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FDA issues final rule on structure/function claims

FDA issued a final rule January 6 for dietary supplement product claims on the effect of the products on the structure or function of the body. The rule contains criteria to determine when a dietary supplement labeling statement constitutes a structure/function (S/F) claim for which no prior FDA review is required, or a disease-related claim for which authorization is required as a health claim or claims under drug provision of the Food, Drug, and Cosmetic Act.

FDA also narrowed the proposed definition of disease (see below) using the preexisting definition for health claims, revised the criterion that applies to conditions associated with natural states or processes such as menopause, aging, adolescence and pregnancy, and revised the criterion that relates to the use in labeling of the titles of publications that refer to diseases so that such use would imply a disease claim “only if in context, it implies that the product may be used to diagnose, mitigate, cure or prevent disease” (e.g., through highlighting, bolding, using large type size or prominent placement of a title of a publication).

A full text of the final rule, which will become effective February 7, is available in the January 6 *Federal Register*. Some highlights follow:

- ▶ The final rule differentiates between S/F claims authorized by section 403(r)(6) of the act and disease claims that may not be made in dietary supplement labeling under the authority of section 403(r)(6).
- ▶ The definition of disease under the rule is already defined for health claims. This definition is the “back-up” approach recommended by CHPA. We had urged that FDA preferably amend the proposed definition to incorporate the concept of adverse and “natural states” (which FDA acknowledges in the preamble to the rule and through a broader list of acceptable S/F claims), but if not, then to adopt the preexisting definition. Considering the diverse and strident views

on the proposed definition by most commenters, it is not surprising that FDA reverted to an existing definition, which the Agency considers a “narrower” definition than it had proposed. However, the Agency notes: “If experience shows a public health need for a different or broader definition, FDA will consider initiating a rulemaking to amend the definition.”

- ▶ FDA states the “the final rule classifies many more claims as structure/function claims than would have been so classified under the proposed rule, thus increasing the amount of information available to the consumer without prior FDA review.” This is accomplished in FDA’s view by not adopting the proposed definition of disease (see above) but using the preexisting definition of “disease or health-related condition” and a “less restrictive interpretation of the types of structure/function claims that can be made about conditions associated with such natural states as aging, pregnancy, and the menstrual cycle.”
- ▶ FDA is issuing a guidance document that will provide examples of claims that would and would not be considered by FDA as disease claims.
- ▶ Re: implied vs. explicit disease claims: FDA states that it “continues to believe that structure/function claims should not imply disease treatment or prevention.” FDA further states: “It has been FDA’s longstanding interpretation of . . . the act that the phrase ‘intended for use’ refers to the objective intent of the manufacturer, which is not limited to a manufacturer’s express representation.”
- ▶ FDA disagrees that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, particularly if the cholesterol levels are in the normal range.
- ▶ FDA states that certain constipation claims should not be disease claims, such as “for relief of occasional constipation,” provided the labeling states clearly that the product is not intended to be used to treat chronic constipation. Note that under the Tentative Final Monograph for OTC Laxatives, the following Category I monograph claim would be allowed as a drug claim, suggesting some conflict: “For relief of occasional constipation” [which may be followed by “(irregularity).”]

- ▶ FDA states that it “has reconsidered proposed Section 101.93(g)(2) and has concluded that it is not appropriate, under DSHEA, to treat certain common, nonserious conditions associated with natural states as diseases,” including adolescence, the menstrual cycle, pregnancy, menopause, and aging.

FDA states, “mild conditions commonly associated with particular stages of life or normal physiological processes will not be considered diseases.” The regulation now states “that a statement will be considered a disease claim if it claims that the product ‘has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm.’” FDA gives the following as examples of conditions about which S/F claims could be made: morning sickness associated with pregnancy; leg edema associated with pregnancy; mild mood changes, cramps, and edema associated with the menstrual cycle; hot flashes; wrinkles; liver spots; presbyopia; hair loss associated with aging; mild memory problems associated with aging; noncystic acne.

As with “relief of constipation” (see above), certain of these are OTC drug claim areas: menstrual symptoms, acne, hair loss. Presumably the OTC/dietary supplement distinction is made on the basis of health maintenance vs. treatment/prevention.

