# Emerging Cosmetics Industry Regulations and Trends

## February 13, 2014 2:00 PM ET

To hear this webinar, please call 866-740-1260 and enter access code 8275782.

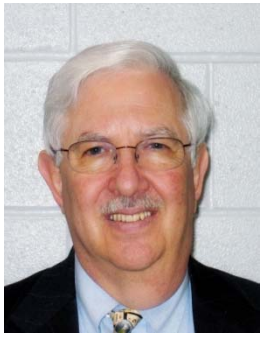
# About the Presenters

## Casey Coy, NSF Cosmetic and Personal Care Program Manager

**13+ years of experience in analytical testing and quality assurance for food, OTC, dietary supplement and cosmetics industries.**

## Jan Warner, Owner of IQA Consulting Services

**25+ years of experience serving in numerous high level QA/QC and compliance positions for companies such as Pall Corporation, L'Oreal, Axiom Pharmaceuticals, Johnson and Johnson and Nobel Biocare**



## David Steinberg, founder of Steinberg & Associates

**40+ years of experience in the cosmetic industry. David founded Steinberg & Associates in 1995, which specializes in cosmetic regulations, preservation and sunscreens.**

# ISO 22716
# Cosmetics Good Manufacturing Practices (GMP) Guidelines

**Jan Warner, Owner of IQA Consulting Services**

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# Scope

**“This International Standard gives guidelines for the production, control, storage and shipment of cosmetic products”. -- *From ISO 22716:2007(E) Scope***

**What it doesn’t cover:**

- **Safety**
- **Environmental protection**
- **Research and Development**
- **Distribution of Finished Products**

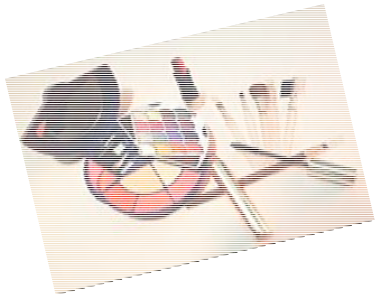
# Overview

- **A non-governmental, international consensus standard for the safe manufacturing of cosmetic products.**
- **Supports compliance to the legally enforceable Regulation (EC) No. 1223/2009 which represents a common European code of law for cosmetics companies.**
- **A resource for cosmetic manufacturers interested in implementing the specific requirements of the standard to support their business at a domestic or international level.**
- **Can be combined into other existing quality systems, e.g.,**
  - ISO 9001
  - ISO 14001
  - British Retail Consortium (BRC) standard for consumer products.

# Objectives

- **Business improvement tool used to continuously improve business operations and manufacturing of cosmetic products.**

- **Effective framework for risk management principles and practices.**



- **Intent is to promote international distribution and commerce for quality, safe cosmetics.**

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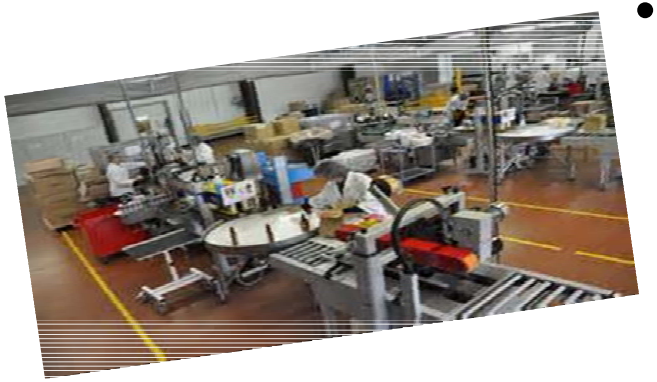
# Target Audience

- **Manufacturers of cosmetic products and suppliers of cosmetic ingredients**

- **Retailers, brand holders and wholesalers of cosmetic products.**



- **Those responsible for packaging, testing, storage, and transportation of cosmetic finished products.**

