

IPEC-Americas News

June, 2008

June 4-6 TriPEC Meetings in Portland, Oregon Summary Report of General Topics Discussion

During the most recent set of planned semi-annual meetings of the three current PECs, the first held in the U.S. since November 2006, IPEC-Americas had six participants: Chairman David Schoneker (Colorcon), Chair-Elect Janeen Skutnik (Pfizer), Immediate Past Chair Dr. Arthur Falk (IPEA), CRC/Harmonization Committee Chair Priscilla Zawislak (Hercules), and two IPEC-Americas staff members, e.g., Executive Director Kimberly Beals and Secretary-Treasurer Alan Mercill.

A number of High Priority General Topics were discussed at length and several were assigned follow-up actions. These included:

IPEC's future strategic planning and prioritization process – and as a first step each PEC's current mission and vision statements need to be circulated for review and future discussion;

Need for a new global name and logo - With the addition of a planned PEC in China during 2008 and possible future organizations created in Brazil and India, the name "TriPEC" has become obsolete. One suggestion discussed was that each region could use "IPEC" followed by their regional or country name. Staff was asked to research how a global federation of associations should be structured and costs involved. Development of a new international IPEC logo also was discussed and it was agreed to circulate any proposals for possible future resolution.

International import safety and quality issues – As a result of recent global events involving the presence of DEG in glycerin and contaminated heparin, it was reported that remedial regulatory and possible legislative actions were under discussion in every region. These will be monitored and where indicated, IPEC regional groups would take active roles. Development of an

IPEC “excipient pedigree” position statement would continue and an effort would be made to publish an article detailing IPEC’s position in connection with supply chain security.

Future excipient qualification guidance and next steps - Based on reports that regional review of finalized EQ guidance could be completed during June in IPEC-Americas and Europe, permission to publish would be sought so simultaneous publication might occur in September. A final document will be forwarded to JPEC for translation, review and comment.

Good distribution practices (GDP) auditing guidance - Work to develop agreed-to IPEC guidance is continuing, as is cooperation between IPEC and other groups in Europe on matters of mutual interest.

Third party certification issues – In response to growing global concern related to import security and excipient lifecycle management issues, etc., regulatory authorities in Europe and the U.S. have begun public discussion about how industry practices in the GMP and GDP areas might assist them to better define auditable standard elements and how auditing could contribute to a government – accepted certification process. In order to provide assistance, IPEC-Americas and Europe will form a joint auditable standards/certification steering committee and make a formal offer regarding collaboration to regulatory authorities in both regions.

As for JPEC, it will review whether the certification concept can fit into the existing GMP/GDP auditing system for Japanese ingredient producers, distributors and finished product manufacturers.

Pediatric medicine initiatives at WHO, within the EU and at FDA – These are expected to have a major effect on how excipients are processed and tested for pharmaceutical use, depending on how the regulations are finally structured and enforced. This will be monitored closely by all three PECs.

IPEC excipient composition guidance – IPEC-Americas would like to publish guidance which includes definitions for mixed and co-processed excipients, and how they are used, etc., before the end of 2008. Europe and JPEC will work to see that their members’ comments are included.

Meeting Highlights

June 5 TriPEC/PDG Dinner

Twenty-five persons attended the semi-annual dinner meeting on June 5, 12 from IPEC associations, 12 from the pharmacopeias that comprise the PDG, and a special guest, Dr. Sabine Kopp of the World Health Organization (WHO) Executive Secretariat.

During the meeting it was reported that harmonization had been achieved on 25 of the 35 general chapters and on 39 of the 62 excipient monographs presently in the harmonization process.

With respect to the heparin situation, it was noted that all three pharmacopeias have taken measures to assure safety and plan to coordinate their efforts in connection with monograph analytical test methods.

Status reports on the ongoing efforts to harmonize a number of excipient monographs also were given and will be provided separately to affected and interested IPEC-Americas members.

Issues related to excipient composition and identification were major discussion points throughout the evening, particularly when tests to determine grade differentiation or functionality attributes may be considered as non-mandatory. EP reported that while it was its position that the inclusion of non-mandatory FRC testing in monographs did not create a disharmonization situation, it would be happy to review specific examples where this has occurred and where changes are needed. It was agreed that any such examples should be brought to PDG for review.

IPEA GMP Auditor Training Workshop

Houston, Texas

Only a few places remain open for the September 23-25 GMP Auditor Training Workshop to be held at the Marriott Houston Hobby Airport hotel. The workshop is limited to 20 participants and is filling quickly. This comprehensive auditing workshop covers essential elements of excipient

good manufacturing practices for materials intended for use in pharmaceuticals, dietary supplements, food, or as industrial chemicals. Focus will be on excipient GMP compliance, auditing techniques, report writing, observation classification, etc., that are important to the manufacture of excipient ingredients. The course also features an interactive demonstration to help participants refine the skills they have learned.

