WHAT'S NEW AT Q

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An ISO/IEC 17025 Accredited Laboratory

FROM THE PRESIDENT'S DESK

Meeting regulatory, compliance and quality standards is a burden with which I'm certain all of you are familiar. Fortunately, here at Q Laboratories, Inc. we have an exceptional Quality Assurance Unit (QAU) that works tirelessly to make certain we are not only meeting or exceeding regulatory and accreditation requirements, but also that we are providing top notch laboratory services to our clients. The QAU maintains our ISO/IEC 17025 accreditation, our FDA Registration status, as well as overseeing all proficiency testing activities, ensuring our laboratories are of the highest quality and efficiency. The QAU also leads any Out of Specification (OOS) or Microbiological Data Deviation (MDD) investigations that develop as well as tracking and trending these activities, along with any Non-Conformance, CAPA or Request for Action items that may arise. All regulatory, accreditation and client audits are conducted through the QAU as well as a continual cycle of internal audits, SOP reviews, laboratory walk-throughs and GLP Audits required for specific studies. Basically the QAU provides oversight and support for all departments of Q Laboratories and ensures all the i's are dotted and t's are crossed and our services are of the highest standards.

David G. Goins

David G. Goins, President

STABILITY

In a previous issue of this newsletter, the document, "Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products," was discussed briefly. The document offers valuable information on selecting batches for stability studies, stating, "Data from stability studies should be provided on at least three primary batches of the drug product. The primary batches should be of the same formulation and packaged in the same container closure system as proposed for marketing. The manufacturing process used for primary batches should simulate that to be applied to production batches and should provide product of the same quality and meeting the same specification as that intended for marketing. Two of the three batches should be at least pilot scale batches, and the third one can be smaller if justified. Where possible, batches of the drug product should be manufactured by using different batches of the drug substance. Stability studies should be performed on each individual strength and container size of the drug product unless bracketing or matrixing is applied."

MEET THE Q LABORATORIES' STAFF

Herb Birkenhauer has been named Chemistry Lab Supervisor at Q Laboratories, Inc. Herb will be responsible for everyday operations in the Chemistry Lab including analyst training, meeting quality and proficiency parameters, achieving technological benchmarks and coordinating the efficiency of sample flow-through in all areas of the Chem lab.

COSMETIC SAFETY

In March, US Representative Janice D. Schakowsky, (D-IL) and 15 co-sponsors introduced H.R.1385, the Safe Cosmetics and Personal Care Products Act of 2013.

One provision of the bill would require companies producing cosmetic products to register with the FDA and pay an annual registration fee. The amount of the annual fee has yet to be determined, and may vary based on the size of the company. The registration information would include, name, address, and legal status of each establishment, and all trade names under which the registrant brings cosmetics to market. Also, a description of the establishment's activities with respect to cosmetics, including a list of all cosmetic products brought to market by the establishment and the functions of such cosmetics; and, the gross receipts or sales for the establishment from cosmetics. Manufacturers would be required to re-register each year, pay the registration fee and notify the FDA of any changes to the information provided previously. When all this information is submitted and approved, the FDA will issue the establishment a registration number.

This new regulation would also require that the label on each package of cosmetics (including cosmetics distributed for retail sale and professional use) bears a declaration of the name of each ingredient in such cosmetic in descending order of predominance.

For the purpose of the regulation, a cosmetic ingredient is defined as: chemicals that provide a technical or functional effect, chemicals that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient, processing aids that are present by reason of having been added to a cosmetic during the processing of such cosmetic, substances that are present by reason of having been added to a cosmetic during processing for their technical or functional effect, the components of a fragrance, flavor, or preservative and any individual component that the FDA deems an ingredient for purposes of this chapter.

Section 615 of the bill addresses cosmetic and ingredient safety information and instructs manufacturers to submit specific information about each ingredient of the cosmetic product and the cosmetic itself, including; functions and uses; data and information on the physical, chemical, and toxicity of each such ingredient or cosmetic; exposure and fate information; results of all safety tests that the brand owner can access or has conducted; and any other information used to substantiate the safety of such ingredient and cosmetic.

Since many cosmetic products are sold over the internet, the bill would mandate, "in the case of a cosmetic sold on the web site of an internet vendor, that the brand owner of such cosmetic provide to such internet vendor a list of the ingredients of the cosmetic; and that each internet vendor display the list of ingredients of a cosmetic sold by such vendor on the web page that is the primary web page providing information relating to the sale of such cosmetic on the web site of the vendor."

TRADE SHOWS

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

- **HBA Global Expo**, June 18-20, New York, NY; **Booth #1128**

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