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FDA takes hard line on OTC labeling

FDA took a hard line on industry proposals at a November 23 public workshop to discuss the Final Rule on OTC label content and format.

The Agency declined to provide general guidance on five types of exemptions CHPA proposed, saying it would consider exemptions on a case-by-case basis, and making it clear that manufacturers would have to explore all other options to meet the letter of the rule, including enlarging the package. FDA stated that packages should be modified (made bigger) to fit the rule, rather than exceptions made to the rule to fit the package.

At the workshop, CHPA proposed five types of common exemptions for packages where there is not enough label space to accommodate the rule precisely as written and asked for an update on progress with decisions on trade dress and extension of the compliance date. Examples of each proposed exemption were presented in advance to the Agency November 2 in the form of package “mock-ups.”

The five exemption types included:

- (1) Use of the space-saving “modified format” without the 60 percent calculation specified in the rule, since the rule makes no readability differentiation between the “standard” and “modified” formats;
- (2) Reduction in type size for labels with small labeling runoffs (a “size-to-fit” approach), which would use type sizes consistent with those FDA permits for all other regulated products;
- (3) Elimination of the “Drug Facts (continued)” heading, in favor of prominent graphic arrows for panel-to-panel flow;
- (4) Moving the “Questions or Comments” section outside the “Drug Facts” box; and

- (5) Use of voluntary warnings and directions in the Drug Facts box and in the calculation of available label space.

CHPA recommended that FDA should respond to a company's exemption request within 14 days and that no response would indicate the request could be considered approved. CHPA also asked for parity treatment of OTC labeling with labeling requirements for all other FDA-regulated products with regard to columns, trade dress (*i.e.*, light print on a dark background) and type size.

FDA did not respond to industry requests for guidance on the trade dress issue and extension of the compliance date for the rule, but reported that the Agency was working diligently to provide answers.

Guidance issued on columns in labeling

FDA issued a draft industry guidance document on the use of columns on OTC labels to conform to the Final Rule on label content and format. While not allowing columns within the "Drug Facts" box, the guidance would allow more than one "Drug Facts" box on a label or carton panel in either standard or modified format. It would require a "Drug Facts (continued)" heading at the beginning of each box after the first and arrows directing the consumer to the next box. The complete draft guidance is available on FDA's Web site at www.fda.gov/cder/guidance/3435dft.pdf. A copy may also be obtained from CHPA's Mary McDonald. Written comments on the guidance are due January 31, 2000.

Task group provides preliminary comments on omega-3 fatty acid health claim

The Omega-3 Fatty Acids Health Claim Task Group, comprised of representatives from CHPA, the Council for Responsible Nutrition and the National Fisheries Institute, submitted comments November 22 responding to FDA's request for scientific information and data to evaluate the relationship between omega-3 fatty acids and coronary heart disease. The submission is available on CHPA's Web site at www.chpa-info.org.

The task group concluded that statements regarding the relationship of omega-3 fatty acids [eicosapentaenoic acid (EPA) and

*More detailed
submission to be
provided by group
upon docket re-
opening*

docosahexaenoic acid (DHA)] and coronary heart disease should be approved by FDA as a “health claim” for inclusion in labeling for both dietary supplements and conventional foods. The claim best represented by the science reviewed to date is:

Consumption of long chain omega-3 fatty acids (EPA and DHA) may reduce your risk of coronary heart disease through lowering triglycerides and other possible mechanisms. The evidence is compelling but further research is needed.

The task group intends to review and collate additional information related to the “other possible mechanisms” for submission to the Agency when the docket is re-opened. FDA promised to re-open the docket in a letter denying the task group’s request for an extension of the comment period to fully develop the science and its interpretation.

FDA prepares strategy for implementation of *Pearson* court decision

FDA published a notice in the December 1 *Federal Register* describing the agency’s strategy for implementation of the *Pearson* court decision (see April 16 *XNL*). The components of FDA’s strategy include:

1. Update the scientific evidence on the four claims at issue in *Pearson*;
2. Issue guidance clarifying the “significant scientific agreement” standard (projected to be published before the end of 1999);
3. Hold a public meeting in the first quarter of 2000 to solicit input on changes to FDA’s general health claim regulations for dietary supplements in light of the *Pearson* decision;
4. Conduct a rulemaking to reconsider the general health claims regulations for dietary supplements in light of the *Pearson* decision; and
5. Conduct rulemaking on the four *Pearson* health claims.

