweet: A Little Background

Stevia (*Stevia rebaudiana*) is a natural sweetener that has been a staple of the natural foods and dietary supplement marketplace for decades. However, until Dec. 17, no stevia ingredient could be marketed as a sweetner because "sweetness" in a food or a dietary supplement is a food claim. Namely, "sweetness" relates to the taste of the ingredient, a technical or functional food effect and not a structure or function dietary supplement effect.

An ingredient for use in food must be an approved food additive, generally recognized as safe (GRAS), or a food itself. Stevia is an ingredient that is added to food for its technical or functional effect (i.e., sweetening), and thus is not a food staple. The Dietary Supplement Health and Education Act of 1994 (DSHEA) did not create an exception from the food additive amendments for ingredients like colors, sweeteners or preservatives which exert only a technical or functional effect in the food. If an ingredient is not an approved food additive (olestra, the artificial fat discovered by Procter & Gamble, was the last major food additive approved by FDA), then it must be GRAS for use in food.

The American Herbal Products Association (AHPA) has historically supported stevia and member companies that have wanted to make stevia available as a sweetener. In 1991, AHPA submitted a petition to FDA asking that FDA agree that stevia is GRAS for use as a flavoring agent in food. However, that petition was not successful. Stevia was not allowed as a sweetener in food and an FDA Import Alert barred its importation.

After DSHEA became law, FDA lifted the stevia Import Alert insofar as it applied to stevia for use as a dietary ingredient in dietary supplements. Note that this change in the Import Alert did not permit the use of stevia as a sweetener, only as a dietary ingredient. Based on this change, many companies used stevia as an ingredient in dietary supplements (with no sweetener claim) and also put out "no claim" single ingredient stevia supplements. As a sweetener, however, stevia remained barred from both foods and dietary supplements.

The Road to a Sweet Claim

In early May 2008, Whole Earth Sweetners and Cargill submitted separate GRAS notices to FDA in accordance with FDA's proposed regulation (proposed 21 CFR 170.36) for notifications regarding substances believed to be generally recognized as safe.

General recognition of safety may be based on use in food prior to 1958 or on "scientific procedures." Scientific procedures means scientific evidence in the form of scientific studies, one or more of which must be published. General recognition also means generally recognized by experts qualified by training and experience to evaluate the safety of ingredients for use in food. The practice is to gather this material together in a well organized dossier and then to have it reviewed by a panel of experts, usually academics and often including retired FDA scientists with experience in reviewing ingredients for use in food.

At this point, companies may choose between one of two regulatory paths to legal sale of an ingredient as GRAS.

Once a panel of experts has reviewed the information in the ingredient dossier, a manufacturer may rely upon that review in using the ingredient in food. This process is called GRAS self-affirmation. If FDA were to see the ingredient in use in food, FDA may ask to see the legal basis for including the ingredient and a dialog would ensue.

If an ingredient supplier or manufacturer wants greater certainty, the company may file a GRAS notification (GRN) with FDA. FDA reviews the dossier and the Panel of Expert report and conclusions. The best outcome is for FDA to publish a letter indicating that the agency "has no questions" at this time regarding the proposed use. That is what occurred with Cargill and Whole Earth Sweeteners with respect to their GRAS notifications.

FDA's letters to Cargill (http://www.cfsan.fda.gov/~rdb/opa-g253.html) and Whole Earth Sweetners (http://www.cfsan.fda.gov/~rdb/opa-g252.html) contain information on the identity, method of manufacture, product specifications and the potential exposure resulting from the intended uses of rebaudioside A. The letters also reference published and unpublished studies related to the safety evaluation of on rebaudioside A, including animal

studies on rebaudioside A, other steviol glycosides, steviol and crude stevia extracts.

What Now? FAQs

What significance do the Cargill and Whole Earth GRAS notifications have for the industry?

First, these notifications mean that these two ingredients may be used in accordance with the terms of their notifications in food or in dietary supplements as sweeteners. Second, these notifications mean that FDA is generally in agreement that stevia is GRAS for use in certain foods under certain conditions. Third, it means that other manufacturers of stevia may go through the GRAS self-affirmation process with some level of confidence that FDA would not dispute their GRAS self-affirmation.

How do I know if my supplier's stevia is GRAS for use in food?

Food or dietary supplement manufacturers who wish to determine whether stevia offered to them is GRAS should ask their supplier to provide evidence of GRAS status directly or under a confidentiality agreement. This is a device commonly used by ingredient suppliers and manufacturers to exchange information that is confidential. Manufacturers should do this to assure that the stevia they intend to use is GRAS for its intended use.

How will FDA enforce the requirement that stevia be GRAS?

