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Ms. Catherine Teti
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

June 28, 2017

FOIA Appeal

FOI Request No. 2017-2455

Dear Ms. Teti,

I submitted a FOI request, requesting internal decisions for "discretionary enforcement" of various cosmetic regulations, particularly those relating to product labeling or allowed ingredients. Information requested included records of any meetings where such decisions were made and any documents, instructions or guidelines, or other materials related to enforcement, sent to individuals or departments normally tasked with investigating violations of and enforcing such regulations. *[A printout of the original request is attached..]*

The request specifically included, but was not limited to, decisions to allow, on a "discretionary basis" the following, which are in violation of current regulations:

- Use of Latin name (rather than the English common name) as the primary identifier of botanical ingredients;
- Use of glitter in cosmetics, particularly colored glitter as a color additive;
- Use of an ingredient name in the name of a product (i.e. "Shea Butter Cream")
- Displaying net contents in only metric measurements.

On May 17, I was informed that the Office of Food Additive Safety (OFAS) had conducted a search and was unable to locate any records responsive to my request, and has closed the file on this case. *[A copy of the letter is attached.]*

I am appealing the decision to close the case and am requesting further search because I believe there ARE documents pertaining to the subject matter requested, based on the following data:

1. Statement made (July 2012) on this page http://phyrra.net/glitter-and-neons-in-cosmetics-unsafe-ingredients.html quoting a response from the FDA concerning the safety of glitter in cosmetics (highlight added):

   > FDA considers glitter and mica-based composite pigments to be non-permitted color additives when used in FDA-regulated products, including cosmetics. However, we are exercising enforcement discretion for a period of time. During this time, we will allow

> glitter and mica-based composite pigments to be released with comment when presented for importation into the US. Once the enforcement discretion period is over, FDA will resume our enforcement of these non-permitted colors.

When was this decision for discretionary enforcement concerning glitter and mica-based composit pigments made? Who has been informed of the decision? What exactly does it cover?

2. Statement made (undated, but prior to July 2012) on this page http://www.tkbtrading.com/additional_info.php?item_id=664 concerning response from the FDA concerning glitter:

> *The FDA has determined that glitter is a color additive which is not listed on their list of approved color additives. This means that a glitter product is not allowed for use in any cosmetic in the USA. Consumers have expressed confusion over this, as it is obvious that there is glitter in all kinds of cosmetics sold currently in the USA and there are no known reports of harm caused by glitter.*
>
> *The FDA has not explained itself to our company, but it has advised us that it recognizes that the cosmetics industry has been largely unaware of this determination and it is essentially providing the cosmetic industry a grace period during which FDA enforcement is "discretionary". This grace period allows the cosmetics industry to "respond". The FDA has not provided us with any information on how long this grace period has been in effect, nor how long it will be in effect. They simply state the the issue is "active".*

When was this decision for discretionary enforcement concerning glitter made, and by whom? Who has been informed of the decision? What exactly does it cover?

3. On the FDA website, this page https://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucm2005218.htm states:

> Cosmetic companies sometimes ask FDA about identifying botanicals only by their Latin names, identifying color additives only by the "CI" numbers used in the European Union, or using terms from other languages, such as "Aqua" and "Parfum" instead of "Water" and "Fragrance." Under the FPLA, however, ingredients must be listed by their "common or usual names," and FDA does not accept these alternatives as substitutes. But FDA does not object to their use in parentheses following the common or usual name in English (or Spanish, in Puerto Rico).

However, a review of cosmetic products on the shelves at any retail store shows a high percentage of products (particularly of those products that are also sold in other countries) identify botanical ingredients by the Latin binomial name first, and frequently without the common English name at all – clearly in violation of the regulations. One would expect that the legal counsel for these companies would only allow such labeling in violation of regulations if there were some certainty that the regulation was not being fully enforced.

In addition, I recall seeing (at some point) a statement on the FDA website that the FDA would not cite businesses for using Latin names in the ingredient dictionary, but I cannot find it on the website at this time (website was revised several years ago).

Has there been a decision allow Latin binomial naming of botanical ingredients, or to use "discretionary enforcement" in this instance? If so, when and where was this decision made, and by whom?

4. It recently came to my attention from a woman who works in the labeling department of a big box store that their standard is that suppliers are allowed +/- 10% of the actual weight when declaring the net contents for a package. She referenced 21 CFR 701.13(s) which states:

> (s) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

All references I have found to the requirements for net weight state that the US operates on a "minimum fill" requirement. By "minimum fill" is meant that the actual net weight may not be less than the amount stated or, in other words, the minimum amount is the amount stated on the package as the net contents. The supposed big box standard compares to the European rules, which allow for a +/- fill of an acceptable percentage (9-10%) based on the average fill for the batch.

Is the current interpretation that the stated net contents may be +/- 10% of the actual fill? If so, when, where and how was this decision made, and by whom? What directions have been given to those reponsible for enforcement?

5. A search of the shelves in any retail outlet shows numerous cosmetics using the name of an ingredient name in the name of the product, in violation of 21 CFR 701(b):

> (b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

Has there been some determination for discretionary enforcement in this instance?

Based on the above documented instances, including statements by the FDA that there will be "discretionary enforcement," apparent assumptions by large companies that the FDA will not enforce, and general failure to enforce, I request that the materials and documents be reviewed again to locate the information that has been requested. This may also include FDA responses to requests (as shown in examples #2 and #3, above).

I have written a book, *Soap and Cosmetic Labeling: How to Follow the Rules and Regs Explained in Plain English*. It is intended for small handcrafted soap and cosmetic manufacturers, to help them understand the basic labeling regulations. It becomes very difficult for these small business owners and entrepreneurs to follow the regulations when the FDA has made arbitrary and unpublished decisions about what will and won't be enforced.

Marie Gale