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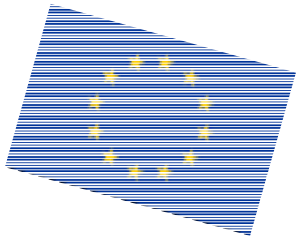
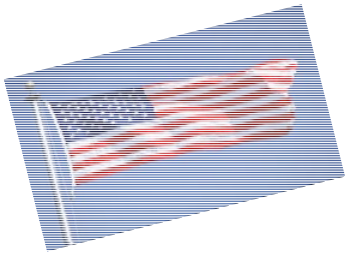
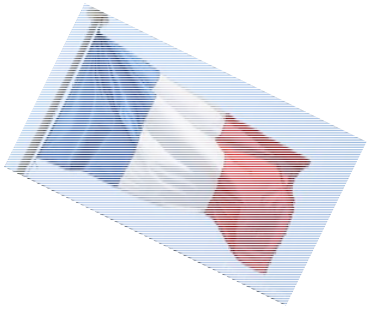
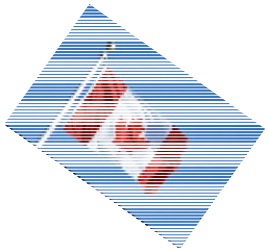
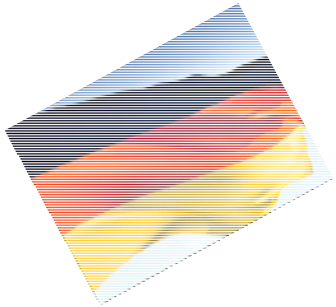
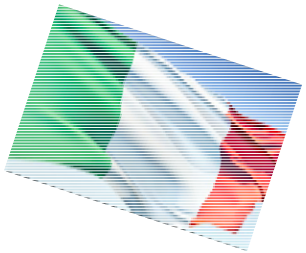
# An International Approach

- **ISO 22716:2007 has been approved and accepted by many standardization and regulatory bodies around the world. *(including the FDA)***

- **All cosmetics products sold into the European Market will have to be produced according to the ISO 22716 standard.**

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# Key Concepts

- Control of raw materials
- Documentation
- Cleaning and contamination control
- Procedures (SOPs)
- Training
- Testing (Analytical/Micro)
- Change control
- Control of non-conformances
- Internal Audits
- Equipment maintenance

# Additional Information

- **Can be used to provide control of product supply chains for cosmetic products**
- **Provides a roadmap for safe and quality cosmetic production**
- **Voluntary standard**

# ISO/TR 24475:2010

- **Used in addition to ISO 22716**

- **Aimed at contributing to the training of personnel in cosmetic production plants while introducing Good Manufacturing Practices.**

# FDA's Current View on Cosmetics

- **Prohibits the introduction or delivery into interstate commerce of cosmetics that are adulterated or misbranded**
- **Guidance for Industry: Cosmetic Good Manufacturing Practices (*Draft June 2013)***
- **Current FDA Guidance on Cosmetics incorporates, modifies and excludes aspects of ISO 22716**
- **Promotes a unified expectation for GMPs in the cosmetic industry**

# GMPs are Not Just for Drugs

- **Cosmetics - cleanse and beautify the body**
- **They do not require pre-market approval by the FDA, but there is voluntary registration.**

- **Adulteration and misbranding specifically prohibited!**
- **Prohibited ingredients** *(21 CFR 700)*
- **Color additive requirements:**
  - Must be approved by FDA, or *(21 CFR 73)*
  - Subject to certification *(21 CFR 74)*

## FDA Guidance for Industry: Cosmetic Good Manufacturing Practices

- **Conveys FDA's current thinking and recommendations on cosmetics**

- **Predecessor was Cosmetic GMP Guidelines/Inspection Checklist *(orig. February 12, 1997; Updated April 24, 2008).***

- **It should be noted that FDA does not have GMP "requirements" *per se* for cosmetics manufacturing because GMPs are not included in FDA regulations.**

# Similarities between ISO 22716 and FDA

**The intent of both is to establish “quality assurance” systems.**

**Both require written policy manuals, procedures, maintenance of records and documents to assure products meet their design specifications.**


**Both also use internal and external audits as periodic checks for conformity to guidelines.**

# Differences between ISO 22716 versus FDA

## ISO 22716

Internationally Recognized

Regulation (EC) No 1223/2009 requires compliance to a harmonized GMP standard

Restricted substances in Chapter IV and Annexes II through VI

## FDA GMP

Based in FD&C Act – adulteration / misbranding

Facility Inspection Guidance

Color additives must be fit for use

Prohibited/Restricted Ingredients Not to be Used

# FDA Guidance for Industry: Cosmetic GMPs Key Concepts

- **Documentation**
- **Records**
- **Buildings and Facilities**
- **Equipment**
- **Personnel/training**

## FDA Guidance for Industry: Cosmetic Good Manufacturing Key Concepts

- **Raw materials: Water**
  - Color additives (per 21 CFR 73, 74 & 82)
  - Prohibited/restricted ingredients (21 CFR 700; b)
- **Production**
- **Laboratory Controls**
- **Internal audit**
- **Complaints, Adverse Events and Recalls**