FDA has been and will probably continue to detain stevia coming into the country if it is labeled for food use. And when detained, they will ask the importer to provide evidence of GRAS status. It is our understanding that company's providing a safety dossier and Panel of Expert report on the material they are importing, are allowed to proceed if FDA has no reason to detain the ingredient. This practice by FDA is good for the industry for two reasons. First, it gives value to the GRAS self-affirmations that several companies in the industry have performed on their ingredients. Second, it assures that the market is not flooded with stevia materials whose safety has not been examined and evaluated.

May we use dietary ingredient labeled stevia for food use or as a sweetener?

Only if you are able to confirm that it is GRAS self-affirmed for use as a sweetener. Changing the status of stevia from a dietary ingredient to a sweetener is risky business now that stevia is available for food use. Accordingly, dietary ingredient labeled stevia should not be used as a sweetener until a successful due diligence on its status has been performed.

Why did it take so long for stevia to become GRAS?

The reason that it has taken so long is that until this year, no members of the industry had made the investment necessary for a thorough scientific review by experts. The law requires GRAS self-affirmations to be credible and complete, and this is a major effort.

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Anthony L. Young is a partner at Kleinfeld Kaplan & Becker (Washington, D.C.). He has practiced food, drug and environmental law for more than three decades. Mr. Young is a frequent lecturer at industry meetings on the implementation of DSHEA and counsels a number of dietary supplement companies with respect to compliance with the Federal Food, Drug, and Cosmetic Act.

March Board Meeting & Member Reception

You're Invited to Attend the IASC Member Reception in Anaheim, California

In conjunction with the Board of Director's meeting in Anaheim, Calif. on Mon., March 9, the IASC will be hosting a reception for members from 6:30pm to 9:30pm in the Green Room at the Hilton Anaheim Hotel in Anaheim, CA. All members are encouraged and welcome to attend, and we hope you will join us for cocktails, hors d'ouerves and networking with other members.

General hotel information:

Hilton Anaheim
777 Convention Way, Anaheim, California, United States 92802
Tel: 1-714-750-4321 Fax: 1-714-740-4460

For more information on the reception, please contact the IASC office.

U.S. REGULATORY

FDA Releases Final Claims Substantiation Guidance

The Food and Drug Administration (FDA) released its "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act" Jan. 2. The document is substantively identical to the draft guidance published in November 2004.

In the document, FDA provides guidance for industry on providing truthful and not misleading substantiation for nutritional deficiency, structure/function and general well-being claims through examples and discussion. Topics addressed in the guidance document include the types of evidence that may substantiate a claim, information useful as background to support a claim and design factors affecting the quality of a study.

The final guidance is available online at http://www.cfsan.fda.gov/~dms/dsclmgu2.html.

The International Aloe Science Council (IASC) hosted a webinar Feb. 5 entitled, "Claims Development & Substantiation: How to Comply with the Law." Presenters included attorneys Marc Ullman and Steven Shapiro, as well as FDA's Robert Moore and FTC's Christine Lee. If you are interested in obtaining an audio copy of the webinar, contact Devon Powell at info@iasc.org or 301-588-1171 x102.

U.S. REGULATORY

FDA Extends AER Label Compliance Deadline By One Year

The Food and Drug Administration (FDA) will not begin enforcing labeling requirements

related to the reporting of adverse events until Jan. 1, 2010, according to a notice published in the Dec. 11 Federal Register.

The notice announces that two draft guidance documents released by FDA in January - one for dietary supplements and one for nonprescription drugs - and described as "intended to assist ... industry" in complying with purported labeling requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act ("the AER bill") have been revised to extend the enforcement date deadline "because the agency is still in the process of finalizing the guidance[s]."

A link to the revised guidance for the dietary supplement industry is here:
http://www.cfsan.fda.gov/~dms/dsaergu3.html

ALOE IN THE NEWS

Aloe Vera for Inner, Outer Beauty (Tapping into Aloe's Magical Powers) - Natural Products Insider, Dec. 18, 2008

Effective Aloe Delivery - Natural Products Insider, Dec. 19, 2008

Selecting Quality Aloe Vera Products - Natural Products Insider, Jan. 13, 2009

Himachal Pradesh to go 'herbal' with massive plantation drives - The Hindu, Jan. 28, 2009

Biofuels cause land scramble in TZ - East African Business Week, Feb. 7, 2009

Another 140 Join The Unemployment Line Due To Financial Crisis - Inside Costa Rica, Feb. 10, 2009

Nigeria: Expectations High As 18 FLP Distributors Gear Up for Sonya Race - AllAfrica.com, Feb. 10, 2009

India logs over 2 lakh traditional medical formulations - Times of India, Feb. 10, 2009

Reviewing the evidence for selecting cleansing fluids for pressure ulcers - Nursing Times, Feb. 11, 2009

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