WHAT'S NEW AT Q

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An ISO/IEC 17025 Accredited Laboratory

FROM THE PRESIDENT'S DESK

The FDA recently took action that will severely impact companies manufacturing antimicrobial soap and body wash products. A proposed rule would require manufacturers to demonstrate that these products provide a higher level of antimicrobial efficacy than plain soap and water, and also to demonstrate that the active ingredients of these products, do not cause deleterious effects, such as bacterial resistance or hormonal effects, from long-term daily use. The FDA is requesting, "adequate and well-controlled clinical outcome studies capable of identifying the conditions of use that reduce the numbers of infections would demonstrate whether there is a benefit from the use of consumer antiseptic washes. Consequently, we are proposing that data from clinical outcome studies (demonstrating a reduction in infections) are necessary to support a Generally Recognized as Effective (GRAE) determination for consumer antiseptic wash active ingredients." The comment period for the proposed rule extends to June 16, 2014. The rule if approved and enacted will provide manufacturers with one year to either provide data proving the product(s) is safe and effective according to the standards specified by the rule, or they will have to either remove the products from the market or reformulate without the questionable ingredients.

David G. Goins, President

SUPPLEMENT OR FOOD

In January, the FDA released a "Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages." According to the document, the purpose of the guidance is to, "help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage. This guidance describes the factors that distinguish liquid products that are dietary supplements from those that are conventional foods. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding their respective ingredients and labeling." The guidance discusses factors that distinguish beverages from liquid dietary supplements, including: labeling and advertising, product name, product packaging, serving size and recommended daily intake, recommendations and directions for use, marketing practices and composition. The determination of whether an item is a beverage or a dietary supplement has an impact on many factors including, raw material standards, testing methodology and labelling requirements.

TRADESHOWS

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

- **Interphex,** March 18-20**,** New York, NY; **Booth #1058**

WEBSITE UPGRADE

Q Laboratories, Inc. has recently upgraded our website to a newer more easily navigable format. The site still contains a listing of the services we provide and other information, but includes more user friendly Sample Submission forms, Request for Proposal forms and Contact Us forms. Please take a minute to visit Qlaboratories.com and check out the new look.

Q Laboratories, Inc. also has a presence on a few of the most popular social networks. Please LIKE the Q Laboratories, Inc. page on Facebook, follow us on Twitter at @qlaboratories and visit our Company page on LinkedIN. There are links to all these locations on the home page of our website. Check in for the latest news and issues relevant to the industries we serve, as well information on what is happening at Q Laboratories, Inc.

HEAVY METALS

After a series of delays and postponements, the United States Pharmacopeia (USP) has announced an effective date for implementation of USP chapters General Chapters <232> Elemental Impurities-Limits, <233> Elemental Impurities-Methods, and <2232> Elemental Contaminants in Dietary Supplements. USP General Notice 5.60.30., "Elemental Impurities in USP Drug Products and Dietary Supplements," will become official on December 1, 2015, making General Chapters <232> and <2232> broadly applicable to drug products (<232>) and finished dietary supplement dosage forms (<2232>) in the USP-NF as of that date. Only in the event that a monograph specifically references one of these General Chapters could they be required prior to December 1, 2015, and then only for the article covered by that specific monograph. These new chapters replace the over a century old Chapter <231> on Heavy Metals which can be difficult to conduct, and can fail to detect some important elements such as mercury at toxicologically-relevant levels. According to USP, " the revisions focus on two areas of work: Updating the methodology used to test for elemental impurities in drugs and dietary supplements to include procedures that rely on modern analytical technology; and establishing limits for acceptable levels of elemental impurities (including, but not limited to, lead, mercury, arsenic, and cadmium) in drugs and dietary supplements." There are still some minor changes to <232> and <233> that will be included in Supplement 1 to USP 38-NF 33 due to be published on August 1, 2015. Be assured that Q Laboratories, Inc. is able to provide services complying with <232> and <2232> for all of your products.

MEET THE Q LABORATORIES' STAFF

Jim Davidson has been named Procurement Administrator at Q Laboratories, Inc. Jim is responsible for preparing, maintaining and organizing all purchasing efforts by the company, including contacts with existing and potential suppliers. He also maintains lines of communication with existing suppliers and generates potential contacts with new suppliers. Jim has been with Q Laboratories since 2003 and previously served as Media Prep Supervisor.

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