For more information, contact Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS-007), FDA, 5600 Fishers Lane, Rockville, Maryland 20852; Tel: (301) 827-6733.



M O R E F D A N E W S

Henney backs mission of PQRI

FDA Commissioner **Jane E. Henney**, M.D., showed strong support for the Product Quality Research Institute (PQRI) in a November 14 speech to the American Association of Pharmaceutical Scientists by calling it “an excellent example of collaboration between FDA, industry and academia.” CHPA is a founding member of PQRI and is presently a member of its steering committee and board of directors. The purpose of PQRI is to provide a science base for Agency regulations and eliminate or reduce the need for certain testing requirements while continuing to maintain high product standards. In line with PQRI’s mission, Henney stressed that, “The research data and information developed by PQRI should allow sponsors and the Agency to introduce novel manufacturing and analytical technology into practice quickly and to eliminate or reduce the need for certain additional tests such as bioequivalence tests in healthy human volunteers without sacrificing product quality and performance.”

The first of PQRI’s 12 identified projects is to assess the value of requiring blend uniformity testing on a routine basis. If the data show that such routine testing adds little value to the product, and the test requirement is eliminated, significant savings for the industry would be realized. The PQRI board is currently working to develop a funding strategy for the projects.

FDA publishes semi-annual agenda

The FDA published its semi-annual regulatory agenda in the November 22 *Federal Register*. Included in the OTC Review were 29 final actions, 11 proposed actions and one advance notice. One Final Monograph (Skin Protectant) is projected for publication by the end of this year, two OTC Review documents (Sunscreen Final Monograph and the Proposed Rule on Otic – Swimmer’s Ear) were published since the last (April) agenda. Two final actions (Emetics and NDA Labeling Exclusivity) and one proposed action (Internal Analgesic Labeling – Revised Indications) have dropped off the agenda.

Projected Final Rules in the OTC Review are:

Final Monographs:

December 1999: Skin Protectant

January 2000: Ophthalmic

March 2000: Cough/Cold Combinations, Laxatives

June 2000: Antiperspirant, Sleep-Aids, Poison Treatment

August 2000: Antidiarrheal

December 2000: First Aid Antiseptic

December 2001: External Analgesic, Menstrual Products, Overindulgence

June 2002: Oral Discomfort Relief

Final Monograph Amendments:

December 1999: Skin Protectant (Poison Ivy)

March 2000: Antacid and Internal Analgesic (Sodium Bicarbonate), Cough/Cold Antitussive (Flammability)

June 2000: Aspirin (Heart Labeling Warning), Cough/Cold Antihistamine (Warning), Cough/Cold Combinations (Ephedrine), Phenylpropanolamine (Labeling)

July 2001: Benzoyl Peroxide Labeling

December 2001: Antacid, Internal Analgesic, Stimulant (Overindulgence)

December 2003: Laxative (Stimulant)

March 2004: Antimicrobials (Diaper Rash)

Other Final Rules:

December 1999: Reye Syndrome Warning (Amendment)

January 2000: Cation (Ca, Mg, K, Na) Labeling

The regulatory agenda also included projections for a proposed rule on OTC ADRs (April 2000); a proposed rule on dietary supplement GMPs (September 2000); and final action on dietary supplement structure/function claims (January 2000).

FDA says materials for CDER advisory committee meetings are subject to FOIA

FDA made available November 30 a guidance for industry entitled "Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research (CDER) Beginning on January 1, 2000." This document, the first of what will be at least two guidances, details FDA's interpretation of the Federal Advisory

*Guidance now
available to
industry*

Committee Act and Freedom of Information Act (FOIA) requirements with respect to disclosing materials submitted to advisory committees. FDA states that whenever practicable and subject to any applicable exemptions of FOIA, those materials must be made available for public inspection and copying before or at the time of the meeting.

