Legislation Requiring Changes in Cosmetics Manufacturing Practices

The Personal Care Products Safety Act of 2015, S.1014

By Jan Warner, President, IQA Consulting Services

INTRODUCTION

On April 20, 2015, Senators Diane Feinstein (D-Calif) and Susan Collins (R-Maine) introduced the *Personal Care Products Safety Act (PCPSA)*. This legislation, currently pending in Congress, will change the way cosmetics' manufacturers operate. In its current state, the PCPSA does not change the definitions of what constitutes a drug, cosmetic or soap but it does significantly restrict how cosmetics and soaps are manufactured.

Current regulatory practices governing cosmetic safety is 75 years old. Until now, the Food and Drug Administration (FDA) had not been given authority to test cosmetic ingredients for safety and Good Manufacturing Practices were merely a suggestion. However, the passage of this bill will give the FDA authority to regulate cosmetics under the same strict operating guidelines as it does pharmaceuticals.

WHO WILL BE AFFECTED?

The legislation contains language that could impact any cosmetics manufacturer averaging over $100,000 in gross annual revenue in three years. All other manufacturers that generate less would be exempt. Currently, registration for cosmetics firms is voluntary. The PCPSA would make it mandatory for any company that manufactures, processes, packs or holds cosmetics to register as well as pay registration fees.

Reports such as these are what have been fueling the advance toward tightening regulations. The issue for cosmetic manufacturers is that stricter regulation over the next few years will require significant changes in almost every aspect of their business.

CHANGES YOU CAN EXPECT

Under this bill, the following activities would become mandatory:

- Electronic filings will be done online to comply with registration, ingredient statements, adverse event reporting, and other aspects of registry provisions. Information would be a part of public record, though registered facilities with residential addresses would not have their location disclosed publicly. Registration information would include:
    - facility name,
    - physical address,
    - business trading names,
    - nature of the business,
    - emergency contact information, and
    - statement permitting facility inspections by the FDA.

- FDA reviews of at least five cosmetic ingredients annually for safety in cosmetic formulation (with the exception of color additives) beginning with:
    - diazolidinyl urea,
    - lead acetate,
    - methylene glycol,
    - propyl paraben, and
    - quaternium-15.

- Annual ingredient statement filings which include:
    - facility identification number tied to their registration,
    - facility name,
    - product name,
    - full ingredient list (with a range of percentages of each ingredient),
    - name and contact information of the person filing the statement, and
    - additional information that is alluded to by the safety substantiation section of the bill which, at present, is unclear and not included in this summary.

(This section does make note of exceptions for small businesses under the definitions of the Small Business Act, but it's unclear what specific exceptions are available or the requirements/determinations needed for compliance as a small business. It provides the FDA the ability to permit manufacturers falling under $500k annual sales to submit "simplified" ingredient statements, but does not mandate that exception.)

- Serious Adverse Event reporting will be mandated within 15 days of receiving information, including individual reports on a short timeline and an annual report summarizing non-serious adverse events.

- Product recalls, for which the FDA would be given authority to inspect records and order recalls.

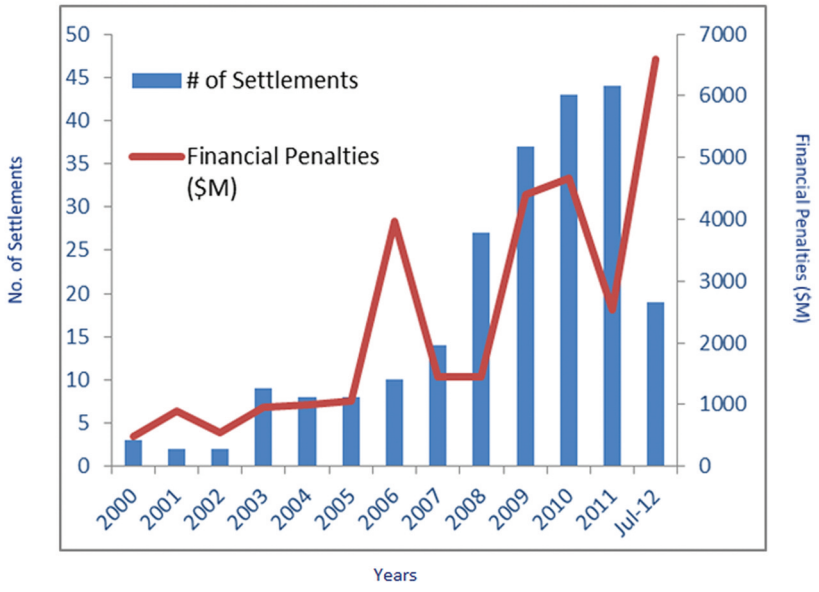
- Extensive labeling requirements, including ingredients not appropriate for children or for professional use only. Additionally, internet websites will need to include the product labeling that appears on packaging. This section also provides the addition of domestic telephone or electronic contact information so Serious Adverse Events can be reported.

