INDEPENDENT BEAUTY ASSOCIATION®

Regulatory Update

Current and Emerging Regulatory Issues
NYSCC Supplier's Day
May 3, 2022

Sharon Blinkoff Esq – Locke Lord
Craig Weiss – Consumer Product Testing
Ken Marenus, Ph.D. Independent Beauty

www.independentbeauty.org

INDEPENDENT BEAUTY ASSOCIATION®

Regulatory Update

Federal Bill Update

State Bills and PFAS

Sunscreens

INDEPENDENT BEAUTY ASSOCIATION®

Regulatory Update

Federal Bill Update

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
Safety standard	The "safety standard" is not present an unreasonable risk of serious harm under instructed or ordinary conditions of use	*New Standard for Safety of Cosmetics* Safety must be reasonable certainty of no harm must be analyzed based upon cumulative and aggregate exposures. In determining safety must also consider vulnerable populations which may entail specific warnings or limitations on use or product distribution. The standard set is the same standard used for i color additives that. It should be noted here that it took the FDA about 50 plus years to review the color additives, so it is highly unlikely any ingredients will in fact be reviewed under the Feinstein bill. Feinstein bill requires serial review of ingredients and non functional cosntitutents. of minor skin irritations will not be deemed to render an ingredient or non functional constituent harmful	Safety Standard does not present risk of serious harm – under directed use - does not require specific form safety substantiation but recognizes CIR and approval by the FDA in other programs as being valid forms of safety substantiation and existing regulations require a warning statement warning that the safety of the product is not confirmed.

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
Registration of facilities	Under Voluntary program manufacturers can register with the FDA but are not required	Requires annual registration of all facilities including Responsible party's contract manufacturers and warehouses required to file annually ally warehouses (every three years Requires payment of user fees with registration As part of the registration filers have to agree to expanded inspection rights included in the bill. foreign manufactures/ RP have to designate l US representative Included are facility address, emergency contact the categories of products manufactured at the facility, the processes conducted at the facility and its unique number assigned by the agency, brand names processed at the facility A written assurance that the products processed at the facility have been substantiated for safety or carry the warning statement n 21 CFR 740.10 Maintain records of safety substantiation for 5 years or 2 for small business after distribution of product has ceased which may be reviewed by FDA inspectors Annual submissions required expect for exempt parties small business and products made in the home with revenues of less than 1 million dollars for products manufactured in a home and $500,000 for other small business. Contract manufacturers must file for exempt entities (A - G)Filers must include exclusive code for manufacturing facility and Downstream warehouses register Every three years	Require registration of all manufacturing facilities Failure to file correctly is a violation of the FDCA and subject to sanction violation of the FDCA Once registered only refile for changes in original filing

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
product ingredient statements/ registration	voluntary program permits filing of ingredient statements which list brand name ingredients marketer and manufacturer	*Rp must file quantitative formulas as well as brand name facility where manufactured listing number of assigned list of ingredients; range of concentrations; list of fragrances and flavors and ranges for fragrances; identify suppliers and code and contact info*	Ingredient states required including ingredients product brand name and name of manufacturer
hair dye exemption	coal tar hair dyes exempt from review under color additives	*Coal Tar Hair dye exemption* - Can be overturned if the FDA finds the dye material not to meet the standards of safety required by the Feinstein bill. The provision in the Feinstein.	Maintains current law exemption of coal tar dyes – from color additive review
Adverse Event Reporting	Adverse Event Reporting There is no requirement for adverse event reporting. This was included in the original voluntary program but the FDA requested that industry stop filing these years ago	Serious Adverse Events death within 15 days also Requires reporting of Adverse Events defined as any health related event associated with use of a product. Annual reporting required of non-serious events By adding this second tier of reporting, which the FDA decided under the voluntary program it did not want, there will be confusion as to what is to be reported and when thereby possibly interfering with the reporting of serious adverse events.	Reporting comparable to OTC requirement. Serious and unexpected adverse event reporting only.