# References/Links

- www.ISO.org
- www.fda.gov
- http://eur-lex.europa.eu

# ISO 22716 Training Course

- **March 25th – 26th, 2014 – NSF Headquarters, Ann Arbor, MI**
- **2 day comprehensive review of ISO 22716**
- **Interpretation of each section, providing an understanding of practical application**
- **Real-world scenarios of compliant vs. non-compliant**
- **Review of recent FDA Warning Letters**
- **Industry Best Practices**
- **Comprehensive introduction for new personnel or for companies seeking to comply with ISO 22716**
- **Serves as refresher training to those in QA/QC, manufacturing, production or R&D to meet GMP requirements**
- **For more information:**

https://www.regonline.com/builder/site/Default.aspx?eventid=1447659

# Speaker Intro

**David Steinberg, FRAPS**

**GMP consultant at NSF International**

**Steinberg & Associates,**

**Founder & Owner**

- **Founded Masters Degree program in Cosmetic Sciences at Fairleigh Dickinson University – faculty member from 1982 to 2000**
- **Founded Steinberg & Associates in 1995, a consulting company specializing in cosmetic regulations, labeling, preservation and sunscreens.**
- **Written 5 books including Preservatives for Cosmetics and the Guide to the European Cosmetic Regulations**

# Speaker Intro

## Topics of Discussion:

- FDA Proposed Rule for OTC Antiseptic Washes
- “Free From” Label Claims in the Marketplace
- Organic and Natural Personal Care Standards

# Competing in 2014 in the Personal Care Market: Critical Issues

**David C. Steinberg, FRAPS**

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# Safety & Effectiveness of OTC Antiseptic Washes

- **12/17/13 the FDA published new Proposed Rules for these products**
- **These cover all consumer antiseptic products used with water**
- **The FDA now calls them Cleansers**
  - Soaps
  - Body washes
  - Hand washes

# What is Not Covered

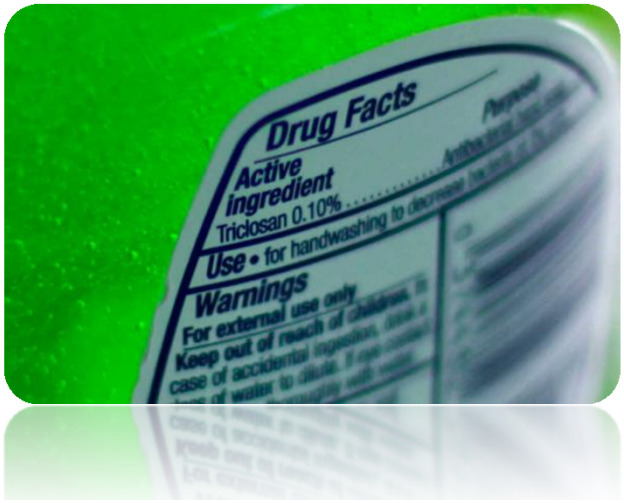
- **“Instant hand sanitizers”**
- **Leave-on products**
- **Other parts of the TFM issued in 1994**
  - Patient preoperative skin preparations
  - Surgical hand scrubs

# Why Now?

- **In 2010, the Natural Resources Defense Council filed a complaint against the FDA (and HHS) for not issuing a Final Monograph for products containing Triclosan**

- **This was settled in a consent decree of 11/21/13**

- **FDA agreed to a timetable for completion of FM for Healthcare Antibacterial washes and hand rubs with triclosan**



# Terms-Hand Washes

- **TFM by 12/16/13**
- **Comment period until 6/16/14**
- **End of time to submit new data 12/16/14**
- **Comment period 2/17/15**
- **FM draft issued 8/31/2016**
- **Publication of FM 9/15/16**

# Terms- Antiseptics

- **TFM 4/30/15**
- **Comment period 10/31/15**
- **Submission of data 4/30/16**
- **Comments of TFM 6/30/16**
- **FM draft 12/31/17**
- **FM 1/15/2018**

# Terms-Hand Rub

- **TFM 6/30/16**
- **Comment period 12/31/16**
- **Submission of data 6/30/17**
- **Comments of TFM 8/31/17**
- **FM draft 3/31/19**
- **FM 4/15/2019**

