



Capsules' Superior Performance Taps Today's Consumer Values

Movements within the food world toward simple, clean, sustainable sourcing of real, whole, safe ingredients present a change that's grown at most every level of society and commerce. Products, packaging and messaging are all under scrutiny by an increasingly sophisticated and technologically competent consumer base.

Today information travels at the speed of millions of fragmented social media feeds, and a 6-month branding campaign can be shaken by the 140-character tweet of the right social influencer. Effectively branding a product today is a mix of marketing strategy and responding to the cacophony of the social universe. All of this is helping to shift power away from the corporation and into the hands of the consumer.

How can companies survive and even thrive in such an environment? By embracing transparency—in product formulation, in manufacturing, and in marketing.

Many natural and organic product brands are building transparency into their packaging—literally. Some nutrition bar brands boast see-through packaging, and more companies are listing ingredients on the front of the package versus requiring consumers to find this information in tiny print on the back label.

Clearly, there's greater transparency in natural and organic foods than conventional. The ingredients in organics have to be traceable all the way

back to the earth. When there's that much transparency in the product, the consumer's going to tend to value it more.

It is this desire on behalf of the rising consumer segment of values-based shoppers that is leading the shift rippling across a wide swath of consumer products. Organic is up.

Non-GMO is up. Kosher, Halal: up. Sustainability. These next-gen shoppers are entering the dietary supplements aisles and remaking the industry with their decisions that have, at their core, shoppers' personal values making those buying decisions.

SUPPLEMENTS' PLACE IN THIS NEW WORLD

A lot of fanfare has arisen recently about innovative new delivery systems for supplement consumers. Gummies have broken out of their hitherto pigeonholed space on the children's supplement shelves and now offer options for pill-weary adults. Dissolving strips, shots, lozenges, patches, beverages and foods all vie for the nutrient attention of shoppers.

But at the end of the day, the vast majority of supplements consumed belongs to the big two: tablets and capsules.

Yet a sea-change is under way in consumer preference between these two supplement forms. It's part of the story that has driven consumer appeal of organic foods, that has led to the mainstreaming

of what may be called “the Whole Foods Market shopper,” and that has led to the awakening in the American conscience of the presence of genetically modified organisms (GMOs) and a desire to have products that contain GMOs labeled. Transparency is more than a buzz word - it's at the core of today's consumer experience.

Consumers are increasingly purchasing products that reflect their personal values. Enter capsules. Compared to tablets, capsules contain fewer non-functional ingredients - these include excipients like binders, fillers, additives, plasticizers, disintegrants, as well as other potential allergens like those from soy.

Capsules also fulfill the concept of product integrity because ingredients housed within them stay closer to the whole product, and the heat and pressure in tablets can degrade nutrients. Consumers are clearly responding to these transparent benefits.

“Surfers set the base with fashion and hippies set the trend in nutrition and supplements. What the Whole Foods shopper is asking today will be the mainstream trend five to ten years from now.”

Brand marketers and retailers in the natural market who are looking to capitalize on today's cultural shifts and trends to get ahead and stay ahead are looking at a range of strategies. For these leading-edge manufacturers and stores, this effort now includes supplements housed in capsules.

THE CLEAN-LABEL PROMISE AND VEGETARIAN SOURCE

When the market first began shifting toward the healthy-living consumer, supplement encapsulation manufacturer Capsugel pioneered VCaps®, in 2003, one of the market's very first vegetarian capsules. This market segment included consumers with cultural and dietary concerns about their supplements.

Vegetarian capsules are made from plant-based materials such as cellulosic fiber or naturally fermented polysaccharides. Newer vegetarian capsules are made through an innovative manufacturing process that is as simple as cellulosic fiber and water. Vegetarian capsules are Vegetarian Board-certified, Kosher and Halal acceptable, gluten and preservative free. And some have now achieved the status of Non-GMO Project certified. Vegetarian capsules are the new premium capsules designed for the needs of the growing and very discerning healthy lifestyle market.

This market is delineated in some recent market-research studies.

- In the U.S., 38 percent of supplement users say vegetarian source is important when choosing a supplement - up from 26 percent in 2006. This group is among the most frequent users of supplements. [Natural Marketing Institute, Supplement.OTC/Rx Database (SORD) Overview, October 2013.]
- Of U.S. supplement consumers who say vegetarian is important, 46 percent are heavy supplement users - they use 9+ supplements a day.
- Of this group of U.S. supplement consumers who say vegetarian is important, 50 percent are Millennials - a driving force in dietary supplement purchase shifts.
- In a study of European supplement users, more than 45 percent said they would be more likely to purchase a supplement if they knew it was in a vegetarian capsule. [Capsugel Non-Animal Portfolio Survey, US, UK, Germany, France & Italy, February 2012.]
- Of U.S. supplement users, 66 percent say they want their supplements to be from a natural source.
- Of U.S. supplement users, 42 percent say they want their supplements to be non-GMO. Moreover, 54 percent of Millennials say they want their supplements to be non-GMO.