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
FDA inspection rights	FDA has the limited authority to inspect cosmetic manufacturing facilities -no authority for records access except records that demonstrate that the ingredients/ products are in interstate commerce	As part of the facility registrations filers agree to expand the FDA's inspection authority beyond what is required by law. FDA under Feinstein will be able to conduct inspections At business offices and has the right on minimal showing to inspect safety substantiation records Inspectors will have access to manufacturing records, complaint files and adverse event files and on a reasonable showing of a safety substantiation files This additional level of inspection is likely to bog down inspections and may well be subject to abuse by FDA inspectors.	Inspections no change from current law. Agency can only conduct inspections at manufacturing facilities not business offices and no right to see records except interstate shipping records, On for cause inspections can get information on fragrances and flavors
Preemption	There is currently preemption for FDA mandatory labeling	Preemption for Registration –entity and formula, good manufacturing practices, or adverse event reporting For ingredient safety preemption If FDA finds after review that an ingredient is safe no state can restrict the use of or require additional labeling with respect to that ingredient. Except for Prop 65 and any other preexisting state laws governing restriction of ingredients or registration which exempted from the preemption provided by the Feinstein Bill even if they are adopted after the Feinstein Bill has been passed into law.	Preemption Complete – preemption from all laws including existing laws like Prop 65. All aspects of the FDA regulatory program are preempted including ingredient safety states prohibited from reviewing ingredients for health and safety reasons all reviews for such left to the FDA States can petition the FDA to review an ingredient

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
Good manufacturing practices	There are no good manufacturing regulations governing the manufacture of cosmetics other than the general requirement that they not be packaged or held under conditions of filth or contain Deleterious matter	*Good Manufacturing* Authorizes the FDA to enact drug like cGMP's which go well beyond what is required to insure the manufacture of safe cosmetic products.	FDA authorized to develop GMPs to insure product is not adulterated – *i.e.*, sanitary as current law.
Professional Product labeling	9. Professional products are currently exempt from compliance with Fair Packaging and labeling	*Professional Products* ❖ Ingredient declarations and other labeling required under Fair Packaging and Labelling will apply to professional products – which facilitates professional products entering the consumer market. ❖ Professional use only labeling permitted	9. Professional Products permits professional use only and prohibits states from passing laws to require ingredient declarations for professional products.

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
Ingredient Review	Review of ingredients through regulatory action, if there are health or safety issues presented	*FDA review of ingredients* FDA will undertake to review 5 ingredients and or nonfunctional constitutes per year based upon recommendations of a list compiled by industry in consultation with the Activists. Beyond an agreement on the ingredients to be reviewed by an advisory committee constituted in part by industry and the Activists, there are other procedural hurtles which must be passed before the FDA can study an ingredient FDA is not required to complete ingredient reviews on any time table, can decide on a notice and comment basis to review any chemical it chooses in addition to the 5 per year. Preemption will be based upon conclusion of the FDA's review which will find an ingredient is safe, safe for use with restrictions/ warnings/ not safe for use.	FDA Ingredient Review continues for cause reviews and Creates classes of ingredients for which safety is considered substantiated Notice and comment rulemaking for ingredient for cause safety review has been eliminated.

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
Fees	No user fees	*Fees RP pay fees for sales in excess of 10 million* ❖ User fees of 20 million dollars per year to be paid to the FDA proportionate for tiers subject to escalation	No user fees.
Exemptions Small business	Exemption. No exemption required as Registration not required	*Exemptions* Purports to exempt businesses listed in Section 10(3) (A-H), but the compliance shifts to the contract manufacturers who will put the cost of compliance back to those so-called exempt entities.	Exemption. Small business deferral of performances exemption for companies with revenues less than $1,000,000.
	Current Law Definition of Cosmetics	No change	Exempt structure function claims for cosmetics that have a temporary effect from being a drug claims
	Safety Substantiation		Recognizes safety substantiation for cosmetics

Legislative Overview

	Current FDA Law Applicable to Cosmetics	The Feinstein Bill	Sessions Bill
Enhanced enforcement Mandatory Recall Cancellation of facility and formula registrations	FDA has no authority to order mandatory recall of cosmetics	Provide FDA with authority to issue mandatory recalls of cosmetic products and cessation of distribution - order to be issued by FDA commissioner Basis reasonable probability of Serious adverse event or death Informal hearing to contest 2 days notice after receipt of order	No authority to order mandatory recall of cosmetics
Registration Requirement for cosmetic manufacturers	Under Voluntary program manufacturers can register with the FDA	Responsible parties (defined as brand owner whose name appears on the product label) except exempt facilities (A – H) manufacturing facilities of exempt RP registers as well as contract manufacturer for nonexempt RP's	Require registration of all manufacturing facilities Failure to file correctly is a violation of the FDCA and subject to sanction
product ingredient statements	voluntary program requires filing of ingredient statements which list brand name ingredients marketer and manufacturer	*Responsible party required to file ingredient statements with range of concentrations as well as identification of fragrance and flavors with manufacture code* *Subject to cancellation if not completed correctly* *warehouses required to register every three years-* *must file quantitative formulas as well*	ingredient statements required including ingredients and brand name and name of manufacturer and marketer

