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# Stuart (Scott) F. Sadoff

## HIGH LEVEL SUMMARY

**Objective:** To provide comprehensive, knowledgeable, and creative scientific regulatory and safety compliance guidance to the development, manufacture, and sale of formulated personal care products.

**Career focus:** My primary focus has been to ensure the initial and sustainable integrity of formulated personal care products, through the collaborative and creative application of a deep knowledge of global regulatory affairs, product safety, and analytical chemistry. Have demonstrated a sustained record of achieving solid business results by working effectively and collegially with R&D, Marketing, Sourcing, Legal, and external technical experts and Trade Associations.

**Communication profile:** Tactful and diplomatic across all functional areas and personalities, to assist advisement and negotiating skills. Very effective at presenting policy guidance and summaries to technical and non-technical audiences alike. Skillful and effective at organizing and presenting complex scientific information. Functionally fluent in French.

**IT Skills:** Microsoft 365 (Word, Excel, Access, and Visio), Adobe Acrobat Professional, and Scientific databases such as CTFA On-Line Cosmetic Ingredient Dictionary, CIR Compendium, and The NOAEL Project.

## PROFESSIONAL EXPERIENCE

**October 2020 to present Personal Care Regulatory & Safety Services, LLC (New Albany, Ohio)**

**Founder and CEO**
**Mission:** To help small to mid-size companies develop safe and compliant personal care products, including cosmetics and topical OTC Drugs. This involves furnishing primarily the following services:

- Safety assessment [through the review of relevant hazard endpoints along with Margin of Safety (MoS) determination when a suitable NOAEL is available] of proposed raw materials and finished formulae for cosmetics and topical OTC Drugs
- Review of Copy Sheets and Artwork to ensure that all labelling information (especially use directions and safety precautions) is compliant and adequate to cover both intended and reasonably foreseeable conditions of product use
- Recommendation of safety and claim substantiation testing plans, including End-to-End Study Stewardship Services (E2E-$S^3$), which involves Study Protocol Development, study scheduling, monitoring, and reporting to client
- Full spectrum services to ensure product compliance with the CARB Consumer Products Regulation (VOCs)
- Global formula compliance review, encompassing US, Canada, UK and EU statutory requirements
- Pre-market Notification of new cosmetic products to Health Canada

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**September 2007 – October 2020 Abercrombie & Fitch (New Albany, Ohio)**

**Director, Global Regulatory & Environmental Affairs || Corporate Chemist**

**Staff supervised**

- Provided ongoing leadership to the Manager, Global Regulatory Affairs, who reported directly to me

**Promotion / recognition**

- In February 2011 was promoted to position from Senior Manager, Sourcing

**Key Duties and Responsibilities**

- Collaborate with Marketing, R&D, Legal, and external Regulatory Agencies to assure compliance of cosmetics and home fragrance products with all applicable local, state, federal, and international regulations, for a variety of internal brands. This includes active review of both quantitative formulae and product labeling, and direction to R&D regarding the choice of clinical and laboratory safety tests to substantiate both safety and claims.
- Provide ongoing and *ad hoc* chemical advisement and risk assessment to multiple internal stakeholders, including Sourcing, Legal, and Marketing, and R&D.
- Ensure the global compliance of our aerosolized store scent system, through collaborative interaction with Marketing, R&D, and with external vendors and regulatory agencies.
- Author cosmetic Product Information Files (PIFs) to assure compliance with the EU Cosmetics Regulation. This includes development and sign-off on the Cosmetic Product Safety Assessment. Generation of the Safety Assessment Section requires an in-depth analysis of physico-chemical, toxicological, microbiological, and clinical data for both ingredients and the finished product.
- Routinely develop new market entry research summaries and detailed implementation plans, to ensure the compliant introduction of existing and new products.
- Advise cross-functional partners on positioning and substantiation of product performance claims, based on ongoing analysis of US and international regulations. This saves the enterprise considerable expense by lessening the need for outside Legal Counsel. Routinely employ solid negotiating skills to assure final claims that are customer-centric and that can also be adequately substantiated.
- Manage several major departmental budgets, including Dues & Subscriptions, External Consulting, External Testing, and Environmental Compliance Fees