It should also be noted that individual states will be prevented from enacting cosmetics legislation in the areas of registration, GMP, recalls, or adverse event reporting. However, the bill does grandfather existing state legislation into the act (like those in California and Florida) and does not specifically mention labeling regulations.

IMPACT OF LEGISLATION

With cosmetics manufacturers subject to the same regulations as their pharmaceutical counterparts, potential fines, consent decrees and recalls are likely to increase as well. Consider the following statistics:

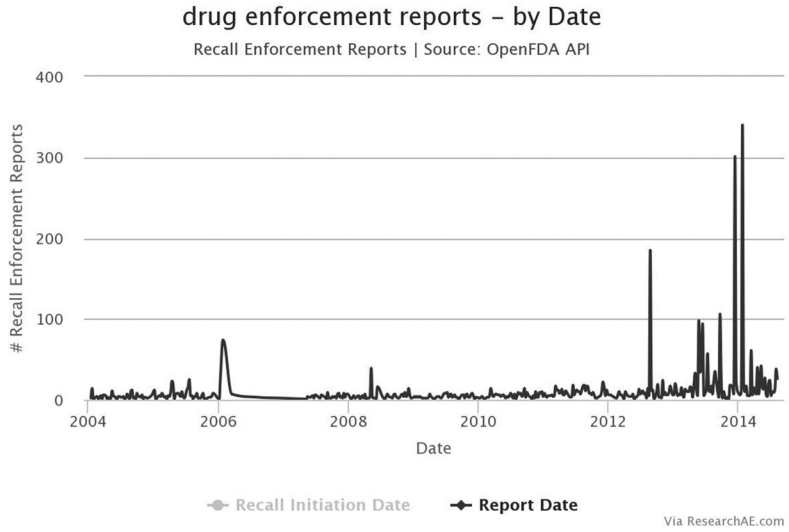
- There has been an increasing trend in financial penalties for pharmaceutical companies, indicative of tighter FDA enforcement.



* Source: Pharmaceutical Industries Civil & Criminal Penalties An Update

- An average consent decree faced by a life sciences company can drag on from three to five years and cost in excess of $500M in fines, penalties, remediation expenses and lost sales. Beyond the hard costs there is also a price to pay to a company's culture, image, customers and patients.*

- Product recalls among pharmaceutical companies have also escalated in the last few years, as shown in the following chart.



Source: Regulatory Affairs Professionals Society

TIMEFRAME

While the bill is not yet set for a vote, the proposed law requiring the FDA to make GMPs and other regulatory practices mandatory is anticipated for passage in 2016. The FDA would then develop and implement actual GMP definitions for all cosmetics manufacturers. Large manufacturers will be given only 180 days to comply while small businesses will be given up to two years.

WILL YOU BE READY?

It is expected that the proposed bill, in its current form, would significantly expand the FDA's authority over cosmetics sold in the United States starting in 2016. This means manufacturers will have a short window of opportunity to create a quality management system that meets these new requirements. Find out now what you need to do to prepare.

(continued)

Call now for a Complimentary Regulatory Review and Product Risk Assessment

Contact Jan Warner at:
973-797-9154
Jan@IQAConsulting.com

Jan Warner is an accomplished, broad-based regulatory, quality and compliance professional. He has over 30 years of experience in: pharmaceuticals, medical devices, OTC and Rx drugs, personal care and cosmetics.

Jan is the owner of IQA Consulting Services, a provider of quality and compliance services to FDA regulated industries. He works with Fortune 500 companies and other leading organizations -- including Johnson & Johnson, SGS, NSF and others -- to successfully improve processes and systems that better meet regulatory requirements. He and his team of consultants also design QA/QC and regulatory programs as a virtual QA department for mid to smaller-sized firms and start-ups that do not have onsite resources. (Visit www.iqaconsulting.com/companies-served.html to view a more complete listing of clients served.)

Prior to founding IQA, Jan had senior management responsibilities in quality assurance, compliance and quality control at L'Oreal, Kiehls Since 1851, Axiom/Halsey Pharmaceuticals, and Nobel Biocare.

Jan received his B.S. in Biology from SUNY Stony Brook and an MS and MBA in Management of Technology from New Jersey Institute of Technology.

** Operating Under Consent Decree: Managing a Life Sciences Company through a Major Regulatory Action, Deloitte*