Cosmetic Manufacturers Be Aware: 8 Ways to Deal with the FDA's Tightening Grip

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INTRODUCTION

The Food and Drug Administration (FDA) – the governmental agency that regulates cosmetics products as well as food, drugs, medical devices and tobacco in the United States – has been less comprehensive in their authority over cosmetics than that of the other products it regulates. Specifically, cosmetics have had more lenient regulations with regard to registration, testing, premarket notification, clearance, approval, good manufacturing practices, mandatory risk labeling, adverse event reports, and recalls. But this trend is changing.

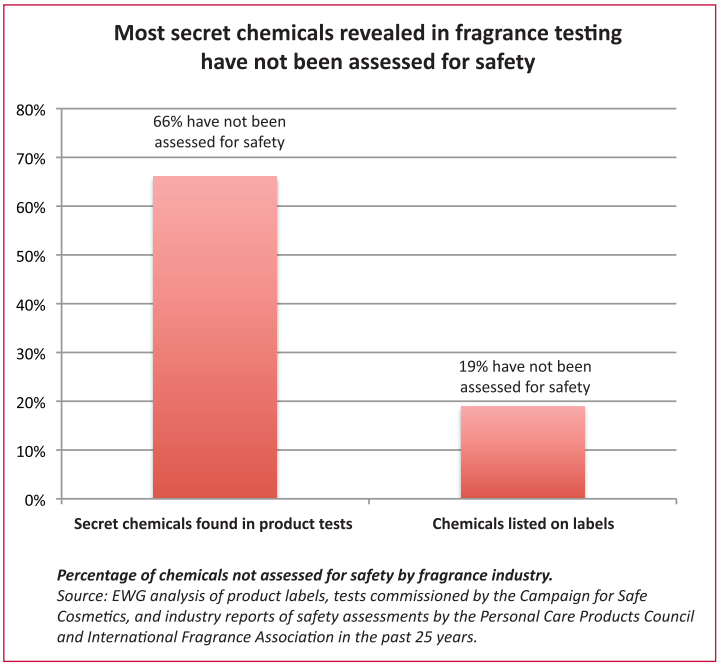
Until recently the only FDA published guidance for the cosmetics industry was the *Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist* which was updated in 2008 after its original issuance in 1997. However, last year the FDA released a new draft: *Guidance for Industry Cosmetic Good Manufacturing Practices* (June 24, 2013). This was a significant move on the part of the FDA as it has made clear its intention to move the cosmetics industry closer to the quality and control expectations found in the manufacture of pharmaceutical products.

It is critical that cosmetics manufacturers quickly review their processes and implement the changes necessary to align with increasingly stricter regulations over the next few years. Not doing so may result in stiff penalties, seizure of product and withdrawal of products from the market.

THE PROBLEM FOR COSMETICS MANUFACTURERS

While the majority of cosmetics manufacturers employ safe and legitimate practices, there have been instances in which products have been mislabeled, contained fraudulent claims or used untested ingredients, thereby putting consumers at risk.

The nonprofit Environmental Working Group reported that 89 percent of 10,500 ingredients used in personal care products had not been evaluated by any publicly accountable institution. They reported finding ingredients — certified as "known or probable carcinogens" by the U.S. government — in one of every 120 cosmetic products on the market, including shampoos, lotions, make up foundations, and lip balm.



Percentage of chemicals not assessed for safety by fragrance industry.
Source: EWG analysis of product labels, tests commissioned by the Campaign for Safe Cosmetics, and industry reports of safety assessments by the Personal Care Products Council and International Fragrance Association in the past 25 years.

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.

Currently, cosmetics compliance requirements are voluntary.
But soon-to-be mandatory requirements will necessitate the implementation of new processes and systems -- or the updating of current ones — which will include:

- appropriate management and control of documentation and records;
- proper and adequate buildings, facilities and equipment;
- education and training for personnel;
- control and testing of raw materials;
- control of production operations;
- laboratory controls;
- internal audits; and
- systems for controlling and documenting complaints, adverse events and recalls.

The change in domestic cosmetic compliance standards is based on an internationally recognized set of rules: ISO 22716, the current international standard for cosmetic GMPs. Some of the more significant rules set under these standards, and for which U.S. manufacturers will need to prepare, include:

