Cosmetic, Drug and Homeopathic Ultimate FAQ Guide

Produced by FDAImports.com

For Guests of the 2012 Personal Care Products Council Science Symposium
Produced by Benjamin L. England and FDAImports.com

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BASIC LABELING

1. What are the mandatory elements on a cosmetic label?
A cosmetic label must contain a legally compliant Statement of Identity, an accurate Net Quantity declaration, the Name and Address of the Manufacturer, Packer or Distributor, a Country of Origin marking, Ingredients List and certain warnings.

2. What is the difference between a certifiable and an uncertifiable color?
FDA must approve all color additives intended for use in cosmetics. Certified colors require FDA approval and each batch of color must be FDA-certified as conforming to the FDA regulations related to that color. Uncertifiable colors, however, require FDA approval but are exempt from FDA batch certification. Certifiable colors are declared by the color name and a number (e.g., “FD&C Blue 1” or “Blue 1”), while uncertifiable colors are declared by the name of the substance, such as zinc oxide or mica.

3. How do I know my colors are batch certified?
Manufacturers of certifiable colors submit samples of their colors to FDA for analysis. After testing, FDA issues batch certificates to color companies that include a batch number corresponding to FDA’s database. Although FDA discourages color manufacturers from distributing copies of the physical certificate, you should seek such copies. You can always use, at least, the FDA-batch number and a color manufacturer COA to assist with answering questions from FDA when importing cosmetics containing certifiable colors.

4. There is no way I can get all that labeling information onto my eye pencils and eyeliners. Are there are exceptions?
Yes. FDA regulations have certain exceptions that allow very small items or containers to convey the required information in smaller than normal font or in firmly attached tags, tape, or cards.

5. We use different ingredients in several versions of our products. Can we say, “May contain” and then list the varying ingredients?
This is important: You can only use the “may contain” statement for color additives in the U.S.A. This is different than the EU. FDA regulations permit this for color matching in a product or for the colors in make-up products from a single brand with the same uses, labels, and composition (except for color).

CLAIMS

6. What kinds of claims can I make on my label?
You can make any truthful and non-misleading claims about your cosmetics on your labels that are consistent with the legal definition of a cosmetic.¹ That is, your claims regarding the performance of your product should pertain to cleansing, moisturizing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.” 21 U.S.C. § 321(i).

¹ The Federal Food, Drug, and Cosmetic Act defines “cosmetics” as “(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.” 21 U.S.C. § 321(i).
beautifying, or altering the appearance of the body. In addition, all of your claims, of all kinds, must be adequately substantiated with competent and reliable evidence.

7. What causes FDA to regulate a cosmetic as a drug? How can I avoid it? Claims asserting that your product treats or prevents disease (e.g., clears up eczema, SPF), or affects a structure or function of the body (e.g., protects the skin, removes wrinkles, etc…) will cause FDA to view your product as a drug. The best way to avoid regulation as a drug is to have your labels and claims reviewed by professionals experienced in identifying claims that will trigger FDA enforcement and help you draft robust cosmetic claims that get closer to where you want to be without triggering FDA’s drug jurisdiction.

8. Tones/Firms/Tightens/Repairs: Where are the “fine lines”? FDA reviews all of these types of claims in the total context of the label, labeling, and advertising. Thus, there is no fine line where a claim crosses over from a cosmetic claim into a structure/function claim. Of these claims, only “repairs” cannot be incorporated into a legal cosmetic claim.

**IMPORTS & IMPORT ALERTS**

9. My imported shipment is FDA detained but it's sitting in my warehouse! Can't I sell it? No. Until FDA releases the detention, FDA can ask Customs to demand redelivery of the shipment. If FDA asks Customs to demand redelivery of the shipment (usually after an FDA issues a refusal but also if the importer fails to hold the product for FDA examination or sampling) and you fail to redeliver, then you (as the importer) will be charged with liquidated damages up to three times the invoice value of the goods.

10. FDA is demanding copies of FDA batch certificates issued to the color manufacturer before it will release my product. Is FDA allowed to demand that? Well, yes – however, FDA has also previously warned color manufacturers not to release copies of their FDA batch certificates for this purpose. There are other identifiers we can use to prove to FDA that the colors in the product are FDA certified without using copies of the actual FDA certificates.

11. I have imported the same product for 5 years and suddenly FDA says I have a problem with a labeling claim. Don't all of those prior shipments have some precedential value? No.

12. My freight forwarder/warehouse/customs broker is charging me a fortune to store FDA-detained products and will not ship the product to me while FDA evaluates the entry. Can they do that? Not unless you agree to it. If you obtain a conditional release of the shipment from Customs custody, the freight forwarder, warehouse or customs broker is not permitted to prevent you from taking custody of your imported goods.
13. My customs broker told me to get a drug registration and drug listing number for my shipment – that was all FDA would want to see, but my shipment is full of cosmetics, not drugs! Should I listen to my broker (or get a new one)?
You should probably get a new customs broker. More importantly, customs brokers are not qualified to give advice about your legal obligations under the FDCA. They are qualified to act as the importer’s attorney-in-fact with respect to declarations to Customs and Border Protection.

