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Systems inspections is the hot topic for FDA/industry summer workshops

The 2002 FDA/industry summer workshops will examine the new FDA systems inspections approach to pharmaceutical plant inspections. This new method was rolled out nationally in February after a six-month pilot program. Because there is a change in how plant inspections are conducted, it is crucial for industry to have a full understanding of how the new systems inspection process works. This new approach focuses on up to six systems. If the systems are working properly, then the products produced by them also will be under control. It is a requirement that the quality system always be inspected, along with one or more of the following: laboratory controls, production, packaging and labeling, facilities and equipment, and materials.

At the workshops, FDA officials instrumental in the development of the program will explain the nuances of the new systems approach, share the results and some case studies from pilot program, and describe how the Agency will review the various systems. Industry experts will offer suggestions on how to prepare for the new inspections, and discuss how they can be mutually productive for both industry and government.

CHPA has developed the workshop program with FDA through a co-sponsoring arrangement. Other associations helping to co-sponsor the workshops include the Pharmaceutical Research and Manufacturers of America, the Generic Pharmaceutical Association, the International Pharmaceutical Excipients Council of the Americas, and the American Council of Independent Laboratories.

The summer workshops will be held in three different locations: June 17 in East Rutherford, New Jersey; July 15 in San Juan, Puerto Rico; and August 5 in Manhattan Beach, California. The draft program with registration information is enclosed with this *XL* and is also available in the "Meetings" section of CHPA's web site at www.chpa-info.org. Early registration is recommended. Due to the popularity of previous workshops, all sessions are expected to quickly fill to capacity.

CHPA contacts: Bill Bradley and Mary McDonald



EYE ON INTERNATIONAL

UK looks ahead on switch

One of the 2002 aims for the United Kingdom's (UK's) National Health System plan is to make more medicines available OTC to widen access and consumer choice. In working toward this goal, a group of stakeholders, including the government's Medicines Control Agency (MCA), the Royal Pharmaceutical Society of Great Britain (RPSGB), the Proprietary Association of Great Britain (PAGB), and others identified three streams of work. For its part, the MCA released proposals to update and simplify its Rx-to-OTC switch process last December. MCA anticipates that its changes will be in place after April 1.

The RPSGB has led the second stream to identify therapeutic categories potentially suitable for switch consideration. Items on the list are not intended as specific recommendations or safety assessments, but rather, the group's thoughts for ingredients and conditions that merit consideration. Included are categories to assist in the management of chronic conditions and health promotion such as hypertension, cholesterol-lowering therapy, chronic stable asthma, and urinary incontinence, among others. The complete list is available at www.rpsgb.org.uk/pdfs/pomtopreclasslist.pdf.

The third stream of work, led by PAGB, is examining information and training needs for health care professionals and consumers concerning potential switch areas. The report contains possible aspects that stretch beyond traditional product labeling that may surround switches in more disease management-oriented categories in the UK. The abridged report is available at www.rpsgb.org.uk/pdfs/pomtopreclassinftr.pdf.

CHPA contact: Dave Spangler

AESGP Annual Meeting

*June 5-7, 2002
Dublin, Ireland*

AESGP annual meeting: great expectations for self-care

Education and the availability of new technologies have given today's consumers high expectations for the products and services they purchase, as well as the companies that supply them. New technologies that are fueling changes in consumer behavior and expectation are obvious, and those same technologies enable companies to respond effectively. But what changes are needed in business models?

The Association of the European Self-Medication Industry's (AESGP's) 38th annual meeting will examine consumer attitudes across Europe on a wide range of questions concerning information, services, and access to OTC medicines and other self-care products. A panel of consumer and patient representatives will look at self-medication through the eyes of the customer, and discuss how expectations can be met.

The meeting, set for June 5-7 in Dublin, Ireland, also will include updates on key revisions to European Union legislation such as on pharmaceutical authorization, labeling, and advertising rules, traditional herbal medicines registration, and food supplement rules. For more information and registration materials, visit www.aesgp.be/meetings.html.

CHPA contact: Dave Spangler

Dietary supplements workshop stresses importance of analytical methods

A final program is now available for an interactive dietary supplements analytical methods workshop to be held April 18 from 8:30 a.m. to 5:00 p.m. at the National Institutes of Health (NIH) campus in Bethesda, Maryland. Organized by CHPA, AOAC INTERNATIONAL, and the NIH Office of Dietary Supplements, this event will explain the significance of appropriately selecting dietary supplement analytical methods, with the overall aim of creating a compendium/database of reference analytical methods.