- ▶ FDA explicitly excludes benign prostatic hypertrophy (BPH) as a condition about which S/F claims cannot be made, because “BPH should [not] be considered a consequence of aging.” FDA states that “helps maintain normal urine flow in men over 50 years old” is an implied disease claim, because “the average or ‘normal’ state in men over 50 years old is diminishing urine flow, in most cases due to BPH, so that the apparent ‘maintenance’ really represents a claims of improvement (treatment).”
- ▶ FDA has modified criteria to narrow the circumstances under which citation to a scientific reference will be considered a disease claim. Placing a citation to a scientific reference that mentions a disease on the immediate product label or packaging will be considered a disease claim, “because of the unusual and unnecessary prominence of such placement.” On other components of labeling, FDA will consider the context of the placement of such citations.

CHPA's Dietary Supplement Strategic Planning Group will evaluate the impact of the final rule and will disseminate interpretations/commentary as needed to the membership. An excerpt from the January 6 *Federal Register* is enclosed with this issue of *XNL*.

CHPA reacts to CFSAN's 10-year strategic plan on dietary supplements

CHPA staff attended a press briefing January 3 at which **Joseph A. Levitt**, director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), unveiled the Agency's 10-year strategic plan to fully implement the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Levitt walked reporters through CFSAN's program goals in the areas of safety, labeling, boundaries, enforcement, science and outreach and then opened it up for questions. The bulk of the inquiries centered on whether FDA would have adequate funding to put the plan into effect. Levitt pointed out that while the Agency hoped for additional staff and funding in the future, for now it would have to "do the best job we can with the resources we have." In his final remarks, Levitt added that, "clearly the faster we can act on issues of safety, the better off the public is."

CHPA President **Michael D. Maves**, M.D., M.B.A., formally responded to the 10-year plan by stating, "FDA has translated a very complicated stakeholder process into a long-term implementation plan. We are pleased to see that FDA has taken our recommendation and placed safety first in its list of priorities. We are hopeful that this plan will translate into a process that will lead to a fully funded FDA. Most importantly, CHPA continues to urge FDA to further develop its enforcement program to ensure the availability of safe, effective and quality dietary supplements."

A complete copy of the plan is available on FDA's Web site at www.fda.gov.

*FDA/industry
recognize the need
for more funding*

M O R E F D A N E W S

FDA makes technical changes to OTC label rule

FDA published a technical amendment to the OTC label rule in the January 3 *Federal Register*. According to the amendment, the rule will now allow for light type on a dark background in the “Drug Facts” box of the label. In its original form, the rule restricted manufacturers to the use of dark type on a light background in the “Drug Facts” box, which may have forced certain products to completely alter their trade dress colors. In the preamble to the amendment, FDA noted its expectation that the color contrast used in the labeling should be at least as high as that used in a product’s principal display panel or other promotional labeling.

Additionally, the amendment called for consistency in the ordering of warnings in the rule and provided slightly different language to allow certain warnings to conform to specific subheadings.

CHPA to comment on “significant scientific agreement” guidance

FDA announced in the December 22, 1999, *Federal Register* the availability of a guidance for industry entitled, “Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements.” This guidance was prepared by FDA’s Food Advisory Committee Working Group in response to the recent court decision in *Pearson v. Shalala* requiring the Agency to clarify the meaning of the standard “significant scientific agreement.” A complete copy of the guidance is available on the Internet at <http://www.cfsan.fda.gov/difference/dms/guidance.html#lab>.

CHPA plans to provide comments on the guidance, which are due February 22. It will be a topic of discussion at the Association’s January 13 Regulatory Forum.

FDA proposes changes to OTC Review eligibility criteria

FDA proposed a rule in the December 20, 1999, *Federal Register* on eligibility criteria for the OTC Review. The proposed rule would change how the Agency looks at both OTCs introduced in the U.S. after the start of the OTC Review in 1972 and OTCs in other countries without U.S. marketing experience.



*Agency meets
industry demands
on trade dress issue*

The proposed rule lays out a two-step approach: first, meeting eligibility criteria for OTC Review inclusion; and second, an assessment of whether the condition is generally recognized as safe and effective. In the eligibility step, FDA would require: (1) OTC status somewhere; (2) if a foreign OTC ingredient and condition are Rx in the U.S., they would not be eligible for Monograph status; and (3) five years minimum OTC experience somewhere would be required.

