WHAT'S NEW AT Q

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FROM THE PRESIDENT'S DESK

In case anyone was wondering if the FDA is serious about enforcing Dietary Supplement GMPs, in late July, the US Department of Justice filed complaints against three Wisconsin-based dietary supplement manufacturers for failing to comply with the current GMPs and misbranding their products. The complaint accuses the firms with failing to comply with cGMPs that, among other things, require manufacturers to establish specifications to ensure the identity and potency of the ingredients in dietary supplements. The complaint also alleged that the firms' products were misbranded because they failed to identify the part of the plant from which the ingredients were derived, did not list the number of servings per container and failed to identify the serving size. In conjunction with the filing of the complaint, the defendants agreed to settle the litigation and be bound by a consent decree of permanent injunction that prohibits them from violating the Food, Drug and Cosmetic Act (FDCA). The consent decree requires the dietary supplement manufacturer to cease all operations and requires that if the defendants wish to resume manufacturing dietary supplements in the future, the FDA first must determine that their manufacturing practices have come into compliance with the law. Since the final rule on Dietary Supplement GMPs was issued in June of 2007, the FDA has assured the industry that enforcement was coming. It looks like that day has arrived.

David G. Goins, President

PERSONAL CARE PRODUCT GMPS

The In April, Senate Bill S.1014, the *Personal Care Products Safety Act of 2015* was introduced to the U.S. Senate by Senator Dianne Feinstein (D-CA). If passed, the bill would require cosmetics companies to register their facilities with the Food and Drug Administration (FDA) and to submit to the FDA cosmetic ingredient statements that include the amounts of a cosmetic's ingredients. Companies would pay a facility registration fee based on their annual gross sales of cosmetics. The bill would order the FDA to develop and implement cosmetic manufacturing standards (GMPs) that are consistent with existing national and international standards and the FDA must review the safety of at least five cosmetic ingredients each year, and it may establish conditions for safe use of an ingredient, including a limit on the amount of the ingredient or a requirement for a warning label. A cosmetic cannot be sold if it contains an ingredient that is not safe, not safe under the recommended conditions of use, or not safe in the amount present in the cosmetic. With passage of the law, the FDA would be allowed to inspect a company's cosmetic safety records. The registration user fee would be used exclusively to fund the enforcement of the law including facility inspections and investigations of adverse reports and other violations. S. 1014 was referred to the Committee on Health, Education, Labor, and Pensions for consideration.

Please visit www.qlaboratories.com for more information

AGs

On April 2nd, fourteen State's Attorneys General, led by New York Attorney General Eric Schneiderman, sent a letter to several members of Congress urging them to "launch a comprehensive inquiry into the herbal supplement industry and give FDA more authority to regulate botanical supplements." The letter was in response to an investigation by the New York State Office of the Attorney General into four major botanical/dietary supplement retailers that found, "many of the products tested were contaminated with allergens, plant species left off the label, or other potentially dangerous substances, or so thoroughly "processed" that the genetic material of the original "natural" plant source was unrecognizable or not present at all." New York AG Schneiderman sent the four retailers Cease and Desist letters, requesting "detailed information relating to the production, processing and testing of herbal supplements sold at their stores, as well as set forth a thorough explanation of quality control measures in place." The AGs' letter indicated they were going to continue to investigate botanical/dietary supplement manufacturers and retailers, but implored Congress to instruct the FDA to more vigorously oversee these products, noting that the FDA has the means and resources to better regulate this industry. Specifically, the AGs asked the FDA to: examine existing quality assurance measures for verifying the source, identity, purity, potency, and quality of ingredients and fillers; review existing regimes for verifying the identity, composition, purity, potency, and quality of the finished products sold by domestic manufacturers and retailers; and, establish and enforce GMPs for the botanical industry.

Subsequently, on May 26th, Attorney General Schneiderman of New York and Attorney General Greg Zoeller of Indiana sent a letter to the FDA Commissioner asking the FDA to, "overhaul federal oversight of the Dietary Supplement industry, including by promulgating enhanced Dietary Supplement Current Good Manufacturing Practices (cGMPs). The letter claims, "the quality control and safety issues facing the dietary supplements industry are a matter of grave public concern."

MEET THE Q LABORATORIES' STAFF

Bryan Wirthwine has been named Analytical R&D Laboratory Supervisor at Q Laboratories, Inc. Bryan will be responsible for overseeing all method development and validation projects as well as method verification/qualification, (including AOAC-RI and OMA projects), method transfer and new technology implementation and utilization. Bryan is a graduate of Ohio Dominican University and has been with Q Laboratories, Inc. since 2010, previously serving as a Chemistry Group Leader.

TRADE SHOWS

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

- **ContractPharma Contracting and Outsourcing Expo, September 17th, New Brunswick, NJ. (Booth# 48)**
- **Supply Side West, October 7-8, Las Vegas; (Booth# 1145)**

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