If you or someone in your organization wants to attend, please call Valeria Stewart, IPEA Workshop Coordinator at 703-351-5266 in order to secure a place.

FDA Adds \$275 Million To 2009 Budget Request

As first reported June 9 by Reuters and later by food and pharmaceutical industry publications, FDA has added an additional \$275 million to its original budget request of \$2.4 billion for fiscal year 2009. If approved as expected by many in and out of Congress, given FDA's needs and wide range of responsibilities, the money could become available to FDA as early as October.

According to FDA Commissioner Andrew von Eschenbach, M.D. who, along with HHS Secretary Michael Leavitt, participated in a June 9 teleconference with reporters, the new money would be used to hire, train, and insert into the field up to 490 additional FDA personnel needed in different product safety areas.

This message was reinforced three days later during testimony of FDA Assistant Commissioner for Food Protection, David Acheson, M.D. before the House Energy and Commerce Subcommittee on Oversight and Investigations. During his testimony, which dealt with implementation of FDA's action plan for import safety and a separate food protection plan, Dr. Acheson noted that \$125 million would be used for people in food safety efforts; \$100 million would go to improve drug, biologic and medical device safety; and the remaining \$50 million will be used to improve FDA's ability to monitor developments in nanotechnology, cell and gene therapies, robotics, genomics, and advancing FDA's Critical Path initiative.

Considering the FDA's current responsibilities and those proposed in pending legislation following the heparin incident and the ongoing tomato/salmonella situation, plus factoring in the age of over 25% of current FDA employees, even more money could be needed in its 2010 budget.

At the present time FDA regulates almost everything American consumers eat in the food area except for meat, poultry and processed egg products (which are regulated by the Department of Agriculture). This is in addition to FDA regulation of pharmaceuticals for human and animal use, medical devices, cosmetics and personal care products, and dietary supplements.

As a result it has been estimated that about one-quarter of every dollar spent this year by Americans will be spent on products regulated by FDA.

**Session on Import Safety
Included on 2008 PDA/FDA
Regulatory Conference Program**

According to the recently-released planned program for the 2008 PDA/FDA Joint Regulatory Conference (September 8-12 in Washington, D.C.), included will be September 9 concurrent afternoon session devoted to import safety issues. The session will be moderated by Dr. Maria Guazzaroni Jacobs of Pfizer and will feature presentations by:

John Ayres, M.D., Director, Global Patient Safety, Eli Lilly & Company;
David R. Schoneker, current IPEC-Americas Chair and Director of
Global Regulatory Affairs, Colorcon;
Janeen Skutnik, IPEC-Americas Chair-Elect and Director of Regulatory
Monitoring, Worldwide Pharmaceutical Sciences, Pfizer Inc. and
Jeff Shuren, M.D. Assistant Commissioner for Policy,
Food and Drug Administration

According to Dr. Jacobs, who chairs IPEC-Americas Excipient Qualification Committee and is Director of Quality and Regulatory Policy in Pfizer's Worldwide Pharmaceutical Sciences operations, session attendees will have an opportunity to learn about steps which companies may need to take to conform with recommendations made by the Interagency Working Group on Import Safety in 2007 and a subsequent Action Plan. Included in the

discussion will be details of ongoing IPEC and other efforts to improve the safety of pharmaceutical ingredient supply chains, the need to establish excipient pedigrees and details of recent agreements with China and other importers to the U.S. For more information go to www.pda.org/pdafda2008

Approval Granted for Three FDA China Inspection Offices

On June 17 Department of Health and Human Services (HHS) Secretary Michael Leavitt announced during a news briefing that China has granted diplomatic approval for the U.S. Food and Drug Administration (FDA) to open three inspection offices in China that will be staffed by FDA employees. The three offices will be located in Beijing, Shanghai, and Guangzhou and it's hoped that all three will be staffed and open before the end of December.

The agreement was reached during a series of talks at HHS between U.S. and China health officials. It also was reported that China's inspection agency and FDA have agreed to terms of a future work plan to tighten existing SFDA food and animal feed standards and to work together to improve the scientific basis for use of traditional Chinese medicines in medical treatments.

2008 IPEC-Americas Regulatory Affairs Conference

Current Program

Monday, September 15

7:30 AM – 5:00 PM	Registration
7:30 AM – 8:00 AM	Continental Breakfast
8:00 AM – 12:00 PM	Morning Session

- **Welcoming Remarks** **Janeen Skutnik, Pfizer**
- **Chairman's Report** **David Schoneker, Colorcon**

- **Panel Session: Supply Chain Integrity**
Moderator: Phyllis Walsh, Schering-Plough

Speakers:

Excipient Manufacturer – Dale Carter, Archer Daniels Midland

Excipient Distributor – Linda Herzog, Mutchler, Inc.

