IPEC-Americas Safety Committee To Present the New Excipient Safety Evaluation Procedure during the Controlled Release Society’s Annual Meeting Poster Session

IPEC-Americas New Excipient Safety Evaluation Procedure was rated as having notable high scientific quality and was accepted for poster presentation at the 39th Annual Meeting & Exposition of the Controlled Release Society (CRS), July 15 – 18, 2012 at the Centre des Congres de Quebec, Quebec City, Canada.

Poster #547, IPEC-Americas New Excipient Safety Evaluation Procedure will be presented by David R. Schoneker, Director, Global Regulatory Affairs, Colorcon on behalf of IPEC-Americas Safety Committee, Chaired by Christopher DeMerlis, Regulatory Affairs Manager, Colorcon on Tuesday, July 17 Session 3.

For 2012, CRS is offering a “Poster Snapshot”, an audio recording that will be available to meeting attendees in the mobile meeting app prior to and during the meeting. This audio tour of the poster viewing floor will ensure that all attendees will hear the research, even if the presenter isn’t present at the poster.

Following is the audio snapshot submitted for IPEC-Americas NESEP:

Excipients are used in all drug products and in most food products. New technologies are being tested to increase the amount or rate of absorption of drugs and new and novel excipients may be included among them. New physical approaches such as nanoparticles of drug and excipients or lysosomes may offer better drug delivery especially of hard to absorb or difficult to formulate oral drugs. New excipients may improve or mask the flavor of foods, drugs, and dietary supplements. Recently, impurities in drug products have become subject to greater scrutiny and various international and national guidelines, guidances, and regulations have been proposed and accepted for use; excipient evaluation is included in these efforts. This poster discusses new developmental concepts and provides a process to promote faster regulatory acceptance of these substances.

The New Excipient Safety Evaluation Procedure is designed to maximize excipient safety, expedite development, streamline approvals and minimize regulatory risk.

This is done through the use of a review process that provides a mechanism for an independent expert review of a new or novel excipient. The review process consists of the New Excipient Evaluation Committee, which is comprised of three experts in "general" toxicology with experience in industrial, academic and/or regulatory toxicology including experience in toxicology laboratories.
The committee:

- evaluates the existing safety data for excipients which are to be used for new routes of administration or higher levels of use than has been previously used in an approved drug, and determines if the new use can be supported by this data;
- Assesses safety bridging arguments to existing data which can be used to minimize the need for performing additional safety studies on the new excipient;
- Provides an expert report which summarizes the opinion of the NEEC in a manner that can be used to support the use of the new excipient or the new use of an existing excipient; and
- Helps excipient manufacturers and pharmaceutical companies expedite the use of new excipients to solve drug development problems and minimize regulatory risk.

The committee’s final report will contain:

- A discussion of chemical and toxicological data and human safety concerns based upon the intended use of the excipient;
- Opinions on conformance with data needs according to the CDER guidance and on the acceptability of bridging arguments if they are mad
- Identification of data gaps, if any;
- And points of review disagreement if not resolved with the reasons identified in the final draft.

For additional information please visit IPEC-Americas website at [www.ipecamericas.org](http://www.ipecamericas.org)