# Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist

The Federal Food, Drug and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of cosmetics that are adulterated or misbranded (Sec. 301).

A cosmetic may be deemed adulterated (Sec. 601) for essentially four reasons, namely:

1. It may be injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance.
2. It contains filth.
3. It contains a non-permitted, or in some instances non-certified, color additive.
4. It is manufactured or held under insanitary conditions whereby it may have become injurious to users or contaminated with filth.

A cosmetic may be deemed misbranded (Sec. 602) for reasons of:

1. False or misleading labeling.
2. Failure to state prominently and conspicuously any information required by or under authority of this act.
3. Misleading container presentation or fill.

To determine whether cosmetic firms manufacture, hold or deliver for introduction into interstate commerce cosmetics that are adulterated or misbranded, and to prevent these and other practices violating Sec. 301 of the FD&C Act, the law gives the agency the authority to enter the establishments of such firms and inspect their facilities as well as all pertinent equipment, finished and unfinished materials, containers and labeling therein. See Sec. 704(a) of the FD&C Act.

Rigorous adherence to good manufacturing practice minimizes the risk of adulteration or misbranding of cosmetics. The following cosmetic establishment instructions, excerpted from FDA's Inspection Operations Manual, may serve as guidelines for effective self-inspection. A good inspection score means that an establishment follows good manufacturing practice.

## Guidelines

1. Building and Facilities. Check whether:

a. Buildings used in the manufacture or storage of cosmetics are of suitable size, design and construction to permit unobstructed placement of equipment, orderly storage of materials, sanitary operation, and proper cleaning and maintenance.

b. Floors, walls and ceilings are constructed of smooth, easily cleanable surfaces and are kept clean and in good repair.

c. Fixtures, ducts and pipes are installed in such a manner that drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment, or finished products in bulk.

d. Lighting and ventilation are sufficient for the intended operation and comfort of personnel.

e. Water supply, washing and toilet facilities, floor drainage and sewage system are adequate for sanitary operation and cleaning of facilities, equipment and utensils, as well as to satisfy employee needs and facilitate personal cleanliness.

2. **Equipment**. Check whether:

a. Equipment and utensils used in processing, holding, transferring and filling are of appropriate design, material and workmanship to prevent corrosion, buildup of material, or adulteration with lubricants, dirt or sanitizing agent.
b. Utensils, transfer piping and cosmetic contact surfaces of equipment are well-maintained and clean and are sanitized at appropriate intervals.
c. Cleaned and sanitized portable equipment and utensils are stored and located, and cosmetic contact surfaces of equipment are covered, in a manner that protects them from splash, dust or other contamination.

3. **Personnel**. Check whether:
a. The personnel supervising or performing the manufacture or control of cosmetics has the education, training and/or experience to perform the assigned functions.
b. Persons coming into direct contact with cosmetic materials, finished products in bulk or cosmetic contact surfaces, to the extent necessary to prevent adulteration of cosmetic products, wear appropriate outer garments, gloves, hair restraints etc., and maintain adequate personal cleanliness.
c. Consumption of food or drink, or use of tobacco is restricted to appropriately designated areas.

4. **Raw Materials**. Check whether:
a. Raw materials and primary packaging materials are stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.
b. Containers of materials are closed, and bagged or boxed materials are stored off the floor.
c. Containers of materials are labeled with respect to identity, lot identification and control status.
d. Materials are sampled and tested or examined in conformance with procedures assuring the absence of contamination with filth, microorganisms or other extraneous substances to the extent necessary to prevent adulteration of finished products. Pay particular attention to materials of animal or vegetable origin and those used in the manufacture of cosmetics by cold processing methods with respect to contamination with filth or microorganisms.
e. Materials not meeting acceptance specifications are properly identified and controlled to prevent their use in cosmetics.

5. **Production**. Check whether manufacturing and control have been established and written instructions, i.e., formulations, processing, transfer and filling instructions, in-process control methods etc., are being maintained. Determine whether such procedures require that:
a. The equipment for processing, transfer and filling the utensils, and the containers for holding raw and bulk materials are clean, in good repair and in sanitary condition.
b. Only approved materials are used.
c. Samples are taken, as appropriate, during and/or after processing, transfer or filling for testing for adequacy of mixing or other forms of processing, absence of hazardous microorganisms or chemical contaminants, and compliance with any other acceptance specification.
d. Weighing and measuring of raw materials is checked by a second person, and containers holding the materials are properly identified.
e. Major equipment, transfer lines, containers and tanks are used for processing, filling or holding cosmetics are identified to indicate contents, batch designation, control status and other pertinent information.
f. Labels are examined for identity before labeling operations to avoid mix-up.
g. The equipment for processing, holding, transferring and filling of batch is labeled regarding identity, batch identification and control status.
h. Packages of finished products bear permanent code marks.
i. Returned cosmetics are examined for deterioration or contamination.