**Key accomplishments since January 1, 2013**

- *March 2020:* Based on measurements performed by One Bond Laboratories, developed CA Proposition 65 Risk Assessments for three Hollister CBD-containing cosmetics products. These assessments demonstrated that each product met Safe Harbor criteria, thus obviating the need for any Proposition 65-related warnings on the product labeling regarding the presence of Delta-9 THC.
- *January 2020:* In concert with outside laboratories, developed a customized suite of *in-vitro* (Mattek Epiderm) and *in chimico* (GC-MS scans, % Ethanol and % Water) tests to accurately differentiate between authentic and counterfeit fine fragrance products. In several instances, the data developed and interpreted helped A&F Brand Protection Department successfully shut down a major source of counterfeit "Fierce Cologne", the company's bestselling SKU.
- *July 2018:* Collaborated with R&D, Marketing and an external clinical testing laboratory to develop and substantiate a first ever "All day moisturization" claim" for Gilly Hicks Hydrating Body Creams
- *September 2014 through September 2016:* Successfully submitted consumer product data on the content of Volatile Organic Compounds (VOCs) to the California Air Resources Board (CARB) on behalf of A&F Trading Co.
- *June through August 2014:* Led a cross-functional team in the re-formulation of our Body Spray to remove Triethanolamine (TEA) as a pH adjuster, due to its association with trace concentrations of Diethanolamine (DEA) a suspected human carcinogen that is an increasingly recognized chemical of concern. Per my initial suggestion, R&D ended up substituting Sodium Hydroxide, an inorganic chemical that is NOT a chemical of concern within the non-corrosive range of pH values used for most personal care products.
- *April 2013 through August 2014:* Led a cross-functional team to re-formulate "A&F Fierce Cologne" (our largest selling cosmetic) by incorporating color-stabilizing additives to greatly reduce the degree of oxidative yellowing over time. The additives I suggested at the beginning of the project turned out to be the optimal solution, as confirmed by the results of Accelerated Compatibility Testing versus the existing formulation.
- *July 2014:* Performed an unfavorable chemical risk assessment of Diammonium Phosphate flame retardant versus intended use as a proposed surface coating for a sweater. I advised our Sourcing Team to not go forward with the project. This compound tends to release ammonia (a potential respiratory irritant), and its high water solubility would decrease flame retardant efficacy with repeated washings.
- *January through July 2014:* Led a cross-functional team included Legal and an external vendor that resulted in the re-formulation of our aerosolized ambient store scent to be acceptable for our France stores. Coordinated sensory validation of the re-formulated scent to show olfactory equivalency; the new formula has been successfully implemented in 13 of the 14 of our France stores.

- *April through May 2014:* Collaborated with an external Board-Certified Toxicologist to develop a Quantitative Risk Assessment Model to assess the safety of Ethyl Alcohol in our cosmetic products. Application of this model validated the safety of our Ethyl Alcohol-containing formulations, from the highest concentration downward, and across both the intended dermal route of exposure and the incidental inhalation route. The results of this project have enhanced the integrity of Safety Assessments as part of the EU Product Information Files (PIFs) required for each of our cosmetic formulae sold in the EU.
- *April through May 2014:* Collaborated with an external Board-Certified Toxicologist to develop a Margin of Exposure Assessment of measured concentrations of Benzidine (a cancer-causing aromatic amine) that was unexpectedly found in an A&F garment. The assessment showed that there was negligible human health risk associated with the maximum concentration of Benzidine detected. I summarized and presented all findings to A&F upper management.
- *July 2013 through April 2014:* Designed Global Label and developed comprehensive Fire Safety Testing Plan to support the successful development and launch of A&F's first ever filled candle in glass.
- *July 2013 through August 2013:* In collaboration with external analytical chemists and cosmetic formulation experts, determined that crystalline material floating in our Body Mists was due to Ethyl Alcohol-induced precipitation of the solid fraction from an Aloe-based Ingredient. Based on my advisement, R&D removed the aloe-based ingredient from the Body Mist base, and there has been no recurrence of the floating crystals problem.

