TRACEGAINS

Health Claims Substantiation for Risk-Free Supplements Innovation

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Council for Responsible Nutrition (CRN)

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I’ve Got a Great Product—But What Can I Say?

Trends and Pitfalls in Claim Substantiation for Dietary Supplements

Steve Mister
President & CEO
Council for Responsible Nutrition

Association Facts

One Association—The Council for Responsible Nutrition (CRN)

MEMBER
Council for Responsible Nutrition
The Science Behind the Supplements
www.crnusa.org

Amount with CRN

Staff	20
Voting Members	122
Finished Product Manufacturers/Marketers	65
Ingredient Suppliers	57
International Members	2
Associate Members	64
Annual budget	$7 million
Years in existence	48

Also contains: scientific, regulatory, international, media relations and government relations expertise not found anywhere else.

Labeling vs. Advertising

- Dietary supplement advertising claims are regulated separately from labeling claims
- Labeling includes all written, printed, or graphic matter accompanying an article at any time while the article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. (i.e., Labeling is not just “the label”.)
- What about the internet?

Types of Label Claims for Dietary Supplements

- Nutrient Content Claims
- Nutrient Deficiency Disease Claims
- Structure / Function Claims
- Health Claims (and Qualified Health Claims)
- PROHIBITED: Disease Claims

Nutrient Content Claims

- **A label claim that characterizes the level of a nutrient in a food.**
- **Permissible** if they have been authorized by FDA and are made in accordance with FDA's authorizing regulations.
  - 21 CFR 101, Subpart D (Specific Requirements of Nutrient Content Claims)
- Nutrient Content Claims cover food and dietary supplements.
- Authorized by the Nutrition Labeling & Education Act of 1990 (NLEA), not by DSHEA.
- Regulations expressly limit use of “A good source of…”, “high in…”, and other similar claims.
- Do not require any pre-market review or notice to FDA.

Nutrient Deficiency Claims

- **A statement that "claims a benefit related to a classical nutrient deficiency disease…"**
- **Permissible** only if it discloses the prevalence of such disease in the United States."
  - 21 USC 343 (r)(6)(A).
- Example: If the product makes a claim that it provides vitamin C to prevent the disease scurvy, the label must also disclose the extremely low incidence of scurvy in the United States.
- For this reason, nutrient deficiency claims are rarely used.

Structure / Function Claims

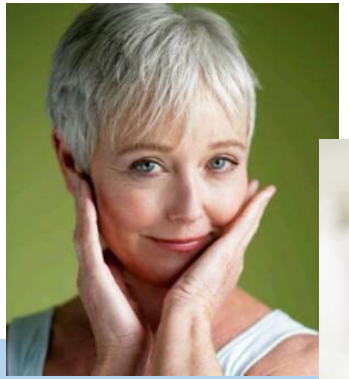
- **A statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient".**
  - 21 USC 343 (r)(6)(A)

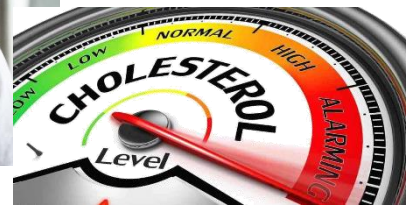
- A S/F claim triggers the requirement for a label disclaimer:

> "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Structure / Function Claims

- A S/F claim also triggers a 30 day notice requirement to FDA – "The manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made."
  - 21 USC 343(r)(6)(C)
- This is not a full review of the claim. Occasionally, FDA issues a letter indicating it does not consider the statement to be a S/F claim, but rather a disease claim.
- *So what is a disease?*

