



BOTANICAL EDUCATION ALLIANCE™
Preserving Plant Legality Through Education

How to Make Your Kratom Business Compliant with FDA Guidelines

There are some things that you as a manufacture, seller or retailer of this product can do.

You need to follow the established government rules both state and federally.

If you are selling your product as a dietary supplement and not for research then you are required to obtain the following documentation if you are buying material that is not branded and pre packaged.

1. A certificate of analysis is something that proves what you are buying and marketing is the product labeled on your packaging. If it has not been adulterated or mixed with other botanicals. Also called a botanical identification. If you are not getting this from your supplier ask or contact one of the following labs to get your material tested. Note if you are repacking this material in any way it is always good to re-test the product.

Please note the BEA is not endorsing these places and in no way benefits from listing them:

<https://chromadex.com>

<http://www.alkemist.com/>

Want to find out more information on what the acceptable levels of Microbs is please take a look at the following website:

<http://www.ahpa.org/default.aspx?tabid=223>

2. Microb panel (note this can be included in the certificate of analysis). This will show that there is no contamination of the material that poses health risks in consumption or contact with the skin.

<https://chromadex.com>

Once you have tested your product and verified it is safe now you can pack it. If you are selling as a Dietary supplement or for use in bath or beauty products then you must be using a facility that is following GMP practices or following these practices yourself.

Please visit here:

<http://www.fda.gov/food/guidanceregulation/cgmp/default.htm>

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Finally, you must then ensure your branded product is labeled with compliant labels. BEA has a labeling document we can provide upon request. Note this document is a guideline and often the FDA changes their process so we recommend your final label being reviewed by your FDA consultant or legal council.

Please visit here:

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm2006823.htm>

If you have further questions please feel free to email BEA at support@botanical-education.org