The implications for companies appearing before advisory committees seem clear. Sponsors should establish a clear dialogue with the reviewing division and advisory committee consultant staff on what aspects of the materials developed by the company and/or the FDA medical and statistical reviewers might be appropriately redacted from public scrutiny under FOIA exemptions. The CHPA Scientific Affairs Committee is addressing this issue through the quarterly dialogue series with CDER review management.

Single copies of the guidance are available by written request to the Drug Information Branch (HFD-210), CDER, FDA, 5600 Fishers Lane, Rockville, Maryland 20857, or on the Internet at www.fda.gov/cder/guidance/index.htm. Comments on the guidance are due by February 28, 2000. For additional information, contact Murray M. Lumpkin, at the above CDER address or Tel: (301) 594-5400.

New guidance for industry on NDAs/ANDAs

FDA has finalized its guidance for industry on reporting changes to an approved new drug application (NDA) or abbreviated new drug application (ANDA). The guidance comes as a result of the FDA Modernization Act of 1997 (FDAMA) which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. The document covers recommended reporting categories for post-approval changes for drugs, other than specified biotechnology and specified synthetic biological products. Included are recommendations for post-approval changes in: 1) components and composition; 2) manufacturing sites; 3) manufacturing process; 4) specifications; 5) packaging; 6) labeling; 7) miscellaneous changes; and 8) multiple related changes. The 38-page guidance is available on the FDA web site at www.fda.gov/cder/guidance/index.htm, under the "Chemistry" section.

Proposed rule on citizen petitions will reduce FDA backlog

FDA issued a proposed rule in the November 30 *Federal Register* that would amend the Agency's regulations for citizen petitions. The proposal is intended to cut down on the abundance of citizen petitions the Agency receives. According to the proposed rule, any person may submit a citizen petition to: 1) issue, amend or revoke a regulation; 2) issue, amend or revoke an order; or 3) take or refrain from taking any other form of administrative action. The document states that individuals wishing to contact the Agency on unrelated matters may do so by using more conventional methods, *i.e.*, letters and e-mail.

The proposal also calls for revisions on certain content requirements for citizen petitions and would allow the Agency to refer petitions for other administrative action, seek clarification of a petitioner's requests, withdraw certain petitions and combine petitions. For more information, contact Philip L. Chao, Office of Policy (HF-23), FDA, 5600 Fishers Lane, Rockville, Maryland 20857; Tel: (301) 827-3380. Written comments are due February 28, 2000.

ON CAPITOL HILL

Congress adjourns for 1999: action taken on key issues for CHPA

The U.S. House and Senate have concluded legislative business for 1999. Prior to its November 19 adjournment, Congress took action on several issues of importance to CHPA, including methamphetamine trafficking, research and experimentation tax credits, and appropriations for FDA, the Drug Enforcement Agency (DEA) and the National Institutes of Health (NIH).

Methamphetamine trafficking and production

The Senate approved legislation designed to deter methamphetamine production and distribution. The measure would increase funding authorizations for federal, state and local law enforcement organizations, prohibit the posting of methamphetamine drug recipes on the Internet and stiffen penalties for illegal production of the drug.

The bill makes certain changes to the law on the handling of precursor chemicals, including ephedrine, pseudoephedrine and phenylpropanolamine. It reduces the retail sales transaction



threshold for non-safe harbor OTC drug products containing pseudoephedrine and phenylpropanolamine from 24 grams to 9 grams. Existing law defines safe harbor packaging as blister packs containing less than 3 grams of the base ingredient with no more than 2 doses per blister.

The bill also requires the Attorney General to conduct a study of the use of safe harbor drug products in the clandestine production of methamphetamine. Based on the results of the study, the Attorney General must submit a report to Congress on the need for additional measures to prevent the diversion of ordinary OTC drug products to clandestine labs.

Additionally, the bill allows DEA to hire more personnel for the Office of Diversion Control and to develop a computer infrastructure sufficient to receive and process enforcement information of suspicious orders received from the OTC drug industry and DEA field personnel. The bill would also exempt from DEA registration and reporting requirements transactions involving the distribution of sample OTC drug products to consumers, but would strengthen existing penalties for illegal trafficking in precursor chemicals.