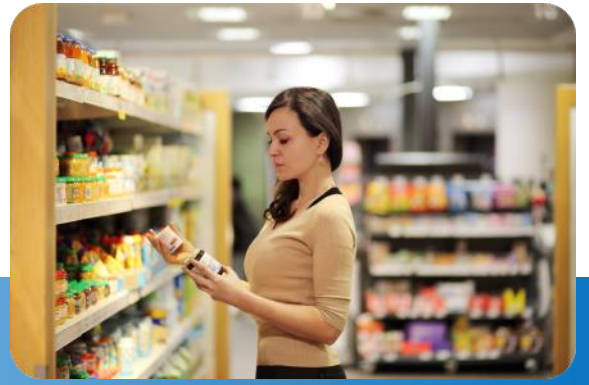




Health Claims

- **A statement that indicates a food component or dietary ingredient may reduce the risk of a disease or a health-related condition.**
- Created by the Nutrition Labeling & Education Act (NLEA), not DSHEA.
  - *NOTE: risk reduction is not disease prevention*
- Unlike other permissible claims, a health claim requires the approval of FDA.
- Approval of a health claim requires **significant scientific agreement** among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship, or
- May be based on an "authoritative statement" from certain scientific bodies of the U.S. Government or the National Academy of Sciences.

Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.



Qualified Health Claims

- Not recognized by statute; a creature of courts and FDA exercise of discretion
- Pierson v. Shalala – FDA may allow a health claim if it is supported by scientific evidence, but does not meet the more rigorous "significant scientific agreement" standard required for an authorized health claim. If the claim can be properly qualified to convey accurately the limitations of the science without misleading consumers, FDA will exercise enforcement discretion and allow the qualified claim.
- To ensure that these claims are not misleading, they must be accompanied by a disclaimer or other qualifying language to accurately communicate to consumers the level of scientific evidence supporting the claim.

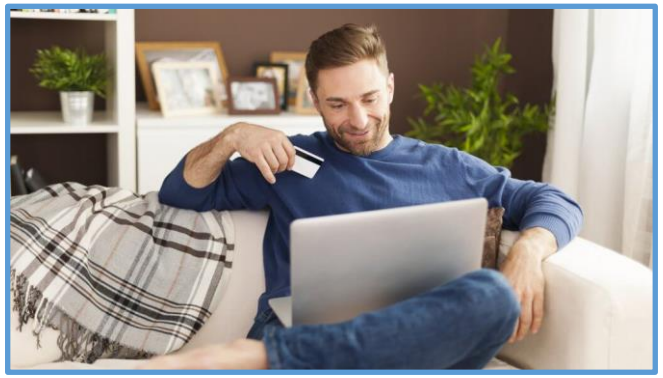
Examples of Qualified Health Claims

"Consuming EPA and DHA combined may help lower blood pressure in the general population and reduce the risk of hypertension. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [__] gram(s) of EPA and DHA."

"Consuming 500 mg each day of cranberry dietary supplement may help reduce the risk of recurrent urinary tract infection (UTI) in healthy women. FDA has concluded that there is limited scientific evidence supporting this claim."

Disease Claims

- **A statement that a product or ingredient diagnoses, mitigates, treats, cures, or prevents a specific disease or class of diseases.**
- **PROHIBITED** for dietary supplements. -- 21 USC 343 (r)(6)(C).
- Using a disease claim on a dietary supplement makes the product a drug in FDA's eyes.



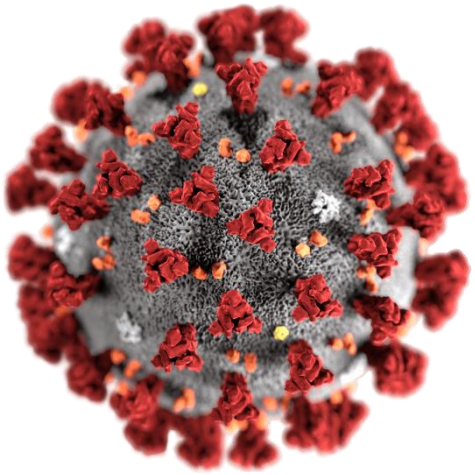
- Context matters: even images or unseen ad words, metatags and paid search terms

Substantiation from FDA's perspective

- All label claims—regardless of which kind—must be truthful and supported.
  - "….a statement for a dietary supplement may be made if—

    (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading,…" 21 USC 343(r)(6)(B)
- FDA rarely takes enforcement action in these cases, focusing instead on impermissible claims.