14. My foreign supplier says they are in import alert, but just a simple test will allow me to buy from them. They are offering me a really good deal. Should I go for it?
Whether you should “go for it” is a business decision for you. However, you should know that if your supplier or its product is on an FDA Import Alert, FDA will automatically detain your shipment when it arrives in the USA. This will result in delays and additional costs above the simple tests, as well as possible damage to your reputation and brand. We can help you assess whether this is a “really a good deal.”

15. FDA does not answer emails or telephone calls. We have been trying to find out the problem with a shipment for weeks. Do I just have to wait?
No. You must not wait, because FDA only provides 3 weeks to respond to charges against your goods and if FDA refuses the shipment while you are waiting for FDA to respond, getting a rescission of the refusal is possible, but will take even more time. Go up the management chain to get a response or call an experienced attorney or import consultant to obtain the information you need, an extension of time to respond, and argue for expedited review.

16. I was waiting for FDA to respond to our questions about a delay and then, suddenly, the shipment was refused! Isn’t anyone accountable for their actions over there? What do I do now?
See Q 15. You might need an attorney experienced in dealing with FDA law and import procedure to represent you before the government to resolve this.

17. FDA refused my shipment and says it has to be destroyed or exported – but it will kill my bottom line to destroy it and cost me a fortune to send it back to the manufacturer. Aren’t there any alternatives?
Yes. Depending on the circumstances, you can ship the goods to another country or even petition FDA to rescind its refusal.

18. What happens during an FDA examination/sampling or detention?
In either case, you set the goods aside and do not manipulate them or ship them until FDA makes a determination. Examination and/or sampling are preliminary, and may lead to an FDA-detention or a release. If FDA detains the goods, it means they have identified something about the goods that appears to violate the law. Once detained, FDA expects you to provide evidence overcoming the appearance of a violation or FDA will refuse the goods. The statute requires refused goods to be destroyed unless they are exported within 90 days.

19. When can I ship it if FDA detained?
You can ship the goods to customers only after FDA releases the goods.
20. Where can I ship detained or FDA sampled goods?
While detained or awaiting FDA results from sampling, you can ship the goods anywhere you want as long as you maintain control of them until FDA releases them or you export or destroy them after refusal. There is no such thing as an FDA “50 Mile Rule.” It is a myth.

21. Who should be talking to the FDA compliance officer regarding an FDA detention?
Resolving an FDA detention requires expertise in federal laws and regulations. Therefore, someone experienced with FDA and Customs laws and regulations should be the point of contact for FDA.

22. What if I shipped my product already and then learned FDA wants to examine?
If FDA wants to physically examine the goods, you need to get them back (or as much as you can). If FDA discovers that you have shipped the goods without a release, FDA will request Customs to demand redelivery of the shipment and the importer will face liquidated damages of up to 3 times the commercial value of any part of the shipment not returned.

23. What is the purpose of the basic importation bond?
The bond acts as constructive Customs’ custody. Customs does not want to (or have the space to) store imported shipments not released by FDA or CPSC (etc.). The bond secures your promise to redeliver the goods if FDA wants to examine them or refuses them. Under the bond you agree to redeliver a shipment conditionally released to you if Customs issues a lawful demand for redelivery. Customs will issue such a notice if FDA refuses the goods or wants to examine a shipment you distributed prior to FDA release.

24. Why, if FDA detained it, is it sitting in my warehouse?
Customs releases the goods to your physical possession conditioned on your promise to return the goods if they are found to violate the law (i.e., FDA refuses them). The basic importation bond secures this promise by obligating the surety (the company that issued the bond) to pay the liquidated damages if the importer, as the bond principal, fails to pay. The surety will then sue the importer for the money.

25. What kind of information does my Customs Broker need to be able to properly clear cargo through Customs and FDA?
The broker needs to know the nature of the goods in order to estimate duties and properly classify the goods under the Harmonized Tariff Schedule of the US (HTSUS). They will also need a bill of lading (or airway bill), commercial invoice and packing list.

26. What are the most frequently used Import Alerts for cosmetics?

- Unapproved Colors
  Import Alert 53-06 ["Detention Without Physical Examination Of Cosmetics Containing Illegal Colors"]

- Anti-aging Claims in conjunction with Other Structure or Function Claims
  Import Alert 66-38 ["Skin Care Products Labeled As Anti-Aging Creams"]

- Unapproved New Drug claims
Import Alert 66-41 ["Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S."]