The event includes a number of focused sessions such as:

- ▶ An industry panel moderated by **Leila G. Saldanha**, Ph.D., R.D., vice president, Nutritional Sciences, CHPA. This panel will offer presentations on how methods are selected, validated, and documented by ConsumerLab.com, NSF International, and the U.S. Pharmacopeia for their respective certification programs.
- ▶ A research and government panel moderated by **Elizabeth Yetley**, Ph.D., lead scientist for nutrition, Center for Food Safety and Applied Nutrition, FDA. This panel will provide FDA perspectives on the level of validation and documentation appropriate for research, compliance, and enforcement purposes.

Workshop attendance is restricted to the first 95 registered individuals - sign up today!

- ▶ An AOAC INTERNATIONAL/National Institute of Standards and Technology panel moderated by **Daryl Sullivan**, senior client manager, Food Chemistry, Functional Foods and Nutraceuticals. This session will comprise presentations on how to validate and document methods that meet AOAC requirements and the development of standard reference materials.

The workshop also will feature a keynote presentation by **Bernard A. Schwetz**, D.V.M., Ph.D., senior advisor for science, Office of the Commissioner, FDA, breakout sessions, and a Q&A panel made up of selected speakers from the other sessions. A copy of the complete program and registration form is available in the "Meetings" section of CHPA's web site at www.chpa-info.org. For more information on the workshop, call RSJ Associates at (301) 774-3038 or rsj@incomnet.net.

CHPA contact: Dr. Leila Saldanha

F D A N E W S

Crawford named FDA deputy, but still no word on top dog

U.S. Department of Health and Human Services (HHS) Secretary **Tommy G. Thompson** named **Lester M. Crawford, Jr.**, D.V.M., Ph.D., deputy commissioner of FDA effective February 25. Crawford replaced **Bernard A. Schwetz**, D.V.M., Ph.D., who had been acting principal deputy commissioner for the Agency since January 2001. According to HHS, Schwetz will now resume his normal duties as senior advisor for science, Office of the Commissioner, FDA.

Crawford most recently served as head of the Center for Food and Nutrition Policy at Virginia Tech. His résumé also includes a stint as administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service (1987-1991) and two non-concurrent terms serving as director of FDA's Center for Veterinary Medicine (1978-1980) and (1982-1985).

Crawford's appointment, which did not require Senate confirmation, makes him the number one ranking official at FDA until a permanent commissioner is selected. The jury is still out on when the White House will finally fill the top slot.

*Deputy
Commissioner
Crawford likely to
be the highest
ranking FDA
official until a
commissioner is
finally chosen*

Schwetz says FDA has learned from tragedy

In opening the 2002 FDA Science Forum, February 20-21 in Washington, D.C., **Bernard Schwetz**, D.V.M., Ph.D., (former) acting principal deputy commissioner of FDA, discussed the role of science in anticipating public health problems in today's world. Citing FDA's history of preparedness for emergencies, Schwetz said that in the wake of the terrorist attacks September 11 and the subsequent anthrax incidents in October, the Agency learned several lessons in the areas of product review and research and in communicating scientific uncertainty to the public.

The overall focus of the science forum was on the importance of decision-making in the many scientific and regulatory disciplines at the Agency — the multidisciplinary foundation of research, review, policy, and regulation. Schwetz stated that FDA's future planning includes a Crisis Management Center, coordination and communication on an emergency issue by one designated department, an Office of Public Health Preparedness, and fine-tuned coordination with other government agencies.

CHPA contact: Dr. Lorna Totman

Enhanced networking at AEC to power your business

Take advantage of the tremendous networking opportunities available at the 2002 Annual Executive Conference (AEC). Eight hours have been set aside for one-on-one interaction among members. The member business appointment set-up is not a "free-for-all" trade show environment. It is structured through specified and confirmed appointments in order to provide the best climate in which to present your company's background and capabilities.

Table space is still available at this time; however, appointments are being made at a fast pace. Don't delay or your prime prospect may be all booked up! For more information or to reserve table space, contact **David Caplin**, CHPA business appointment coordinator at (330) 655-5840 or dcaplin@earthlink.net.

CHPA contact: Phyllis Taylor



2002 CHPA Annual Executive Conference

*May 16-19, 2002
The Greenbrier
White Sulphur Springs,
West Virginia*

CPSC proposes HRT exemption

The Consumer Product Safety Commission (CPSC) has proposed exempting most hormone replacement therapy (HRT) products from child-resistant packaging (CRP) requirements. All prescription products for oral administration are currently required to be packaged in CRP. In its proposal, published in the February 19 *Federal Register*, CPSC cited the relative lack of toxicity of such products, and previous experience with overdoses and accidental ingestions. Exempt under the proposal are "Hormone replacement therapy products that rely solely upon the activity of one or more progesterone or estrogen substances." The comment deadline is May 6.