Case Study: COVID-19 related claims



- Nutrient Content Claim:
  - **“A good source of zinc.” “High in Vitamin D.”**
- Nutrient Deficiency Disease Claims
  - N/A
- Structure / Function Claims
  - **“Helps to strengthen the immune system.”**
  - **“Provides support for a strong immune function.”**
- Health Claims (and Qualified Health Claims)
  - **“Achieving higher blood levels of Vitamin D helps to reduce your risk of COVID-19.”** *(would require significant scientific agreement of that conclusion.)*
- PROHIBITED: Disease Claims
  - **“Prevents COVID-19.”**
  - **“Reduce the severity of symptoms from the corona virus.”**

Advertising Claims - FTC

- Federal Trade Commission / Federal Trade Commission Act
  - Unfair methods of competition
  - Consumer Protection from false and misleading advertising
- FTC is not concerned with categorizing claims—it simply asks if the claim is truthful, not misleading and properly substantiated.
- The amount of substantiation required is a flexible standard that may depend on the nature of the claim.
- The burden is not on FTC to initially prove falsity; rather when the FTC opens an investigation, the burden is on the advertiser to prove the claim is truthful and properly substantiated.
- The advertiser is expected to already have substantiation prior to making the claim.

Competent & Reliable Scientific Evidence

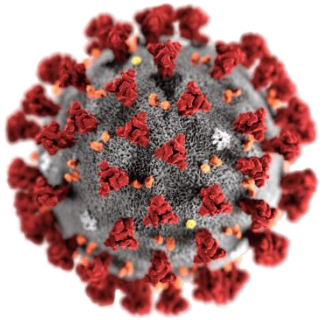
- FTC Substantiation Standard: Competent & Reliable Scientific Evidence – How much is enough?

- Competent & Reliable Scientific Evidence is considered “tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”

“Hot Buttons” at the FTC

- Claims representing a high level of support
  - **“Clinically proven…”** **“Doctor recommended…”**
  - **“Scientifically backed…”**
- Quantifiable Claims
  - **“See results twice as fast.”**
  - **“Four out of five doctors recommend…”**
  - **“Three times the absorption of…”**
- Testimonials and Endorsements without Disclosure
  - Especially social media influencers or celebrities
- Be careful of Implied Claims
  - FTC looks at the totality of the ad; may even conduct consumer research to determine their take away

Case Study: COVID-19 related claims

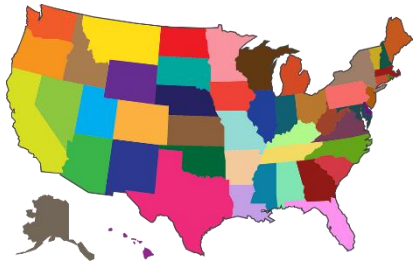


- COVID related claims require extremely high degree of substantiate:
  - "Natural Prevention for Coronavirus"
  - "A customer recently wrote to us about her sister-in-law who contracted the coronavirus and how [XXX] greatly improved her breathing and helped ease her coughing."
  - "Another customer told us about her nephew and his wife – both frontliners in a New York City hospital – who also became infected with COVID-19. They both began taking [XXX] and within three days, they were feeling much better.
- Even implied claims get FTC attention:
  - "I take Vitamin C daily and just reordered some to be sure I don't run out before Coronavirus season does!"
  - "We offer immunity building protocols and treatments that may help during the spread of COVID-19 virus."
  - "Here are several ways CBD can help you with your immune system in the current crisis..."
  - "This pure essential oil is ideal to use during a chill or the cold season because of the powerful anti-viral and antiseptic properties of these essential oils."