# Also

- **FDA to submit status reports to court and plaintiff every 6 months**

- **FDA may ask for extension from plaintiff and the court**

# FDA's PR for Washes

- **None of the current 22 allowed active ingredients will be considered as safe and effective**
- **Most submit new data**
- **Changes the standards for this**

# New Testing For Approval

- **Old method involved laboratory testing to demonstrate the product kills microbes**
- **New method is similar to an NDA-preclinical and placebo test on thousands of subjects which will take a long time to complete and cost mega bucks**
- **Compare infection rates of placebo group to active users.**
- **This is more stringent than what is required for a new drug!**

# Safety Testing

- **To approve an active you will need these tests:**
  - Animal pharmacokinetic absorption, distribution, metabolism and excretion
  - Human pharmacokinetics
  - Carcinogenicity
  - Development toxicity
  - Reproductive toxicity

- **These assays all involve animal testing; which will prohibit their use in the EU and other regions of the world as they have or will likely ban animal testing**

# Current Products

- **Does not change anything for now except moves PVP-I from Category I to III. All current actives for cleansers are now Category III**

- **This will negatively impact this product category when this becomes final, as the cost will be too high a burden for industry**

- **FDA will consider extending this deadline for data if preliminary data is considered potentially acceptable**

# Conclusions

- **The court favored with the NGO's on a triclosan ban and reflected by FDA's action**

- **They cite that soap is just as effective as the actives, which may be true, however:**
  - This is based on the time and conditions of hand washing
  - This puts a large burden on the FDA making it unfavorable for businesses in this product category

# Also

- **What will happen if the FDA is targeted with comments by the same groups who want the FDA to ban Triclosan and TCC (e.g. 2007 these same activists filed about 3,000 identical comments to the FDA on their Proposed Rules for UVA Sunscreen labeling and testing)?**

- **Will there be more litigation to force the FDA to finalize all of the other TFM's?**

- **The FDA will need a larger budget if this were to happen**

# “Free-From” Claims

- **Industry started making claims about the absence of certain chemicals in the early 80’s**
- **The use of “PABA-free” changed the active ingredients used by the sunscreen industry, even though PABA was rarely used, rather a chemical that had the word PABA in its INCI name resulted it its loss of use by these claims**
- **One major issue with “free-from” claims is the question: are there trace or measureable amounts found in a product even though it is not added as an ingredient?**
- **These lead to false or misleading advertising → Misbranded Product**

# Prevalent “Free-From” Claims

- PABA
- Oil
- Parabens
- Sulfates
- Silicones
- Triclosan
- Phthalates
- Chemicals


- Bisphenol A
- Phosphates
- Lead
- Mercury
- Arsenic
- TCC
- DEA
- Petroleum origin

# The Truth about these “Chemicals of Concern”

- **PABA-first universally allowed UV filter**
- **Oil-law suits occurred over what this means**
- **Parabens- have been evaluated as safe and is a highly studied preservative**
- **Sulfates-confuses chemistry-they mean Sodium Laurel Sulfate (also safe as used)**
- **Silicones-Confuse breast implants (now found to be safe) with cosmetic ingredients**
- **Triclosan-only use in cosmetics is in deodorants (the rest are drugs)**
- **Phthalates -(DBP was used in nail polish but now removed) DEP in fragrances and found safe by everyone**
- **Formaldehyde-so natural it is in every cell in our body**
- **Chemicals-chemical free is not scientifically…unless the product is a real good vacuum!**

# What should you do?

**Despite studies demonstrating safety of some of these ingredients at specified levels, consumers and NGOs are pushing retailers and manufacturers to phase out some of these "chemicals of concern" from their products:**

- **Johnson & Johnson – committed to phasing out triclosan and phthalates from all products; agreed to replace formaldehyde and 1,4 dioxane in products**
- **Proctor & Gamble – committed to phasing out triclosan and phthalates from all products by 2014**
- **Walmart working with suppliers to remove 10 "high priority" chemicals from its household cleaning, personal care, beauty and cosmetic products**
- **Other retailer initiatives (Target, Walgreens, etc.)**

# What should you do?

- **Determine your company's level of "risk"**
- **Determine approach for handling these "chemicals of concern"**
- **If no action is to be taken:**
  - Ensure safety substantiation information available for all ingredients in product
- **If "free-from" claims to be made on product:**
  - Substantiate "free-from" claims through 3rd party verification

# Canada's Rules on Advertising

- **Competition Bureau and Advertising Standards consider "free-from" claims to be false and misleading**
- **Example: Hydrogen Cyanide free**
- **They have issued conditions which must be met to make such a claim**