CHPA strongly supports the bill. Similar legislation has been introduced in the House of Representatives.

R&D tax credit “extender” bill passes

Prior to adjournment, Congress approved and sent to the President legislation that would extend various tax credits for businesses and middle-class taxpayers. Included in the bill is a five-year extension of the research and experimentation tax credit through June 30, 2004. The legislation is expected to be signed into law by the President.

Federal appropriations for agency spending

Despite a multibillion dollar surplus in the Federal budget, Congressional appropriators gave only modest increases to fund FY 2000 programs for agencies that regulate OTCs and dietary supplements, with the exception of NIH. All of the funds discussed in this report are subject to a .38 percent across-the-board cut in discretionary budget authority; however, Congress will allow specific agencies flexibility to tailor the cuts within their designated budgets.

At FDA, the Center for Drug Evaluation and Research will receive \$309 million and the Center for Food Safety and Applied Nutrition (CFSAN)

will receive \$269 million for FY 2000. Congress did not specifically earmark funds for the Division of OTC Drugs, or money requested to enhance the adverse event reporting system at CFSAN.

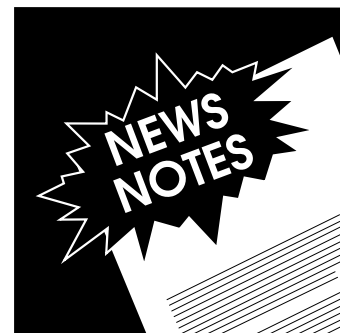
The National Center for Complementary and Alternative Medicine has been funded at \$68.7 million, an \$18 million increase from FY 1999. Funding for the Office of Dietary Supplements (ODS) is included in an appropriation of \$283.5 million for the NIH Office of the Director. However, Congress did not specifically designate funds for ODS. The Senate indicated its strong support for the important work of ODS and the great need for additional research to better inform consumers of the health benefits of supplements. The Senate also noted that the President's Commission on Dietary Supplements recommended that ODS be funded at its fully authorized level of \$5 million.

The Department of Justice will receive \$35.6 million to be used for state and local law enforcement policing initiatives to combat methamphetamine production, distribution and use. The money will also be used for proper removal and disposal of hazardous materials at clandestine methamphetamine labs. Additionally, Congress designated that these funds should be used to award specific program grants to fight methamphetamine in Arizona, California, Nevada, Illinois, Iowa, Nebraska, New Mexico, Utah, Tennessee and Wisconsin. DEA will receive an additional \$9.7 million to assist regional enforcement teams in the western United States and to provide training and enforcement for state and local authorities along the Southwest border.

NEWS NOTES

NDAC renewed for two more years

FDA recently announced that it will renew the charter for the Nonprescription Drugs Advisory Committee (NDAC) an additional two years beyond its original expiration date. The new date of expiration for the committee is now August 27, 2001.





FDA releases document on mercury compound in drugs and food

FDA announced in the November 19 *Federal Register* the availability of a document, "Mercury Compounds in Drugs and Food." This document discusses drugs (including biologics) and food products containing intentionally introduced mercury compounds and also provides a quantitative and qualitative analysis of those compounds. Single copies of the document may be obtained by sending a self-addressed stamped envelope to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, Maryland 20857; or on the Internet at www.fda.gov/cder/index.htm.

Mazzucca moves to Parade

CHPA received word November 24 that **Daren Mazzucca** has been named vice president, advertising director, for *Parade* Publications Inc. Prior to that, Mazzucca held the position of publisher for *New Choices* Magazine, Reader's Digest Special Interest Publications. Since both *Parade* and Reader's Digest are CHPA Associate Members, the Association is pleased to note that Mazzucca will remain a member of the business program and general activities committees for the 2000 Annual Executive Conference.

California updates Proposition 65 list

Enclosed with this *XNL* is a November 26 list of "Chemicals Known to the State to Cause Cancer or Reproductive Toxicity," published by the state of California. Any new additions to this Proposition 65 list are underlined.

Enclosure: California Proposition 65 List



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