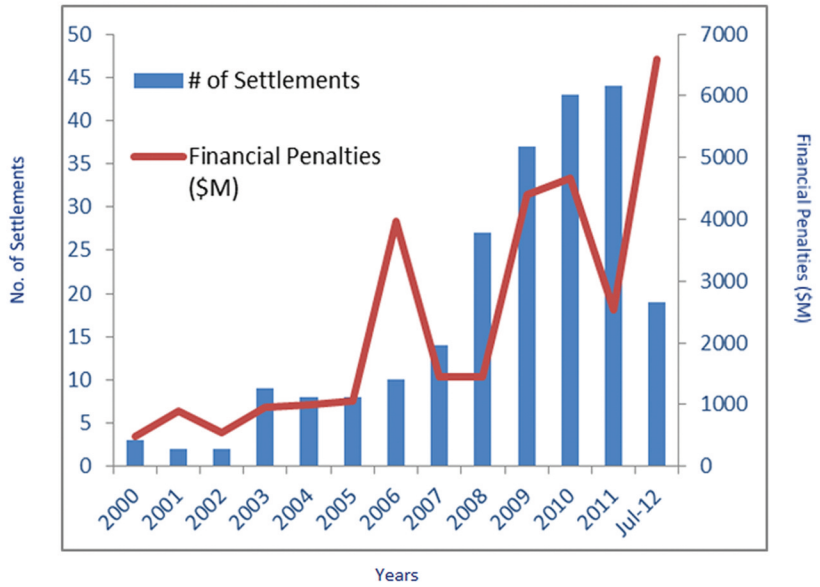
- *Records and documents:* This includes mandatory documenting and controlling procedures that describe all of the processes in the manufacture of cosmetics including: production; quality assurance; manufacturing; testing; and training.

- *Introduction of the 'responsible person':* This states that a cosmetics manufacturer needs to identify an independent person that is responsible only for quality assurance. This can either be an employee or outside consultant or firm, but this person or entity needs to report directly to management, not production.

- *Reporting of adverse events:* The responsible person will have a duty to inform the governing body (the FDA, in the case of the U.S.) of serious undesirable effects.

POTENTIAL RISKS OF NON-COMPLIANCE

As cosmetics regulations become closer to those of the pharmaceutical industry, so too will the penalties. The chart below shows the increasing trend in financial penalties for pharmaceutical companies, which may indicate signs of what's to come for cosmetics companies as well.



* Source: Pharmaceutical Industries Civil & Criminal Penalties An Update http://www.citizen.org/documents/2073.pdf

A 2013 article that appeared in the Pharmaceutical Compliance Monitor reported these sobering statistics:(1)

- **$7.2 Billion** – Costs related to regulatory infractions by 8 leading pharmaceutical companies over the past 5 years
- **500** – Product recalls since 2011
- **$250 Million and 3-5 Years** – Typical impact of Consent Decrees to Life Sciences companies

The Solution: Prepare Now!

It is clear that the regulatory landscape is changing. The good news for U.S. cosmetics manufacturers is that you can prepare now and avoid the pitfalls. The horizon is set for approximately one to three years before the tightening of regulations are more fully realized. The following are eight ways you can prepare for a successful transition to not only ensure full compliance but to also get a competitive edge in the quality and marketing of your products.

1. *Responsible Person:* Identify an experienced individual – be it a staff member, consultant or outsourced virtual quality department – who will be responsible for quality … and only quality. Have them report directly to executive management.

2. *Gap analysis:* Audit your current quality system from its current state of compliance as compared to the new FDA draft guidance.

3. *Documentation:* Prepare and implement documented procedures for all necessary operations.

4. *Employee Training:* Assess the current level of training and knowledge of your personnel and educate them on the current standards.

5. *Deviations:* Ensure your people understand that exceptions from documented practices do occur but that documenting these deviations are what is important.

6. *Adverse Events:* Implement a system for tracking and monitoring adverse events and complaints.

7. *Management's Role:* Ensure management provides the right support for quality operations throughout the company.

8. *Quality Culture:* Instill a "Quality State of Mind" where staff understands compliance is a team effort and no one person is fully responsible.

Conclusion

It is a given that standards are becoming stricter. There is no getting away from it. To successfully remain in the market, cosmetics manufacturers must deal with all of the consequences.

It may seem daunting at first, but you can minimize operational burdens with the support of an experienced compliance expert. You may even be surprised to find that the solutions are less painful than you think. Surely the pain of FDA fines, recalls and the potential withdrawal of your product from the market are far greater.

The downsides of non-compliance are too great of a risk while the rewards of full compliance can be significant. By achieving full compliance, you can potentially get your product to market faster and improve quality without necessarily impacting your margin. By proactively dealing with these regulatory changes, you will have the potential to enhance customer loyalty, increase market penetration and improve overall sales for your company.

Call now for a Complimentary Regulatory Review and Product Risk Assessment

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Jan Warner is an accomplished, broad-based regulatory, quality and compliance professional with over 25 years of experience in: cosmetics, pharmaceuticals, medical devices, OTC/Rx drugs, personal care, homeopathic drugs, and dietary supplements. He has held senior management responsibilities at L'Oreal, Luitpold Pharmaceuticals, Axiom Pharmaceuticals and Nobel Biocare and has worked as a consultant for Johnson & Johnson, Wyeth, Merck, Pfizer, Proctor and Gamble, and Reckitt Benckiser. Jan leads a team that understands how to work within the matrix-management environment of Fortune 500 companies while offering a more streamlined and specialized approach for mid-sized firms and start-ups.

(1) Source: Pharmaceutical Compliance Monitor, *Current Trends in Regulatory Enforcement*, by William Greenrose, Deloitte and Touche LLP (April 8, 2013)

(2) Source: www.fda.gov *"Understanding Barriers to Medical Device Quality"* October 31, 2011