Beyond FDA and FTC—Other Enforcers

- Private Class Action Litigation

- State Attorneys General



- National Advertising Division

- Lanham Act litigation brought by competitors

Private Class Action Litigation

- Significant increase in new cases targeting dietary supplements
- Old standard: Plaintiff had to prove falsity of the claim
- New standard: Courts willing to look at totality of the evidence
  - Question of fact: Which side has the better evidence?
  - Is the evidence equivocal?
  - Becomes a Battle of the Experts; more difficult to get case dismissed quickly
- Recent case recognized pre-emption of state law by DSHEA
  - “Biotin helps support healthy hair and skin.”

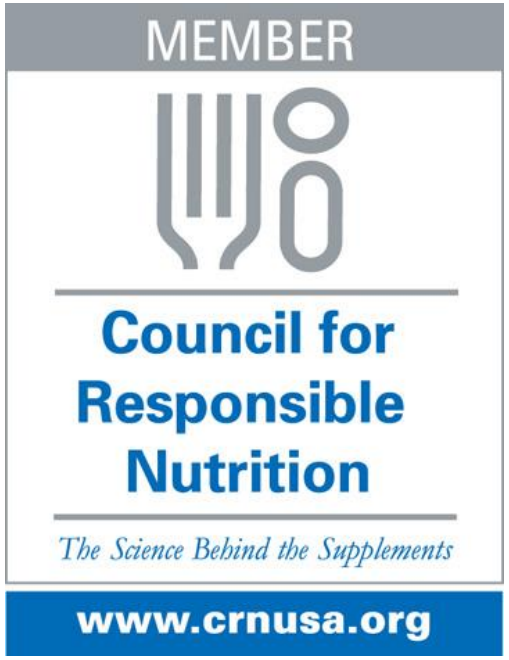
States Attorneys General & COVID-19

- **New York** – Cease and desist letters sent to numerous marketers of coronavirus treatments, including Jim Bakker

- **Oregon** – Emergency regulation makes it “unfair and deceptive” to represent that a product will prevent, treat, diagnose, mitigate or cure coronavirus without competent and reliable scientific evidence
  - Includes a private right of action as well as state AG enforcement

National Advertising Division

- Voluntary self-regulatory program of the CBBB.
- Challenges are brought by competitors or NAD itself as watchdog.
- Uses the same standards of FTC – “competent and reliable scientific evidence.”
- Issues a decision and may recommend modification or discontinuance of the advertising.
- No enforcement, but may recommend non-cooperating cases to the FTC.



Thanks for Listening!

- For more information, see our website at www.crnusa.org or contact me at smister@crnusa.org or (202) 204-7676

Introducing the TraceGains **Networked** Product Development Suite

Digitize and streamline new product development from concept through production for better, faster innovation.

Formula & Recipe Data is Siloed

Data is Scattered Across Departments and Facilities

As much as 75% of your supply chain data lives with your suppliers

Formula Management Can Be Overwhelming

- ✓ Change Management
- ✓ Claims Substantiation
- ✓ Product Criteria
- ✓ Raw Material Costs
- ✓ Regulatory Requirements
- ✓ Research
- ✓ Supply Chain Fluctuations
- ✓ Version Control
- ✓ Testing

Cross-Department Collaboration

R&D and Innovation

Procurement

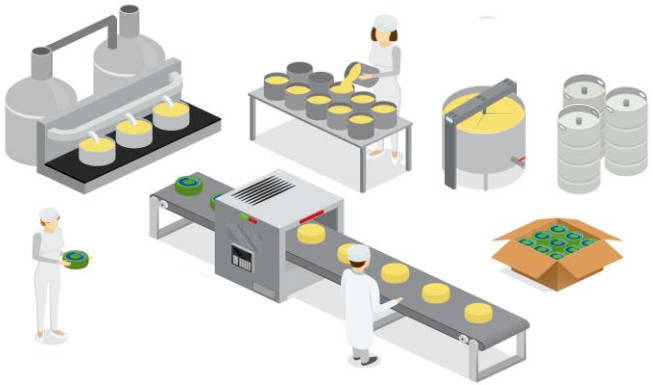
Quality

Regulatory

Networked Formula Management

With TraceGains, your team connects with supply chain partners to collaborate and we help automate the rest.

