Clean Label & Quality Metrics
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Defining the Need

55 million US adults with Multiple Chemical Sensitivities

- Headaches, asthma, rashes, fatigue, GI issues…

Nielsen Survey (2016):

>60% try to avoid artificial flavors, colors, preservatives

>50% avoid artificial sweeteners, GMOs, gluten, MSG

Due to perceived impact on health (>80%)

36% of households report some sort of food allergy or intolerance

One-fourth avoid gluten

55% say current products don’t meet their needs!

https://www.hopkinsmedicine.org/health/conditions-and-diseases/multiple-chemical-sensitivity
Common Culprits in Dietary Supplement Products

Consumers actively seeking to avoid...

- **Common allergens (ingredients derived from wheat, rye, barley, peanuts, egg, tree nuts)**
- **Gluten**
- **Magnesium stearate**
- **Shellac**
- **Hydrogenated or trans fats**
- **Artificial colors**
- **Artificial sweeteners**
- **Artificial flavors**
- **MSG**
- **Titanium dioxide**
- **High fructose corn syrup**

- **Carmine**
- **Glycerol monostearate**
- **Butylated hydroxytoluene (BHT)**
- **Butylated hydroxyanisole (BHA)**
- **Talc**
- **Sodium benzoate**
- **Triethanolamine**
- **Aluminum acetate**
- **Sodium lauryl sulfate**
- **Propylene glycol**
Defining Clean Label

NOT by what’s “IN” the bottle
✓ GMP audits
✓ Label claim

But by what’s “NOT” in the bottle
X Gluten
X GMOs
X Magnesium Stearate
X Hydrogenated Fats
X HFCS, MSG
X Coatings and Shellacs
X Other unnecessary binders, fillers, or preservatives
X Artificial Colors, Flavors, and Sweeteners
X Contaminants like heavy metals, pesticides, solvents, glyphosate

“CLEAN LABEL” DS
✓ Higher standard
✓ Clearly defined
✓ Easily understood
✓ 3rd-party verified
“Clean Label” is Self-explanatory

Most respondents find the ‘clean label’ claim self-explanatory and well understood and believe it has to do with the product **not including any ingredients not found on the label or detrimental to the product**

Question: What does ‘clean label’ mean to you? How would you define this?

*Note: most words (such as additives, chemicals, contaminants, etc) were used in the context of ‘clean label’ meaning the products would not include these*
“Clean Label” Resonates

Most believe this is very or extremely important to them, their patients, and will be a positive differentiator.

If a Pure Encapsulations product was verified as 'clean label' by a trusted third party,

Answered: 1,882  Skipped: 0

- How important would this be to you?
- How important would this be to your patients?
- How differentiating is this be versus other supplement brands?

Not At All Important  Slightly Important  Neutral  Very Important  Extremely Important
Available Certification Programs fall short

- No current programs cover the comprehensive needs of a “Clean Label” certification
  - GMP audit preparedness
  - Label claims- purity and potency
  - Non-GMO
  - Pesticide residue free
  - Certified allergen free
  - Gluten free
  - Glyphosate residue free
  - Banned substances
  - Specialty requirements of probiotics, fish oils
  - Authentication of raw materials
  - Organic
  - Specialty diets- vegan, paleo, ketogenic, low fodmap
What would “Clean-Label” Certification need to do?

**Confirm/verify label claims for “what’s not in the bottle”**

- Extensive testing for contaminants, e.g., residual solvents, pesticides, heavy metals, allergens, glyphosates, polycyclic aromatic hydrocarbons
  - Verify any “free” claims, e.g. gluten-free, soy-free

- GMO-free, and other free-from claims

- Allergen testing and process controls, cleaning validation, etc.

- Avoiding unnecessary binders, fillers, or preservatives in the manufacturing of dietary supplements

- “Bright-line” list of commonly avoided by sensitive consumers
  - NO Magnesium stearate
  - NO Trans-fats or hydrogenated fats
  - NO Gluten
  - NO Coatings, shellacs
  - NO Artificial colors, flavors, or artificial sweeteners

Requires a combination of product testing and process controls
CRITERIA:

- Full annual GMP audit of manufacturing and packaging facilities, with special focus on:
  - Staff training program
  - Supply chain controls, supplier qualification and raw material controls
  - Condition, function and design of facility and equipment, and equipment cleaning validation
  - Allergen cross-contact preventive controls and sanitation practices
  - Label controls for allergen and free-from labeling
  - Laboratory controls for both internal and external laboratory sample testing for components/ingredients and finished products

- Documentation review for a (risk-based) number of components/ingredients and finished products, with special focus on:
  - Specifications, including the establishment of contaminant (e.g., allergen) thresholds
  - Avoidance of Bright-line Ingredients (e.g., artificial colors, flavors, and sweeteners; excipients like magnesium stearate, hydrogenated fats)
  - Testing protocols and results
  - Finished product formulation and product labeling

- Annual laboratory sample testing for a (risk-based) select number (√N) of components/ingredients and finished product testing
Conclusion

- Clean Label is about what’s NOT in the bottle
- Clean Label is about the ingredients, not about the labeling
- Any Clean Label program needs to address common ingredients that consumers want to avoid
- A program that focuses only on the well established contaminants (e.g. heavy metals, pesticides) will fall short of consumer expectations
- A successful program will employ a combination of cGMP audit, process controls, document review, and product testing
Thank You