**2003 – August 2007 Beauty Avenues (a division of Limited Brands, Inc.) (Reynoldsburg, Ohio)**

**Manager, Regulatory Assurance**

- Collaborating with Marketing, Product Safety, and Legal, my group assures compliance of cosmetic, OTC Drug, and Consumer Products with all applicable local, state, federal, and international regulations, for a variety of internal clients, including Bath & Body Works, White Barn Candle Company, and Frederic Fekkai Haircare.
- Advise cross-functional partners on positioning and substantiation of product performance claims, based on ongoing analysis of FDA and FTC regulations along with NAD case precedent. This saves the enterprise considerable expense by lessening the need for outside Legal Counsel. Developed the Establishment Claims Monograph system to clarify operational definition and substantiation approach for claims. Routinely employ solid negotiating skills to assure final claims that are customer-centric and that can also be adequately supported.
- Provide upstream project guidance to Marketing, R&D, and Product Development by performing analysis of New Product Briefs for personal care and home fragrance products. Worked collaboratively with key stakeholders to develop the electronic Product Brief Form, which has been adopted as a best practice to promote proactive identification, communication, and management of regulatory And safety issues, to support project timing.
- Interact regularly and effectively with a variety of Trade Associations (CSPA and CTFA) and regulatory agencies, including FDA, EPA, CPSC, and the California Air Resources Board (CARB) to clarify interpretation and to influence policies to assure accurate guidance to internal customers and to protect our brands. For example, in July 2006, contributed to Technical Presentation to CARB (at CALEPA Headquarters in Sacramento) on the public health benefits of Waterless Hand Sanitizers, for which CARB had proposed an unrealistic VOC limit. As a direct result of this presentation, CARB removed this proposal from consideration under CONS-2 Consumer Products Rule in progress.
- Enhanced speed to market for Third Party products by developing and implementing a "SmartTouch" model for the regulatory review Of Third Party Branded products. Presented model to Upper Management, who received enthusiastically. Now in use across the enterprise, this approach allocates regulatory review only to high risk product categories to effectively balance speed versus risk.
- As head of the Air Quality Compliance Regulatory Center of Excellence, provide routine formulation compliance advisement across personal care and home fragrance products, along with regulatory intelligence monitoring and reporting to internal and external stakeholders. Created and maintain VOC compliance work aids to facilitate understanding and strong ongoing compliance. Active member of the CTFA Air Quality Committee.
- Routinely monitor FDA ListServe issues of relevance to my internal clients, and provide customer-friendly analyses to assure understanding of the potential scope and impact of emerging regulations.
- Edit and issue monthly "Integrated Regulatory Assurance Metrics Report to upper management. Developed novel statistical reporting approach that not only drives progress on deliverables but is also being incorporated into a divisional metrics report as a best practice.
- Chief Regulatory liaison with SAP-based software implementation team. Conduct weekly Ariel data down-loads into SAP Specification database, to assure accurate inputs into automated regulatory reporting. Collaborated routinely with internal SAP data team to develop automated formula screening to facilitate compliance assessment for new markets.

**1999 – 2003** **Bath & Body Works (a division of Limited Brands, Inc.) (Reynoldsburg, Ohio)**

**Product Safety Manager**

- Developed and maintained electronic database for the management and archiving of all safety and efficacy substantiation. Database is still in use to manage a world-class safety and efficacy testing program.
- Collaborated directly with contract Clinical Test Laboratories to develop protocols, schedule tests, and interpret results, including communication to upper management.
- Assured cost savings to enterprise by negotiation of volume discounts on key clinical safety tests.
- Managed implementation of enterprise-wide Chemical Hygiene Plan, in close collaboration with corporate Regulatory Affairs department.
- Developed Standard Operating Procedures for key Product Safety Section processes, resulting in more efficient work flow.
- Served as a member of the corporate DOT Shipping Task Force, which implemented improved shipping procedures for Hazardous Materials (Hazmats).