INDEPENDENT BEAUTY ASSOCIATION®

Regulatory Update

Most Frequent Activity In States

Prohibition of Animal Testing

PFAS/PFA and other ingredient Bans

Microbeads

Cannabis

INDEPENDENT BEAUTY ASSOCIATION®

Regulatory Update

Sunscreens

Status of OTCs and Sunscreen Monograph

Technical Issues

Sunscreens Changing Regulations and Emerging Issues

CONSUMER PRODUCT TESTING℠ COMPANY

70 New Dutch Lane, Fairfield, NJ 07004-2514

+1 973 8087111 |
sales@cptclabs.com | www.cptclabs.com

FDA Registration# 1000151293
DEA Registration# RC0199744 Schedule I-V
US EPA/NJ DEP Registration# NJD982726648
ISO/IEC 17025:2017 Accredited

We comply with:

FDA GMP GCP GLP ISO EPA USP

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

- Accepted methods
- MUsT
- Proposed Order 000008
- Benzene contaminates
- Benzophenone contaminates
- Reef safe
- Data integrity

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Accepted Methods

- US
  - Final Rule 2011
  - Broad spectrum
- EU and most of the rest of the world
  - ISO 24444
  - ISO 24443 or 24442
- Japan
  - ISO 24444
  - ISO 24442
- UK
  - ISO 24444
  - ISO 24443
  - Boots star
    - optional

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

JAMA | Preliminary Communication

Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients A Randomized Clinical Trial

Murali K. Matta, PhD; Robbert Zusterzeel, MD, PhD, MPH; Nageswara R. Pilli, PhD; Vikram Patel, PhD; Donna A. Volpe, PhD; Jeffry Florian, PhD; Luke Oh, PhD; Edward Bashaw, PharmD; Issam Zineh, PharmD, MPH; Carlos Sanabria, MD; Sarah Kemp, RN; Anthony Godfrey, PharmD; Steven Adah, PhD; Sergio Coelho, PhD; JianWang, PhD; Lesley-Anne Furlong, MD; Charles Ganley, MD; Theresa Michele, MD; David G. Strauss, MD, PhD

IMPORTANCE The US Food and Drug Administration (FDA) has provided guidance that sunscreen active ingredients with systemic absorption greater than 0.5 ng/mL or with safety concerns should undergo nonclinical toxicology assessment including systemic carcinogenicity and additional developmental and reproductive studies.

OBJECTIVE To determine whether the active ingredients (avobenzone, oxybenzone, octocrylene, and ecamsule) of 4 commercially available sunscreens are absorbed into systemic circulation.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial conducted at a phase 1 clinical pharmacology unit in the United States and enrolling 24 healthy volunteers. Enrollment started in July 2018 and ended in August 2018.

- Twenty-four subject
  - Six subject per formula
- Two sprays
- One cream
- One lotion
- Applications 4 times per day for 4 days
  - 2mg/cm^2
  - 75% body surface
- Blood collections for seven days after initial application

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Avobenzone
All 4 sunscreen products resulted in avobenzone exposures, with plasma concentrations exceeding 0.5 ng/mL on day 1 for all products and through day 7 for all products except the cream

Oxybenzone
All 3 products with oxybenzone resulted in oxybenzone exposure, with plasma concentrations exceeding 20 ng/mL on day 7.

Octocrylene
All 4 products resulted in octocrylene exposures, with plasma concentrations exceeding 0.5 ng/mL, starting from day 1 and

- Consistent absorption of all major organic active tested
  - Greater than the 0.5 ng/ml plasma level
- FDA began the rule making procedure 2019
  - Since replaced by administrative order OTC 000006
  - Final monograph 1999
  - Testing and labeling Final Order 2011
- PROPOSED ORDER (OTC000008)
  - Changes
    - aminobenzoic acid (PABA) and trolamine salicylate moved to non-monograph (Category II)
    - cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, or avobenzone insufficient data (Category III^{SE})

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

- Need for Additional Safety Information

Clinical data:

- Dermal irritation and sensitization testing
- Phototoxicity and photoallergenicity testing
- Human maximal use bioavailability studies
- Postmarketing adverse event reports

