WHAT'S NEW AT Q

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An ISO/IEC 17025 Accredited Laboratory

Celebrating 50 Years of Scientific Excellence and Service

FROM THE PRESIDENT'S DESK

We pride ourselves on being a versatile service provider and therefore offer testing services for a variety of product types including pharmaceuticals, cosmetics, dietary supplements and health & beauty care products. This gives us the ability to analyze products that overlap product-type categories, or are considered combination products, such as a dandruff shampoo. For example, a dandruff shampoo is a cosmetic because its intended use is to cleanse the hair. It is also considered a drug because it claims to be an effective means to treat dandruff. Consequently, an antidandruff shampoo is regulated as both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs. What that means is that product would have to meet the microbiological standards of both FDA-BAM Chapter 23 (cosmetics) and USP Chapters 61 & 62 (pharmaceuticals). Our ultimate goal is to provide our clients with exceptional laboratory services and our ability to cross-over product types gives us the ability to adapt to the needs of our clients.

David G. Goins, President

MEDICAL DEVICES

The *FDA Center for Devices and Radiological Health* released a guidance entitled, "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff*." According to the document, "(t)his guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices….the focus of this document is to provide guidance to medical device manufacturers in the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended."

Two documents referenced in the guidance are helpful in determining how to proceed are "AAMI TIR30:2011 - *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*," and "AAMI TIR12:2010 - *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*."

These documents cover a wide range of products and multiple processes and methods. Contact Q Laboratories, Inc. to speak to an analyst to determine your needs and how we can design a study or studies to help you achieve compliance with these guidelines.

DIETARY SUPPLEMENT GMPs

The Code of Federal Regulations, Chapter 21, Part 111, *Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, or Holding Operations For Dietary Supplements*, has quite a bit of useful information for dietary supplement manufacturers and distributors on how to meet FDA compliance for their products. In Subpart E--*Requirement to Establish a Production and Process Control System, Section 111.65,* the regulation reads, "(manufacturers) must implement quality control operations in your manufacturing, packaging, labeling, and holding operations for producing the dietary supplement to ensure the quality of the dietary supplement." Part 111.70 elaborates on what specifications must be established, including: "(y)ou must establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record…for each dietary supplement, and component of a dietary supplement, that you manufacture you must establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement…. If you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order."

Section 111.75, establishes what firms must do to determine whether specifications are met: Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient (or) rely on a certificate of analysis from the supplier of the component that you receive, provided that: You first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations; and the certificate of analysis includes a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations; You must ensure that the tests and examinations that you use to determine whether the specifications are met are appropriate, scientifically valid methods."

Q Laboratories, Inc. can provide many of the services to help you meet the requirements of these regulations. For adulteration such as heavy metals, microbiological contamination or allergen ingredients, we can analyze your products to determine compliance. We can also offer Certificate of Analysis qualification in many cases if there is a compendial guidance for the material or the supplier indicates the methodology utilized to establish the C of A.

IT'S EASY BEING GREEN

In the future, if you want to receive this newsletter via email, simply send an email to mg@qlaboratories.com with the words "EMAIL ONLY" in the subject line.

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