**1993 – 1999** **Crabtree & Evelyn, LTD (Woodstock, Connecticut)**

**Manager Regulatory and Analytical Services**

- Increased global sales by registering cosmetics, topical OTC Drugs and household products worldwide, including Poison Control.
- Managed all aspects of initial OTC Drug (DIN) Product introduction into Canada. Worked closely with new distributors to register products for entry into six Pacific Rim Asia markets. Interacted directly with government agencies where necessary.
- Substantiated human safety and efficacy for all new products.
- Interacted on a regular basis with the CTFA, FDA, Health Canada, other foreign agencies and local distributors to clarify, formulate and execute regulatory compliance strategies.
- Helped design and review label copy for all new products.
- Managed compliance with Federal and State VOC regulations.
- Prepared MSDS's for all finished products. Also designed and implemented more concise, readable document format.
- Designed and maintained comprehensive formulation database, capable of generating Ingredient Certificates to support domestic and international registration requirements.
- Created computer database for cosmetic product Dossiers, to facilitate compliance with the EU Cosmetics Directive.
- Helped assure unimpeded product flow by providing DOT Shipping Classification Information to Operations.
- Enhanced customer service function by providing technical informational support on all products.
- Established QA testing program for all fragrance oils approved by R&D.
- Developed and maintained stability testing protocols for OTC Drugs.

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**1984 – 1993** **Procter & Gamble Cosmetic and Fragrance Products (Hunt Valley, Maryland)**

**Analytical Chemist, Research & Development Division**

- Developed and validated a variety of instrumental and wet chemical test protocols, including chromatographic methods for the quantitation of sunscreens and volatile silicones in cosmetics.
- Conducted shelf-life testing of OTC Drugs, including acne-care and sunscreen formulations. Modified the Analytical Lab's Shelf-life test protocol to improve predictive accuracy.
- Developed XRF methods to analyze for inorganic sunscreen actives in SPF-rated cosmetics. Trained QC Technicians to use this method, which reduced average assay time by a factor of ten.
- Prepared raw material specifications.
- Coordinated all contract analytical laboratory testing.

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**1981 - 1984** **Gascoyne Laboratories, Inc. (Baltimore, Maryland)**

**Analytical Chemist in the Organic Analysis Department**

- Analyzed environmental samples for EPA Priority Pollutants, using chromatographic and wet chemical techniques.
- Set up and was responsible for Total Organic Halide (TOH) determinations, using micro-coulometry.

## EDUCATION

**1993 University of Maryland (Baltimore, MD)**

**Master of Science (MS) in Chemistry**

- GPA= 3.4
- Pursued this degree while working full time at P&G

**1979 Washington College (Chestertown, MD)**

**Bachelor of Science (BS) in Chemistry**

- GPA = 3.3
- made Dean's List during four semesters

**Continuing Education:**

- June 2013 passed EU Safety Assessor Certification Exam as part of the updated course "Safety Assessment of Cosmetics" given at the Vrije Universiteit Brussel in Belgium. This version of the course focused on changes to Cosmetic Safety Assessment requirements associated with the Cosmetics Regulation that came into force in July of 2013.

- April 2008 passed EU Safety Assessor Certification Exam as part of the course "Safety Assessment of Cosmetics" given at the Vrije Universiteit Brussel in Belgium. The initial version of the course focused on Cosmetic Safety Assessment requirements associated with the EU Cosmetics Directive.

**Professional Memberships:**

- 2021 to present: Full Member of the Society of Toxicology (SOT)
- 2020 to present: Associate Member of the Personal Care Products Council (PCPC)
- 2018 to present: active member of the PCPC Safety & Regulatory Toxicology Committee (SRTC)
    - Served on the Program Committee for the 2020 and 2021 installments of the PCPC Safety Symposium

**Recent Professional Presentations:**

- July 2019 (Sacramento, CA): "Deodorant Body Sprays"; a detailed VOC-regulated product category survey that was co-presented with Unilever at the invitation of both the CA Air Resources Board and the General Counsel of the Personal Care Products Council (PCPC)
- February 2019 (Long Beach, CA): "Chemicals of Concern: Definition, Examples & Risk Management" at a Product Safety and Compliance Seminar of the American Association of Footwear and Apparel (AAFA)

**Avocations:** Music (jazz piano and guitar), dogs, swimming / boating, travel, and foreign languages.

**References:** Available upon request