Internal Departments + Suppliers + Co-Manufacturers

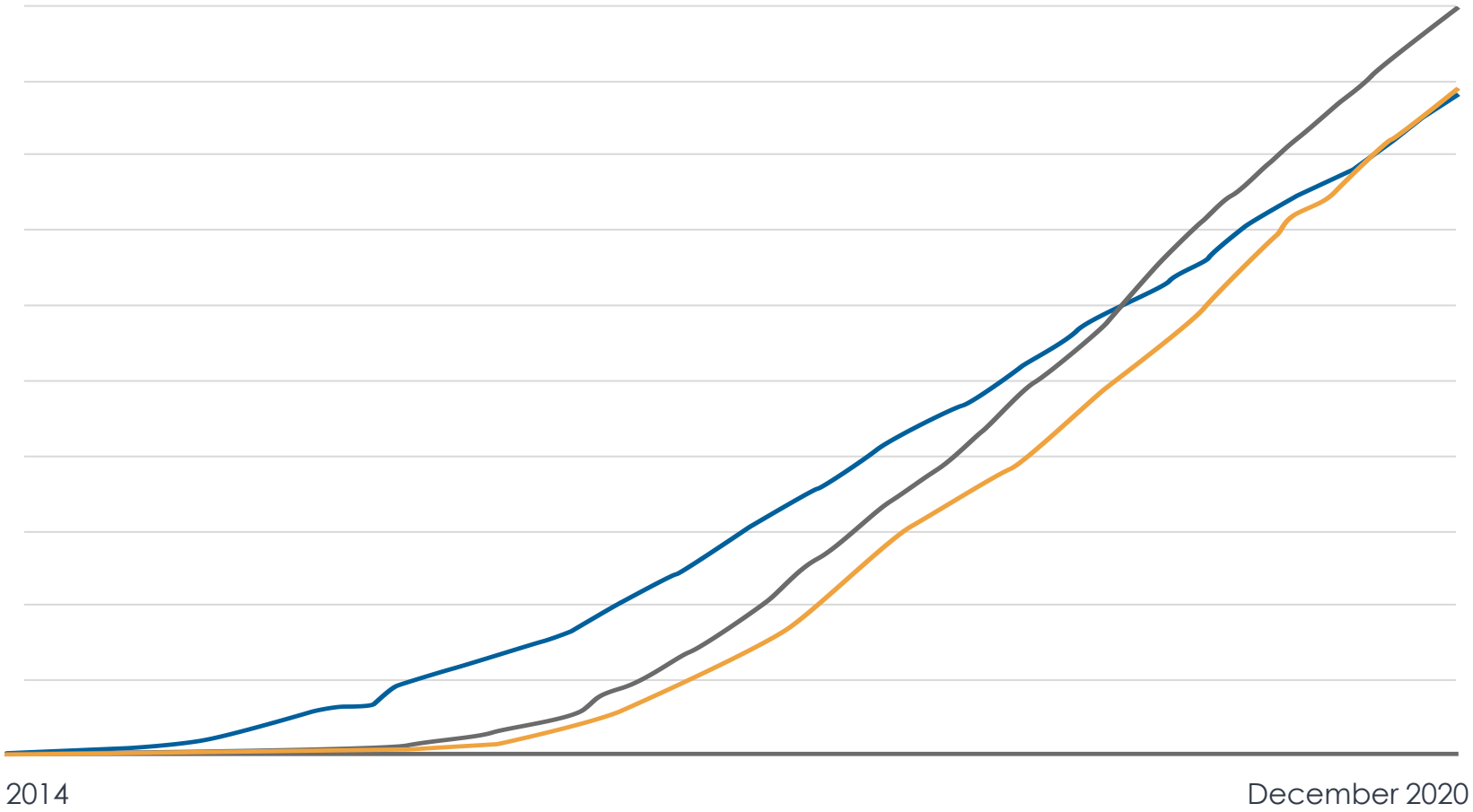


TraceGains Network

Freedom from tracking down suppliers and requesting information or documents

- ✓ 35K Supplier Locations
- ✓ 300K Items & Ingredients
- ✓ 2M+ Supplier, Item & Ingredient Documents
- ✓ 150+ Standardized Online Forms
- ✓ 120+ Supplier Countries