Microbiological contamination
Import Alert 53-17 ["Detention Without Physical Examination of Cosmetics Due To Microbiological Contamination"]

27. How do I get my supplier off an FDA Import Alert?
To get off Import Alert your supplier needs to submit a petition to FDA. An effective petition provides legal arguments and evidence assuring FDA that the manufacturer has identified and adequately fixed the problem that led to its addition on the Import Alert. This usually includes (but is in no way limited to) a series of shipments that are automatically detained, tested by private laboratory, and FDA released after testing.

28. Does C.I.T.E.S. apply to herbal ingredients in cosmetics?
It sure does - and failing to comply with C.I.T.E.S. is a sure way to get your products seized.

REGISTRATION

29. Do cosmetic establishments have to register with FDA?
No. FDA’s cosmetic registration is voluntary.

30. Should cosmetic establishments register with FDA?
It is up to you. The cosmetics industry enjoys certain benefits, as a whole, from registering with FDA. The two biggest benefits of registering are a) if FDA determines that a particular cosmetic or cosmetic ingredient is harmful, FDA can quickly notify manufacturers and distributors in the VCRP database, and b) the VCRP helps the Cosmetic Ingredient Review Expert Panel (CIR) prioritize which cosmetic ingredients it will evaluate for safe use.

CALIFORNIA

31. What about state governments? California?
Under the California Safe Cosmetics Act of 2005 ("the Act"), enforced by California’s Department of Public Health’s ("CDPH") “California Safe Cosmetics Program" (CSCP), cosmetic companies, with $1,000,000 or more in sales, are required to provide a list of products that contain ingredients designated by the State of California as “known” or “suspected” to “cause” cancer, birth defects, or other reproductive toxicity. However, there is otherwise no registration requirement simply because you import or distribute cosmetics in CA.

32. California Prop 65 applies to food and water, but does it apply to cosmetics?
Yes. It applies to any product that exposes consumers to chemicals “known to the State of California” to cause cancer or reproductive harm.
33. The CA Prop 65 warnings will kill my marketing. Are there any exceptions or ways to avoid the warnings?
Yes. There are exceptions for small companies and lower-limit “Safe Harbor” levels below which the warning is not required.

COMBINATION PRODUCTS

34. What is a combination cosmetic/OTC drug? Examples?
A combination cosmetic/OTC drug is a drug that also has significant cosmetic intended uses. Typical examples are toothpastes, dandruff shampoo, and make-up with SPF protection.

35. What is the difference? How does that affect my business? (i.e., registration, listing, claims, labels).
FDA regulates combination products primarily as drugs, requiring OTC drug labeling, claims, as well as mandatory facility registration and product listing.

36. What is different about the labeling requirements?
Drugs must be labeled according to the FDA’s drug labeling regulations. In addition, there are differences in the way ingredients are listed on the label.

37. What kinds of claims can I make for a combination cosmetic/OTC drug product?
You can make any truthful claims that you can typically make in any cosmetic product. In addition, you can include structure/function and disease claims that are approved in the applicable OTC Monograph.

38. What is the difference between a regular OTC and homeopathic drug?
OTC drugs are made of well known, safe and effective active ingredients administered by certain well-known routes within certain dosages, concentrations and conditions. These parameters are provided for in the FDA’s OTC Monographs outlining the approved claims, labeling and formulation. If your OTC drug complies with the Monograph, then there is usually no FDA-approval requirement (this is not always true but it is almost always true).

Homeopathic drugs do not require pre-approval of their formulation and labeling by FDA, but must consist of active ingredients approved by the Homoeopathic Pharmacopoeia of the United States (“HPUS”) and comply with FDA general drug labeling requirements.

39. What are Homeopathic Drugs?
A homeopathic drug is simply a drug recognized by the HPUS. Homeopathic drugs are intended to treat the syndromes of disease with remedies shown to produce similar syndromes and conditions in healthy subjects.

40. Do I need to register a manufacturer of an OTC or homeopathic drug? What about list with FDA?
Yes to both questions and both types of drugs.
41. I thought FDA did not like topical homeopathic drugs. Isn't that correct?

No. FDA does not have a policy against topical homeopathic drugs. FDA is likely to object to systemic homeopathic drugs intended for transdermal delivery. In 1999, FDA issued a Warning Letter requiring one company to file a new drug application for its homeopathic product purportedly because the homeopathic community does not recognize transdermal delivery of homeopathic drugs. Since then, the FDA official who signed the Warning Letter (now retired) and a member of the HPUS board have indicated what we suspected: the 1999 Warning Letter reflected an internal political decision at HPUS, rather than the homeopathic community’s view or an identifiable FDA legal or regulatory policy. Recently a number of companies have introduced transdermal homeopathic drugs into the market. It remains unclear whether FDA will take any action.