6. **Laboratory Controls**. Check whether:

a. Raw materials, in-process samples and finished products are tested or examined to verify their identity and determine their compliance with specifications for physical and chemical properties, microbial contamination, and hazardous or other unwanted chemical contaminants.

b. Reserve samples of approved lots or batches of raw materials and finished products are retained for the specified time period, are stored under conditions that protect them from contamination or deterioration, and are retested for continued compliance with established acceptance specifications.

c. The water supply, particularly the water used as a cosmetic ingredient, is tested regularly for conformance with chemical-analytical and microbiological specifications.

d. Fresh as well as retained samples of finished products are tested for adequacy of preservation against microbial contamination which may occur user reasonably foreseeable condition of storage and consumer use.

7. **Records**. Check whether control records are maintained of:

a. Raw materials and primary packaging materials, documenting disposition of rejected materials.

b. Manufacturing of batches, documenting the:
   i. Kinds, lots and quantities of material used.
   ii. Processing, handling, transferring, holding and filling.
   iii. Sampling, controlling, adjusting and reworking.
   iv. Code marks of batches and finished products.

c. Finished products, documenting sampling, individual laboratory controls, test results and control status.

d. Distribution, documenting initial interstate shipment, code marks and consignees.

8. **Labeling**. Check whether the labels of the immediate and outer container bear:

a. On the principal display panel:
   i. In addition to the name of the product, the statements of identity and net contents,
   ii. The statement "Warning--The safety of this product has not been determined" if the safety of the respective product has not adequately been substantiated. Determine whether and what toxicological and/or other testing the firm has conducted to substantiate the safety of its products. See 21 CFR 740.10.

b. On the information panel:

   i. The name and address of the firm manufacturing the product or introducing it into interstate commerce.
   ii. The list of ingredients (only on outer container) if intended for sale or customarily sold to consumers for consumption at home.
   iii. The warning statement(s) required at 21 CFR 740.11, 740.12 and 740.17.
   iv. Any other warning statement necessary or appropriate to prevent a health hazard. Determine the health hazard or their basis for a warning statement.
   v. Any direction for safe use of product.
   vi. In case of a hair dye product, the caution statement of Sec. 601(a) of the Act and appropriate directions for preliminary patch testing. This warning only applies to coal-tar hair dyes which, if so labeled, are then exempted from the adulteration provision of the Act.

9. **Complaints**. Check whether the firm maintains a consumer complaint file and determine:

a. The kind and severity of each reported injury and the body part involved.

b. The product associated with each injury, including the manufacturer and code number.

c. The medical treatment involved, if any, including the name of the attending physician.

d. The name(s) and location(s) of any poison control center, government agency, physician's group etc., to whom formula information and/or toxicity data are provided.

10. **Other**. Check whether the firm is:
a. Participating in the program of voluntary registration of:
i. Cosmetic manufacturing establishments (21 CFR 710).
ii. Cosmetic product ingredient and cosmetic raw material composition statements (21 CFR 720).
b. Using a color additive which is not listed for use in cosmetics (21 CFR 73, 74, and 82) or which is not certified (21 CFR 80).
c. Using a prohibited cosmetic ingredient (21 CFR 700).

For important information on international approaches to Good Manufacturing Practice, please refer to International Cooperation on Cosmetic Regulation Outcome of Meeting, September 26-28, 2007.

## The Big Kratom Question: Not for Human Consumption or For Human Consumption?
## By: Botanical-Education.org

The age-old question that has existed for as long as the kratom industry has lived circa 2008: Not for Human Consumption or For Human Consumption? (For Retail Stores)

It's a heated debate that will turn friends into enemies and companies into court cases. The following below has been written and approved by our lawyers ($$$) so you can bet your bottom dollar that this is not just our opinion but a legal opinion from some of the best in the business.

Please note that this messaging is in regards to retailers selling Kratom that is for Human Consumption. If you are selling a product that is Not for Human Consumption, there is no problem with it if you are following the law and your product really is not for human consumption.

### 1. "Not For Human Consumption" Labeling is Dangerous for Retailers:

Any product sold for consumption, whether it is food, a drug, or dietary supplement, must be labeled and sold according to FDA regulations. Some manufacturers have tried to circumvent those regulations by labeling their products as "Not For Human Consumption." ("NFHC") However, these attempts to skirt FDA regulations are likely to be unsuccessful, and they put most of the legal risk on the retailer. Retailers who sell products that are labeled NFHC run the risk of charges of mislabeling under the Food, Drug and Cosmetic Act, ("FDCA") or fraud under state laws.

### 2. Mislabeling:

The Federal Food, Drug and Cosmetic Act (FDCA) defines a products' label as both the actual label affixed to the product, and also any written material contained in any product wrapper and also anything accompanying the product. As if that weren't bad enough, courts have allowed the FDA to define "accompanying" extremely broadly.