CHPA contact: Bill Bradley

Opportunity to submit nominations for evidence-based practice centers

The Agency for Healthcare Research and Quality (AHRQ) at the U.S. Department of Health and Human Services is currently seeking nominations for evidence reports and technology assessments on topics relating to the prevention, treatment, or management of diseases and conditions, as well as to the organization and financing of health care. Past topics that have been reviewed through awards from AHRQ include chronic asthma management, effect of seasonal allergies on working populations, management of allergic rhinitis, and the use of garlic for cardiovascular disease.

According to the notice published in the February 14 *Federal Register*, topic nominations are due April 15, but AHRQ also accepts them on an ongoing basis. Interested parties should submit nominations to Jacqueline Bestemen, J.D., M.A., director, Evidence-based Practice Centers Program, Center for Practice and Technology Assessment, AHRQ, 6010 Executive Boulevard, Suite 300, Rockville, Maryland 20852; (301) 594-4017.

NEWS NOTES

Commerce Department goes to China

U.S. Department of Commerce Secretary **Don Evans** will lead a delegation of U.S. business executives seeking new opportunities in China to Beijing and Shanghai, April 21-25. The Commerce Department is seeking business participants for the mission, with



medical products as a target sector. Meetings with both the Chinese government and potential business partners are central to the trade mission. For more information on the mission, visit www.doc.gov/chinatrademission, or call the Commerce Department's Office of Business Liaison at (202) 482-1360.

FDA and DIA collaborate on agency/industry interactions workshop

FDA and the Drug Information Association (DIA) are hosting a joint workshop April 30 - May 2 at the Hyatt Regency in Bethesda, Maryland: "Effective Agency/Industry Interactions to Expedite Drug Development." The workshop is designed to bring representatives together from FDA and industry with the goal of challenging current assumptions in developing new approaches needed to improve communications and key decision making between the Agency and industry. To view full program details or to register, visit www.diahome.org.

CFH/FDA offer Spanish-speaking consumers a new resource

Drug Interactions: What You Should Know – the Council on Family Health (CFH), the National Consumers League (NCL), and FDA's popular consumer education brochure – is now available in Spanish. *Interacciones de Medicamentos: Lo que usted debe saber* also is endorsed by both FDA and NCL and describes the different types of drug interactions of which consumers should be aware. In addition, it offers valuable information on how to read medicine labels and provides examples of drug interaction warnings on certain OTC medicines. To view this brochure, visit the Spanish section of CFH's web site at www.cfhinfo.org; copies also may be ordered on the site's publications order form.

FDLI presents its 45th annual educational conference

The Food and Drug Law Institute (FDLI) will hold its 45th annual educational conference April 16-17 at the Renaissance Hotel in Washington, D.C. A diverse group of representatives from industry and FDA's Center for Food Safety and Applied Nutrition and its Center for Drug Evaluation and Research are scheduled to participate in the meeting. The agenda covers topics such as the direction and future of product liability and what the industry should do in an era of refocused good manufacturing practices, as well as a panel with **Daniel E. Troy**, chief counsel, FDA, entitled "Dan Troy, Speaking Freely." For more information, visit www.fdpi.org or call (202) 371-1420.



Guide and briefing teach the art of combating pharmaceutical counterfeits

Reconnaissance International is in the process of finalizing an industry guide that teaches industry executives how to develop strategies and solutions for fighting the counterfeiting of pharmaceutical products. *Protecting Medicines & Pharmaceuticals: A Manual of Anticounterfeiting*, a 200+-page guide available to the public in April, will be used as the syllabus for the Third Pharmaceutical Anticounterfeiting Solutions™ executive briefing, also sponsored by Reconnaissance. The briefing is scheduled for April 22-23 at the Hotel Washington in Washington, D.C. To secure an advance copy of the soon-to-be-released guide or to register for the briefing, log on to www.reconnaissance-intl.com.



CALENDAR OF EVENTS

Dietary Supplements Analytical Methods Workshop

April 18, 2002
Natcher Center, NIH Campus
Bethesda, Maryland

2002 CHPA Annual Executive Conference

May 16-19, 2002
The Greenbrier
White Sulphur Springs, West Virginia

Systems Inspections 2002: FDA/Industry Workshop

June 17, 2002
Sheraton Meadowlands
East Rutherford, New Jersey

Systems Inspections 2002: FDA/Industry Workshop

July 15, 2002
San Juan Marriott Resort & Stellaris Casino
San Juan, Puerto Rico

Systems Inspections 2002: FDA/Industry Workshop

August 5, 2002
Manhattan Beach Marriott
Manhattan Beach, California

Manufacturing Controls Seminar

October 10-11, 2002
Hilton Parsippany Hotel
Parsippany, New Jersey

Research & Scientific Development Conference

November 7-8, 2002
Hyatt Regency Hotel
Bethesda, Maryland

Enclosures: FDA/CHPA summer workshop brochures
Dietary supplements analytical methods workshop programs