WHAT'S NEW AT Q

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An ISO/IEC 17025 Accredited Laboratory

FROM THE PRESIDENT'S DESK

Implementation of USP Chapters <232> and <233>regarding Elemental Impurities, has again been delayed beyond the previously proposed date of May 1, 2014. A new implementation date has not been specified as of the publishing of this newsletter. The reason given is that the USP is working with industry stakeholders to assure the chapters are effective and accomplish the goals of implementation, but also are not so burdensome to the industry as to be financially and/or technically prohibitive. Another reason is the attempt to align with the process of implementing ICH Q3D on the international level. ICH Q3D is still hammering out the details on what metals should be included, and what acceptable levels should be established for each pertinent metal. The USP chapters may not completely mirror the ultimate findings of ICH Q3D, but the intent is to harmonize the two guidelines as closely as possible as a recognition that many manufacturers market their products in Europe as well as North America.

David G. Goins, President

COMETICS IN EUROPE

The long anticipated Regulation (EC) No. 1223/2009 was officially implemented on July 11th of this year. This regulation deals with cosmetic products sold in the European Union and replaces Cosmetic Directive 76/768 EEC. One requirement of 1223/2009 is every cosmetic product marketed in Europe must include a Cosmetic Product Safety Report. This report must contain information on: Quantitative and qualitative composition of the cosmetic product; Physical/chemical characteristics and stability of the cosmetic product - The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product. The stability of the cosmetics product under reasonably foreseeable storage conditions; Microbiological Quality – including microbiological specifications of the substance or mixture and the cosmetic product and results of preservation challenge test; Impurities, traces, information about the packaging material – including verification of the purity of the substances and mixtures. If you currently market your product(s) in Europe or intend to in the future, Q Laboratories, Inc. can provide services to help you comply with Regulation (EC) No. 1223/2009.

CHALLENGING

While Regulation (EC) No. 1223/2009 requires a "preservation challenge test", the document does not specify what protocols are acceptable to use to meet the standard. Some methods recommended for preservation challenge testing include USP <51>, and a newer protocol, officially introduced in 2012, ISO 11930 - "Evaluation of the Antimicrobial Protection of a Cosmetic Product." ISO 11930 was prepared by Technical Committee ISO/TC 217, Cosmetics. USP <51>and ISO 11930 are almost universally accepted in Europe and North America. Q Laboratories, Inc. can perform both of these protocols for your products and help you achieve compliance.

HERBALS

The U.S. Pharmacopeial Convention (USP) has introduced an online resource, the Herbal Medicines Compendium (HMC), to help ensure the herbal ingredients used in herbal medicines meet uniform standards for quality and safety. According to a USP Press Release, "HMC monographs provide quality specifications—tests, procedures and acceptance criteria—with validated analytical procedures and allied reference materials that aid in conformity assessment. HMC monographs and associated general chapters can help ingredient manufacturers, herbal product manufacturers, regulatory agencies, and other stakeholders to assess conformance of herbal medicinal ingredients with independent public standards and control the quality of articles moving in international commerce." For more information about HMC, visit hmc.usp.org.

INTERNATIONAL COOPERATION

Members of the cosmetic industry may have noticed in recent FDA guidances and other documents, language about FDA's attempts to meet or at least come close to harmonization with the International Cooperation on Cosmetic Regulation (ICCR). According to the FDA website, the ICCR is, "an international group of cosmetic regulatory authorities from the United States (Food and Drug Administration), Japan (Ministry of Health, Labour, and Welfare), the European Union (European Commission, DG Enterprise), and Canada (Health Canada). This multilateral framework maintains the highest level of global consumer protection, while minimizing barriers to international trade." The ICCR first met in September 2007 and continues to meet annually to discuss harmonization and other objectives, including GMPs, test methodology, ingredient safety, as well as proposed rules and proposed changes to regulations of each member organization. Cooperation with the respective cosmetic industries is encouraged as per the "Terms of Reference" for the group, "it is recognized that successful implementation requires the input of a constructive dialogue with the cosmetics' industry trade associations and potentially other stakeholders."

MEET THE Q LABORATORIES' STAFF

Kenny Zampelli has been named Chemistry Group Leader-Pharma at Q Laboratories, Inc. Kenny's responsibilities will include monitoring sample flow-through for all pharmaceutical, cosmetic, OTC and health and beauty care samples analyzed in the Chemistry Lab, as well as meeting compliance requirements, over-seeing analyst training in pharmaceutical analytical methodologies and helping clients interpret results. Kenny is a graduate of the University of Cincinnati.

TRADE SHOWS

Q Laboratories, Inc. will have representatives at the following industry events in the upcoming months:

- **AAPS Annual Meeting and Expo, November 10-14, San Antonio; (Booth# 242)**

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