For Most Companies, the Majority of Suppliers are already on TraceGains Network



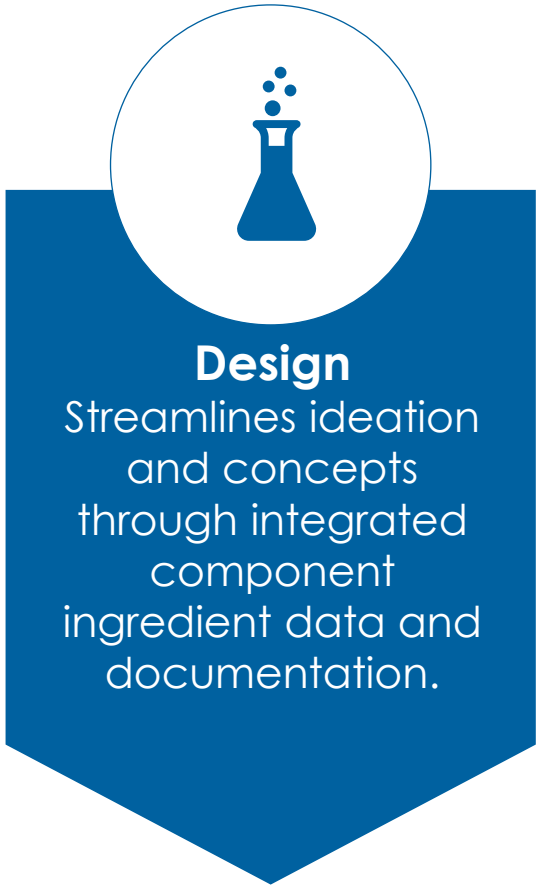
36K+
SUPPLIER LOCATIONS

305K+
ITEMS

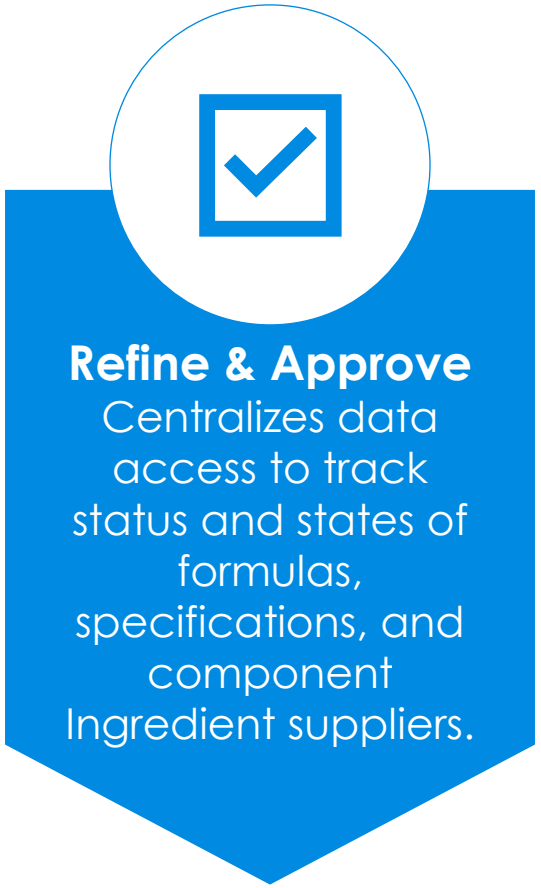
2.4M+
DOCUMENTS

Unified Teamwork Across All Your Internal Departments and Supply Chain Partners

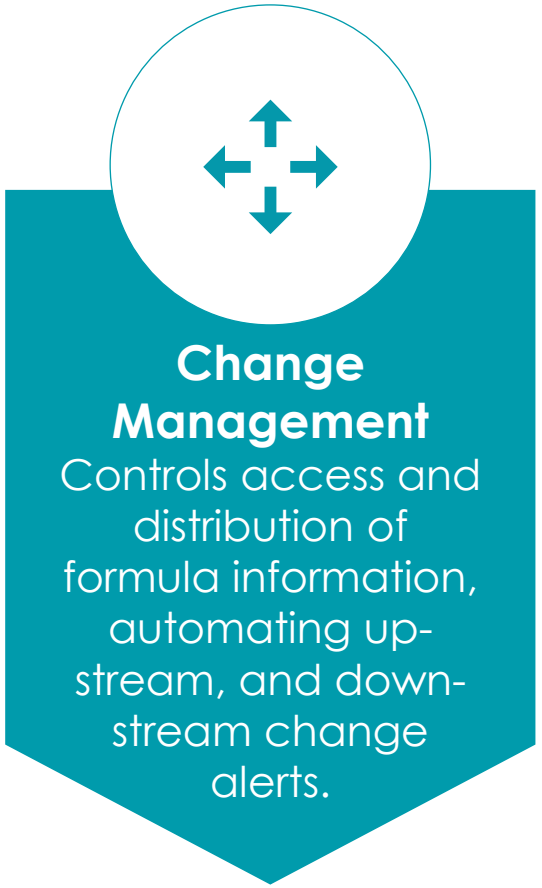
TraceGains Drives Product Innovation



Design
Streamlines ideation and concepts through integrated component ingredient data and documentation.



Refine & Approve
Centralizes data access to track status and states of formulas, specifications, and component Ingredient suppliers.



Change Management
Controls access and distribution of formula information, automating up-stream, and down-stream change alerts.

TraceGains supports all stages of product development from design to approval to production, with automated version control and rapid digital recipe iteration.

Teams Struggle to Substantiate Label Claims

- ✗ Managing compliance can be a bottleneck to formula and recipe development
- ✗ Fulfilling FDA requirements can require extensive research
- ✗ Teams lack visibility into upstream and downstream impacts
- ✗ Invalid label claims introduce significant risks

Allergens, Claims & Criteria

Report on Allergens • Label Claims • Thresholds • Nutrition Profiles • Ingredient Declarations

- ✓ **Allergens**: Manage allergen declaration attributes for approved ingredients and compare the impact of item replacement on recipes, examining the change in nutrition values across multiple formulas
- ✓ **Claims**: Substantiate label claims with access to over 300,000 scientific studies