FDA proposes a specific format for an eligibility submission, which would need to include extensive compilations of the ingredient/condition's status and regulatory conditions for countries in which it had been marketed. The Agency would evaluate the eligibility submission and, if it found the ingredient/condition eligible, OTC Review-style consideration would follow. Comments on the proposed rule are due by March 22.

This proposed rule provides more specifics to an October 1996 advance notice of proposed rulemaking (ANPR) on this matter. CHPA submitted comments on the ANPR, supporting the general concept of including foreign marketing information, but noted a number of challenges and the need for more flexibility in FDA's suggested approach.

FDA announces FY 2000 user fees

FDA issued a notice on FY 2000 user fees for new drug applications and certain Rx new drug establishment and products fees in the December 28, 1999, *Federal Register*. The two fee categories and corresponding fees affecting OTCs are: 1) applications requiring clinical data — \$285,740; and 2) supplements requiring clinical data — \$142,870. These fees are retroactive to the beginning of the fiscal year (October 1, 1999).

FDA issues second draft guidance on making CDER advisory committee materials open to public

FDA issued a notice in the December 22, 1999, *Federal Register* stating that a draft guidance is available on disclosing information provided to Center for Drug Evaluation and Research (CDER) advisory committees on new drug matters. This guidance follows the settlement in a Public Citizen case and FDA's November 30, 1999, guidance on how the Agency interprets the Federal Advisory Committee Act and the Freedom of Information Act (see December 3, 1999, *XNL*). The draft guidance is intended to address procedures for how sponsors should organize advisory committee

submissions; submission timing; CDER's review and redacting process; and the impact of all of this on timing in the review cycle. Full copies of the guidance can be downloaded from the Internet at: www.fda.gov/cder/guidance/index.htm. Comments are due by February 22.

Changes at FDA — Bowen leaves, Midthun named CDER division director

FDA announced that **Debra Bowen**, M.D., resigned January 1 as deputy director, Office of Drug Evaluation V, for the Center for Drug Evaluation and Research (CDER). Bowen has accepted a senior leadership position with CHPA Active member McNeil Consumer Healthcare (Johnson & Johnson).

FDA also announced the appointment of **Karen Midthun**, M.D., as CDER's director of the Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products. Midthun had been serving as acting director of that division since June 1999.

CHPA again urges consumers to beware of GBL products

CHPA again urged consumers to beware of using gamma butyrolactone (or GBL)-containing products. The Association issued a news release December 28, 1999, in response to reports that a near-fatal seizure recently suffered by Phoenix Suns forward **Tom Gugliotta** was most likely caused by a dietary supplement containing GBL.

Reports of serious adverse effects of GBL – including one death – led FDA to request manufacturers to voluntarily recall their GBL-containing dietary supplements and to issue warning letters to those companies that had not yet voluntarily complied with the request. In January of last year, CHPA alerted its network of consumer groups such as the National Consumers League, United Seniors Health Cooperative, the YWCA and others to this concern (see January 22, 1999, *XNL*).

“We support FDA taking action against the manufacturers of GBL. Although we understand that none of our members make GBL, we believe it is important to take a stand against GBL because it is a substance susceptible to abuse with very serious side effects,” said CHPA President **Michael D. Maves**, M.D., M.B.A. The reported

adverse effects include consumers who became unconscious or comatose, or experienced seizures, vomiting, slow breathing and slow heart rate.

GBL has been marketed as a dietary supplement making a variety of claims, including those relating to enhanced muscle performance, anti-aging effects and sexual function enhancement.

CHPA staff gearing up for AEC 2000

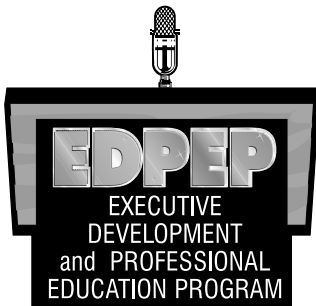
Enclosed (to CHPA members only) with this week's *Executive Newsletter* are registration materials for CHPA's May 2000 Annual Executive Conference (AEC). All pertinent information and necessary forms to register for the conference are included in this packet – meeting registration, hotel reservation, charter flight reservation, sports events – with specific details to guide the process.