Nonclinical (toxicology) data:

- Dermal carcinogenicity
- Systemic carcinogenicity
- Developmental and reproductive toxicity (DART)
- Toxicokinetics (including absorption, distribution, metabolism, and excretion)
- Additional testing when data suggest a concern about other long-term effects, such as endocrine effects

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

- Since 2013 cosmetics are “cruelty free” in the EU by regulation
- Sunscreens are cosmetics in the EU

=

- TiO_2 and ZnO the only category I
  - 25% maximum each
  - Maximum SPF approximately 40

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

VALISURE NEWS

Valisure Detects Benzene in Sunscreen

Team Valisure

VALISURE DETECTS HIGH LEVELS OF KNOWN HUMAN CARCINOGEN BENZENE IN SEVERAL SUNSCREEN PRODUCTS AND REQUESTS FDA ACTIONS

78 sunscreen and after-sun care products contained benzene, an industrial chemical known to cause cancer and other potentially serious health risks

NEW HAVEN, CT – MAY 28, 2021 – Valisure LLC has tested and detected high levels of benzene, a known human carcinogen, in several brands and batches of sunscreen, which are considered drug products by the Food and Drug Administration (FDA), as well as in after-sun care products, which are generally regulated by FDA as cosmetics. Benzene is known to cause cancer in humans according to the **U.S. Centers for Disease Control and Prevention**

- Issues with the data
  - Method “adapted’ from alcohol method
  - Validation?
- FDA issued a method
- USP Residual solvent method
- Possible sources
  - Ingredient degradation
  - Ingredient contamination
  - Propellant contamination (real aerosols)
    - Isobutane

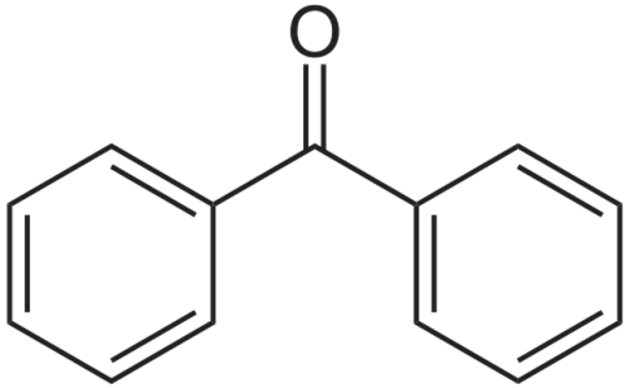
CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Bloomberg

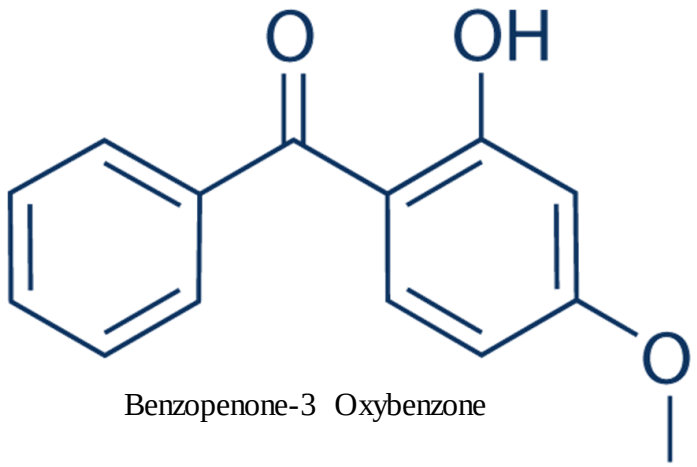
Sunscreen Worries Grow as Another Potential Carcinogen Found

- Researchers ask U.S. to pull more sun products from shelves
- Study finds cancer-linked chemical that also affects hormones

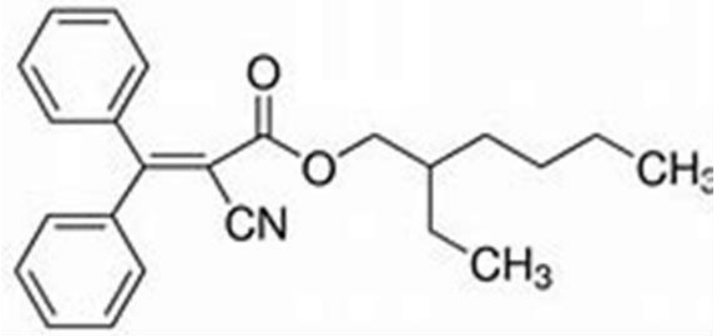
- Benzophenone NOT Benzophenone 3 (Oxybenzone)
  - Adhesives and sealants
  - Paints and coatings
  - Plastic and rubber products