Pharmaceutical Manufacturer – Robert Wiens, Eli Lilly & Co.

FDA spokesperson – TBA

U.S. Customs representative – approved – to be announced soon

Panel discussion and audience questions to follow

12:15PM – 1:30 PM Luncheon

1:45 PM – 5:00 PM Afternoon Session

- **Panel Session: Excipient Qualification Next Steps**
Moderator: Dr. Maria Jacobs, Pfizer
Planned Topics/Speakers:
Excipient Pedigree – Dr. Arthur Falk, IPEA
Quality Agreements – Londa Ritchey, Wyeth Consumer Healthcare
New Excipient Qualification Guidance – Dr. Chris Moreton, FinnBrit Consulting
- **Panel Session: Excipient Information Protocol (EIP) Implementation**
Moderator: Alexa Smith, Colorcon
Planned Topics/Speakers:
Excipient Manufacturer’s Perspective – TBA
Distributors Perspective – TBA
User’s Perspective – TBA

5:30 PM – 6:30 PM Reception

6:30 PM – 8:30 PM Dinner

Speaker – Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
Food and Drug Administration

Tuesday, September 16

7:30 AM – 5:00 PM Registration

7:30 AM – 8:00 AM Continental Breakfast

8:00 AM – 12:30 PM Morning Session

- **Panel Session: Excipient Quality by Design – Functionality and Performance**
Moderator: Janeen Skutnik, Pfizer
Planned Topics/Speakers: from the perspective of the EDQM, USP, an excipient manufacturer and a pharmaceutical manufacturer David Hobbs, Eli Lilly & Co. (proposed)
- **Panel Session: Novel Excipients and their Approval Process**
Moderator: Christopher DeMerlis, Colorcon
Role of Excipients in Drug Delivery – TBA
Current Methods for Excipient Safety Assessment – Dr. Jay Goldring, Wyeth Consumer Healthcare
Procedure for Ingredient Safety Evaluation – Dr. Robert Osterberg, Aclairo PDG, Inc.
Excipient Safety Assessment New Paradigms – Dr. William Brock, Brock Scientific Consulting

12:30 PM – 1:45 PM Luncheon

2:00 PM – 5:00 PM Afternoon Session

- **Panel Session: New and Co-Processed Excipients**
Moderator: Janeen Skutnik, Pfizer
Planned Topics:
How co-processed excipients are defined – Dr. Chris Moreton, FinnBrit Consulting
How co-processing takes place in excipient manufacturing – Dr. Brian Carlin, FMC BioPolymer
What the regulatory implications are – Jon Clark, FDA

Discussion Topic: The Need for a Global Excipient Forum and Whom Should Participate

Online Regulatory Conference Registration Now Available!

Online registration for IPEC-Americas 2008 Regulatory Affairs Conference, September 15-16, at the Embassy Suites Old Town in Alexandria, Virginia is now available! Cost for IPEC-Americas member company employees will be \$795; non-members \$895; \$150 for government/USP/academic faculty

registrants; and \$50 for graduate students in pharmacy and related sciences. Hotel fees are extra, but an excellent rate has been obtained for conference attendees. Hotel reservations should be made early, as those who tried to register late last year discovered. The Embassy Suites Old Town is a popular stay-over site for Alexandria visitors; it contains a fine restaurant, is adjacent to the city's historical district, and is directly across the street from King Street Metro station whose Blue and Yellow lines both service Reagan National Airport and the District of Columbia. To make hotel reservations call: 1-800-362-2779 or 703-684-5900. To receive the \$239 rate you need to mention IPEC-Americas.

Or register at:

<http://www.hilton.com/en/es/groups/personalized/WASOTES-SIA-20080915/index.jhtml>

Important Industry Meetings June & July 2008

July 12-16

35th Annual Meeting and Exposition of the Controlled Release Society –
Responding to Global Needs Through Delivery Science
Hilton New York, New York City, New York
Register: www.controlledrelease.org/meeting

July 14-17

Cleaning Validation and Critical Cleaning Processes
Renaissance Chicago Hotel, Chicago, Illinois
Register: www.ivthome.com/cleaningvalidation

July 21-23

Pharmaceutical Technology's Quality and Process Excellence Conference
Westin Arlington Gateway Hotel, Arlington, Virginia
Register: www.pharmtechevent.com

July 28-30

3rd Annual Drug Delivery 2008 – Where Science and Business Converge
(sponsored by Pharmaceutical Education Associates LLC)
Hilton San Diego/Del Mar Hotel, San Diego, California
Register: www.pharmedassociates.com