Please note:

- ▶ The meeting registration form (in the pocket of the folder) should be mailed directly to CHPA.
- ▶ The sports events form should also be mailed directly to CHPA (preferably along with the meeting registration form).
- ▶ The hotel reservation form should be mailed or faxed directly to The Greenbrier and any questions pertaining to hotel room types should be directed to **Brenda Crawford** at The Greenbrier, Tel. (304) 536-1110, ext. 7355. Rooms cannot be held or confirmed via telephone; all room reservations must be made with the accompanying hotel form.
- ▶ The charter flight reservation form should be mailed directly to **Melanie Huckstep** at Association Travel Concepts; reservations will not be held without the form and the signed release document on its reverse side.

Hearst to sponsor AEC Breakfast Session

As in past years, *Hearst Magazines* will sponsor the speaker at the May 19 Breakfast Session (**Cokie Roberts** in 1999 and **Doris Kearns Goodwin** in 1998). Members of the Business Program Committee are currently discussing possible speakers for this year's event. Please note that we are asking individuals to sign up (and pay for their food) in advance for this breakfast so that we may have a



2000 CHPA Annual Executive Conference

*May 18-21
The Greenbrier
White Sulphur Springs,
West Virginia*

valid count and sufficient seating for what has been a “sell-out” event for the past two years.

Additions and/or changes to the AEC program/agenda will be included in future issues of the *XNL*. For information and registration packets, please contact **Kass Kassouf** or **Maria Sarabia** in the CHPA meetings department, Tel. (202) 429-3544 or 3545.

CHPA dues deadline reminder

CHPA member dues statements for the year 2000 were sent out December 1, 1999. Dues for Active members should be calculated on total net sales of OTC and dietary supplement products. For advertising agency members, dues should be calculated on total billings for these products. Member dues payments should be received no later than January 31. Payments not received by February 29 are subject to a 1 percent per month late fee. **Please note: AEC registration confirmations will be provisional until member dues are paid.** If you have not received your dues statement or have any questions, please contact CHPA's **Roman Blazauskas**.

Washington Business Information, Inc.'s Chairman David Swit dies

David Swit, chairman, Washington Business Information, Inc., died at the age of 65 from complications associated with idiopathic pulmonary fibrosis. A memorial service held January 3 at The Newseum in Arlington, Virginia, drew more than 200 people from around the country to reflect on the life of a truly unique, independent spirit, dedicated to the highest standards of journalism.

Swit founded Washington Business Information, Inc. (WBII) in 1972. WBII, headquartered in Arlington, Virginia, currently publishes a range of regulatory newsletters, including *Washington Drug Letter* and *The Food & Drug Letter*.

The Swit family has requested that donations be made to the following: Newsletter and Electronic Publishers Foundation, c/o Patti Wysocki, 1501 Wilson Blvd., #509, Arlington, Virginia 22209-2403; the National Press Foundation, c/o Laura Forman, 1211 Connecticut Ave., N.W., #310, Washington, D.C. 20036; or the Sigma Delta Chi Foundation, c/o Amy Fickling, P.O. Box 1955, Washington, D.C. 20036.



NEWS NOTES

February NDAC canceled, rescheduled for March

FDA has canceled the Nonprescription Drugs Advisory Committee (NDAC) meeting tentatively scheduled for February 28-29 and set a tentative new date of March 29. Tentative dates for additional meetings in 2000 are June 22-23, October 19-20 and December 7-8.

CHPA staff to speak at Nutritional 2000 conference

Nutritional Outlook magazine is sponsoring a conference and exhibition for the nutritional supplement industry February 9-10 in Anaheim, California. Attendees of the conference will hear from more than 20 speakers, including CHPA's **R. William Soller, Ph.D.**, senior vice president and director of science and technology, and **Leila G. Saldanha, Ph.D.**, vice president, nutritional sciences. The event will focus on product development and marketing and 150 exhibitors will be on-hand displaying raw ingredients, processing and packaging equipment, containers and materials, and contract services. For more information or to register, contact Mary Thorne at (610) 647-8585.

Communicating in Y2K

To ensure that CHPA made it into the year 2000 unscathed, any members who contacted CHPA staff within the past two weeks and have not received a response are encouraged to place another call or send another e-mail.

State legislative session schedule for 2000

Enclosed with this issue of *XNL* is this year's state legislative session schedule.

Enclosures: Excerpt from January 6 *Federal Register*
 AEC Meeting Registration Packet (Active and
 Associate Members Only)
 "State Legislative Session Schedule for 2000"



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