Benzophenone



Benzopenone-3 Oxybenzone



Octocrylene

- Benzophenone in sunscreen most likely from
  - Degradation of octocrylene
  - Residual in manufacturing of octocrylene

Environ Health Perspect. 2008 Apr; 116(4): 441–447.
Published online 2008 Jan 3. doi: 10.1289/ehp.10966
PMCID: PMC2291018
PMID: 18414624

Research

- Sunscreens Cause Coral Bleaching by Promoting Viral Infections
- Roberto Danovaro,[1] Lucia Bongiorni,[1] Cinzia Corinaldesi,[1] Donato Giovannelli,[1] Elisabetta Damiani,[2] Paola Astolfi,[3] Lucedio Greci,[3] and Antonio Pusceddu[1]
- Author information Article notes Copyright and License information Disclaimer

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

- **What qualifies as the best reef safe sunscreen? (google)**
- "Both nano particle—a smaller particle size—and traditional zinc oxide sunscreens are both safe and effective, and both will be considered safe for reefs. The only difference is the cosmetic feel on the skin." So you're pretty much good to go with a mineral-based option
- TiO2 and ZnO
  - 25% maximum each
  - Maximum SPF approximately 40
- The new Hawaiian law went into effect January 1, 2021
  - First in the nation
  - Many more in process
- Controlled laboratory studies have not validated the findings of coral bleaching

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Interlaboratory Variability - Bias

Information bias – bias from measurement error

Confounding bias – a second variable distorts outcome

Selection bias – participation of a subject in a clinical trial is dependent on the likelihood of having the outcome of interest

Subversion Bias – manipulation of subject recruitment

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Interpreting Data - Validity

ID #	Gender	MED/Hr	Skin Type	MED (mJ/cm²)	MED (mJ/cm²)	Standard	I.P.
7549	F	125.7	II	4.62	4.62	16.30	34.50
5881	F	126.2	II	4.62	4.62	16.30	30.00
4505	F	128.7	II	4.62	4.62	16.30	34.50
9662	F	129.7	II	3.03	3.03	16.30	34.50
5464	M	126.3	II	4.62	4.62	18.75	34.50
4829	F	127.7	II	4.62	4.62	16.30	30.00
9991	F	127.4	II	4.62	4.62	18.75	34.50
1858	M	125.4	II	4.62	4.62	18.75	34.50
6483	M	126.5	II	4.62	4.62	16.30	30.00
8768	F	128.3	II	3.03	3.03	16.30	30.00

Mean SPF	17.04	32.70
Standard Deviation	1.18	2.32
Standard Error	0.37	0.73
N	10	10
Upper 5% t-distribution	2.2622	1.8331
A	0.84	1.34
Label SPF Value	16	31

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Interpreting Data - Validity

ID #	Gender	Age	Skin Type	MED (mJ/cm²)	MED (mJ/cm²)	Standard	I.P.
4319	F	59	III	22.5	22.5	20.1	12.3
4864	F	61	I	12.8	16.0	12.9	19.4
55995	M	57	II	17.7	17.7	16.1	23.1
6857	F	70	II	26.1	26.1	16.1	14.6
10990	M	67	I	12.7	12.7	16.1	34.3
82099	F	37	II	25.0	25.0	14.2	14.2
10747	F	44	II	14.1	14.1	16.3	16.3
11437	M	62	I	23.9	23.9	12.3	12.3
67125	F	54	II	27.9	27.9	13.0	13.0
45626	F	65	II	29.9	29.9	16.3	16.3

Mean SPF	15.3	17.6
Standard Deviation	2.32	6.78
Standard Error	0.73	2.14
N	10	10
Upper 5% t-distribution	1.83	1.83
A	1.34	3.93
Label SPF Value	14	13

CONSUMER PRODUCT TESTING™ COMPANY
cptclabs.com

Contact Information:

Craig Weiss
President
CPT Labs
70 New Dutch Lane
Fairfield NJ 070004
Phone: (973) 808-7111 Ext. 210
Email: crweiss@cptclabs.com

INDEPENDENT BEAUTY ASSOCIATION®

Regulatory Update

Open Discussion

Please contact our technical concierge service at info@independentbeauty.org if you have additional questions.