Facebook likes are defined as labeling! Websites are defined as labeling!

Anything on a manufacturer's website or social media that references consumption, in any way, could lead to a charge that the product is mislabeled. A customer posting a testimonial on a manufacturer's website about the benefit she got from consuming the product, if it is "liked" by the manufacturer, would count as "labeling" and could lead to a mislabeling charge.

Are you certain that there is nothing on your manufacturer's Facebook page that implies consumption? The distributor?

The danger of NFHC-labeling is that it makes prosecutors' jobs very easy. To prove mislabeling, they simply have to prove that the product is intended for consumption.

**3. Fraud:**

If a retailer is selling a product that is labeled NFHC, but it is, in fact, for human consumption, that could support a charge of fraud. Prosecutors will look well beyond the labeling of a product to determine that it is intended for human consumption – an NFHC label is meager protection. And retailers have been charged with fraud. A store was charged in 2012 with fraud for selling kratom tea and capsules that were labeled NFHC. The prosecutor pointed to the facts that the labeling included directions for steeping the tea, and employee recommendations for how to smoke the products in a pipe. Many prosecution manuals explain what evidence to look for in determining that a product is for human consumption, but Sarasota County, Florida, spelled out in their recent designer drug regulation some specific indices of human consumption, including:

- The product is packaged in quantities that suggest human consumption.
- The product is displayed alongside other human consumables.
- Significant price differences between the substance sold and the substance as it is purported to be.
- The product is kept behind the counter or hidden from ordinary view, or sold with a code word.
- The product is kept in close proximity to drug paraphernalia.
- As a retailer, are you certain that the product labeled "NFHC" is selling for the same price as similarly labeled incense? Bath salts? Botanical samples?

**4. The Retailer Faces a Greater Risk from NFHC than the Manufacturer:**

A retailer selling a product labeled NFHC presents a compelling target for state and local prosecutors, much more so than the manufacturer. A manufacturer might be out of state from the prosecutor. The manufacturer might be able to pick up and move, compared to a retailer who is unable to close up shop and relocate. The manufacturer is primarily regulated by the FDA, and is a little fish compared to the large pharmaceutical companies the FDA normally targets. By contrast, a retailer is primarily regulated by state and local prosecutors and may represent a much greater target relative to other businesses.

Consider: The FDA has to decide between prosecuting a multi-billion-dollar pharmaceutical giant or a minor manufacturer. A state or local prosecutor may be deciding between prosecuting a multi-million dollar a year retailer and a low-level dealer.

**5. Dietary Supplement Labeling Can Provide Protection to the Retailer:**

Selling a product that is labeled as a dietary supplement is much less risky to the retailer. It implies that

the manufacturer has done the due diligence to get the product on the market appropriately. A retailer can compare the labeling of an established dietary supplement to the proposed new product and get a sense of whether the manufacturer has made a good-faith effort to comply with FDA regulations.

Ask your manufacturer or distributor through what regulatory pathway is the product on the market? A dietary supplement must be one of the following:

- An "Old Dietary Ingredient" – one that was on the market prior to October 15, 1994
- A "New Dietary Ingredient" with a New Dietary Ingredient Notification submitted to the FDA
- A "New Dietary Ingredient" that is exempt from the Notification requirements.

Several manufacturers have done the due diligence and determined that their kratom is appropriately on the market as a "New Dietary Ingredient" exempt from notification requirements because it was in the food supply in Thailand.

Selling a product that is labeled as a dietary supplement provides a good-faith defense to the most likely charges. To prove mislabeling, a prosecutor would have to prove that the product in question is not a dietary supplement, but a drug – that statements made in labeling suggested the product was intended to treat, cure, or diagnose a disease. That's more difficult than simply proving that the product was intended to be consumed. Also, dietary supplement labeling will almost eliminate the risk of fraudulently labeling a product NFHC when it is actually for human consumption.

**6. Applying these tests to an unnamed NFHC product:**

Some packages say that the product is intended only as a "botanical specimen" and that the capsules are intended only as carriers to "help facilitate the handling of raw powder." But, the packages also note that the kratom contained therein is the "most potent in the world." These packages also contain the warning that the FDA has not evaluated the product and that it is not intended to diagnose, treat, cure, or prevent any disease. On their website, they warn that pregnant women should not use the product. They suggest that retailers try a sample package and "test the results for yourself." Each of these would support a court finding that the products are, actually, intended to be consumed. Even their warning that they cannot provide dosages or dosing instructions (don't even ask) would be evidence that the product is intended to be consumed. If the product were actually being sold as a botanical specimen, and the capsules really were to facilitate the handling of raw powder, none of these warnings or disclaimers would be necessary.

Retailers need to ask themselves, if prosecutors come knocking, would you rather be defending products that are obviously falsely labeled, or would you rather be defending products that made a good-faith effort to comply with FDA regulations?