



GMP labeling rules can feel intimidating, restrictive, and downright frustrating – but personally, i also think they can open up not just a lot of creative avenues for us to share product information with customers, but even ways for us to strengthen the herbal community!

Maybe that sounds overly optimistic, but i really see it working out that way, and hopefully this presentation inspires you to feel optimistic too!

## Just the facts...

### you **MUST** include:

- ✓ All ingredients
- ✓ Contact information (must include a physical address or website with physical address)
- ✓ Batch number
- ✓ "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."  
(it can be small to fit on your label)

### you may **NOT** include:

- ✗ Don't include any health claims (ie: "pain relief" or "anti-viral")
- ✗ Don't include drug names (ie: "better than aspirin")
- ✗ Don't include illness names (ie: "fibro relief")
- ✗ Don't include images that show a disease, even if it's a cartoon



*for example: even though this is a cartoon, it is clearly an illustration of a covid infection, and putting this on the label implies that the product will cure covid.*

### words the FDA lists as potentially problematic

ie, they're watching for these words because they likely imply a health claim

restore support maintain raise lower	promote regulate stimulate mitigate	<i>and of course, never:</i> prevent diagnose treat cure
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*Note: the words "organic", "made in USA", and "allergy-free" or "[allergen]-free" are also regulated in the same way that these phrases are for any other product.*

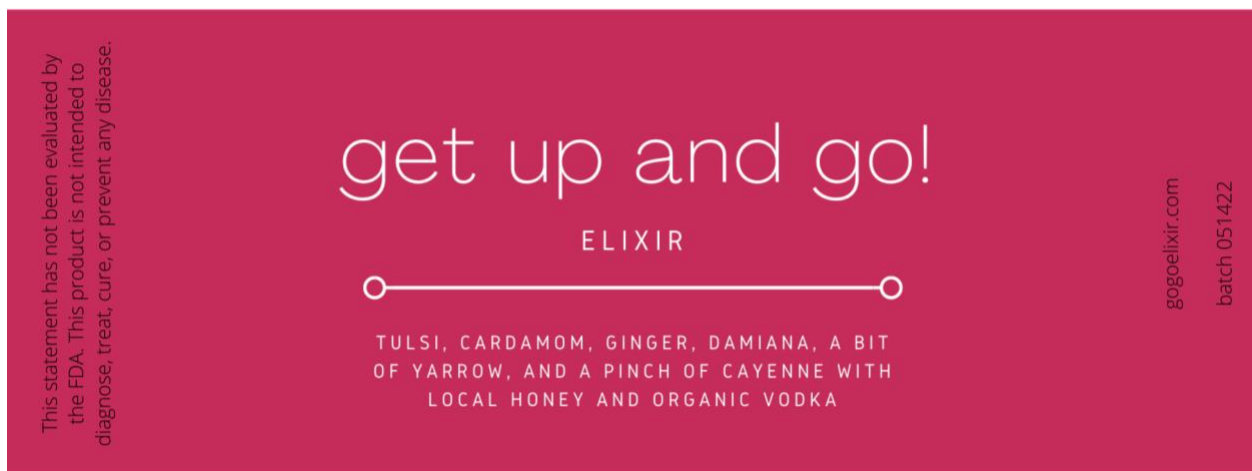


## So what CAN you say?

Try to think about how you want your product to make your customers FEEL, and express that kind of feeling in a way that shows your personal style – but without using a disease name, or even a body-part name. This allows you to make a clear picture for your customer BUT ALSO to let them see your personality, and get to know you better! You can brainstorm this with friends, put it on a whiteboard, anything that makes the process fun and lets your personality shine through!

For Example:

A formula that might be helpful for someone who is feeling mild depression, or seasonal affective disorder, or even someone who is struggling with low thyroid function. We can't say any of that - but what we can say is:



We could also have named it:  
get yer motor runnin'.  
revv it up.  
va-va-va-voom!  
ready-set-go.  
crush your to-do list.  
whistle while you work.

*all of these names give people the idea of how it will **feel** to take this elixir – a mood boost with a bit of stimulation – but without making any claims.*

*each of these product names will “speak” to different customer groups. choosing a name that resonates with you and your own personal style lets customers know that you’re “speaking their language”!*

*you’re following the rules AND letting customers get to know you all at the same time!*



How about a formula that might be helpful for someone with insomnia or anxiety that is preventing sleep – but you can't say that! What we can say is:



Or perhaps a formula for sluggish stagnant menstrual flow, maybe with cramping:



We didn't have to say any of that to get the point across!

Notice in all of these examples, the color of the label is also contributing to the feeling we're trying to get across... You have a lot of tools to communicate with!



Find the video version of this presentation here:

[youtube.com/commonwealthherbs](https://www.youtube.com/watch?v=commonwealthherbs)

Find the full GMP guidelines for small producers here:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-current-good-manufacturing-practice-manufacturing-packaging-labeling>

You can find every warning letter that's ever been sent here:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-current-good-manufacturing-practice-manufacturing-packaging-labeling>

This is a great way to learn what kinds of things the FDA does not allow.

You can search for specific herbs, or just on "herb" or "herbal" in the search box to filter out all the other types of products. For example, if you search on "elderberry", lots of results come up. Here is one i chose at random:

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/flora-inc-613310-06072021>

Reading through this letter gives you concrete examples of how the FDA is implementing these guidelines, and specific things you can't say.

## Questions?

Feel free to contact me in the AHG Herbal Business Chapter Facebook group or directly at [info@commonwealthherbs.com](mailto:info@commonwealthherbs.com)

love and chamomile,  
katja