# Conditions for “Free-From” Claims In Canada

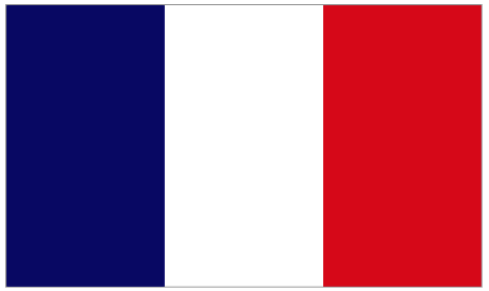
- The product must have contained this ingredient and was on the Canadian market with established registrations and dates
- The Government must be notified that you removed this ingredient
- Outside analysis must show that **ZERO** amount of this ingredient can be detected
- You are than allowed to make the claim…..free for only 1 year
- At the end of 1 year, <u>all products must be removed from the shelf</u>

# What You Can Say

- **This product was never formulated with hydrogen cyanide**
- **This product naturally contains no hydrogen cyanide**
- **We do not have hydrogen cyanide in this product**
- **However all of these claims must be true and proven**
  - How?
    - Self-substantiation
    - 3rd party certification

# Results

- **Consumers have been aware of products with this claim in Canada and will not buy products that are “free”.**
- **Canadian retailers refuse to stock products with this claim.**
- **England and France have followed suit, as will the entire EU in the future.**



# Minnesota

# HF 458

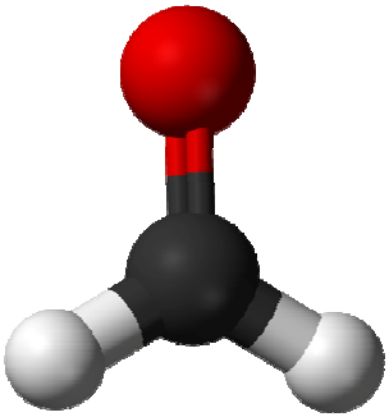
- **Passed 5/13/13**
- **Prohibits formaldehyde, or formaldehyde releasers from any children's products (not restricted to cosmetics) as of 8/1/14**
- **Children are defined as  under 8 years**
- **Cannot replace this in cosmetics with  any chemical known or suspected to:**

# Suspected (continued)

- **Development toxicity**
- **Cause cancer, genetic damage or reproductive harm**
- **Disrupt endocrine or hormone system**
- **Damage nervous system, immune system, or cause systemic toxicity**

# Leaving

- **Limited problems for anhydrous products**
- **And no known preservatives that work in surfactant based cleansers.**
- **What about traces of HCHO found in fatty alcohols which are the base for all surfactants and many esters?**



# Formaldehyde Releasing Preservatives

- **Imidazolidinyl Urea**
- **Diazolidinyl Urea**
- **DMDM Hydantoin**
- **Quaternium-15**
- **Sodium Hydroxymethylglycinate**
- **Methenamine***
- **5-Bromo-5-Nitro-1,3-Dioxane***
- **2-Bromo-2-Nitopropane-1,3-Diol***

***rarely used**

## Conclusions

**Without Federal preemption, the NGO's may target other states like they did in Minnesota or they may sue like they did over triclosan to force the FDA to issue Final Monographs for all OTC drugs.**

**This will result in difficulties selling identical brands in all 50 states.**

# Current NSF Industry Standards

- **NSF/ANSI 305 – Organic Personal Care**
  - Encourages use of organically grown ingredients in supply chain
  - Used by companies who may not be able to meet USDA organic food regulation for cosmetic products
  - 70% certified organic minimum
  - Technical Review and Annual inspection
  - NSF/ANSI 305 Joint Committee meeting held prior to ExpoWest/Engredea in March in Anaheim – if interested in attending, contact Jessica Evans at jevans@nsf.org

- **NSF/ANSI 384– Natural Personal Care**
  - Currently in development
  - Joint Committee meeting held prior to ExpoWest/Engredea in March in Anaheim – if interested in attending, contact Jessica Evans at jevans@nsf.org

# Q & A

- **Questions can be asked through ReadyTalk “Chat” Box**
- **Question will be repeated and answered in order of receipt**
- **Questions received and not answered will be answered in follow up email**
- **Recording of webinar will be available for download at [www.nsf.org/info/cosmetics](www.nsf.org/info/cosmetics)**

**For Additional Questions Contact**:

**Casey Coy**

**734-904-2995**

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