- ✓ **Criteria**: Digitally model formula variations with real ingredient and supplier data to meet cost, nutrition, allergen, and claims targets before physical trial testing.

Benefits of Claims Substantiation from TraceGains

- ✓ Address claims and other compliance-related requirements upfront
- ✓ Build substantiation files
- ✓ mass update capabilities
- ✓ Share details with manufacturing systems, stakeholders, and co-manufacturers in real-time.
- ✓ Bulk compare recipes
- ✓ Instant access to regulatory compliance documentation, citations, established business rules, and more than 300,000 scientific studies.
- ✓ Verify existing claims post recipe modification
- ✓ Digitally model ingredient and raw material variations before physical trial testing.

TraceGains Formula Management Features

Digital Formula Management to Keep Pace with Consumer Demand

Ingredient Mass Updates

Run simulations to remove or replace an item across all recipes

Rapid Formula Iteration

Create unlimited recipe variants with side-by-side, on-screen comparison

Configurable Reports

View formula cost estimates, allergens, nutrition profiles, & more

Formula Traceability

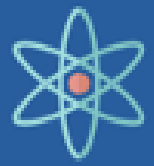
Trace component ingredients and raw materials to their source

Intermediate Formulas

Quickly update multiple finished goods formulas and report changes

Allergen Management

Compare the impact of item replacement on recipes



Networked Platform

Organize and digitizes all relevant formula and recipe data

Change Management

Get notified when formulas or recipes change

Digital Audit Trail

Digitally Track ingredient details for a complete audit trail

Live Q&A

Thank You

Plug In. Go Faster.