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"Our use of vegetarian capsules before 2000 was maybe 5 percent, 10 percent tops of our capsule demand. Today it's about 40 percent," said Val-labhaneni. "We make amino acid-type products, things people don't really think of premium, and our customers all want vegetarian caps. Our standard core products are vegetarian capsules, and all the new products we do are vegetarian capsules."

For some real-world advice on why this is so, the cutting edge of supplements innovation traditionally lies with multi-level marketers (MLM), also known as network marketers - the Herbalifes of the world. Mark Pedersen, ND, is senior vice president of research and development at Cornerstone, based in the heart of MLM manufacturers in Utah. Pedersen seconds the sentiments voiced by Vallegghaneni about the early-adopting consumer driving the market.

"People who really know and use health foods, maybe 20 percent of the population, they're looking for products with a natural presentation, and vegetarian capsules appeal to them. In what our industry specializes in, they're looking at excipients, added colors and flavors, and that market is growing and people are paying more attention."

Vegetarian capsules, says Pedersen, are "the real clean-label promise. A lot of people really like non-animal products. Clean label means you don't have to add anything to it."

From a pure delivery system standpoint, capsules are "cleaner" and that resonates across the spectrum of natural retail outlets.

THE CLEAN-LABEL PROMISE: GMO-FREE

The non-GMO food and supplements category is the fastest-growing sector in the natural products industry, with non-GMO product sales recently surpassing \$3.5 billion.

To date, three Northeastern states have enacted GMO labeling laws, although only Vermont passed a clean bill that does not have a "trigger" clause saying the rules will go into effect only if a certain amount of other states pass similar legislation. Bills have been introduced in at least 22 other state legislatures. Meanwhile, the U.S. Congress is considering the Safe and Accurate Food Labeling



Act (HR 4432), which would set national voluntary labeling standards for finished products.

Perhaps the biggest indicator that GMOs have reached a tipping point is not from any legislation but rather from the free market. Case in point: General Mills' recent decision to remove GMOs from Cheerios cereal.

"My gosh, if Cheerios - the ubiquitous, all-American cereal brand - says no to GMOs, well then, we should all take heed," said Mary Haderlein, principal at Hyde Park Group Food Innovation. "Once non-GMO labeling is approved, the trickle will become a flood, and marketers who successfully made the transition will win with the consumer."

In another significant market-based solution, the Non-GMO Project was launched in 2010, its mission to offer North America's only third-party verification and labeling for food and products made according to best practices for avoidance of GMO ingredients. In the second quarter of 2012, the project had 194 verification program enrollment inquiries. By the second quarter of 2013, that number had risen to 797. In March 2014 the Non-GMO Project reported it has verified 4,622 products representing 1,500 different brands.

In the wake of mainstream media coverage, increased consumer awareness of food sensitivities and Whole Foods Market's drive toward GMO transparency, demand for products free of GMOs is clearly gaining steam. Traditionally, the dietary

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supplements industry has met this demand with self-verification. But now the Non-GMO Project offers the promise of uniting the supplements industry under one standard and one seal.

The dietary supplements industry has been the laggard among product categories in natural food stores because of the many issues supplement-style ingredients have in complying with non-GMO standards.

The first challenge in securing Non-GMO Project verification lies in the inherent nature of supplements. "The project's process was originally designed to verify, primarily, food products," said Gerda Endemann, PhD, senior researcher at Source Naturals, which has attained certification for its tongkat ali product. "Applying this same process to dietary supplements is more challenging because of the greater complexity of our supply chain, the large number of vitamins and herbs in many products, and the current lack of GMO-free forms of some ingredients."

Often overlooked in the GMO-free supplements rubric is the actual delivery form itself. Many of the fillers in tablets are among the most difficult and intransigent to be able to comply with non-GMO standards.

In fact, it was only in the fall of 2013 when the first supplement capsule was awarded Non-GMO Project verification. That went to Capsugel's Vcaps®, Vcaps® Plus and Plantcaps. Manufacturers who source capsules from the company are already finding value in so doing.

"NOW Foods is pleased that Capsugel has received verification from the Non-GMO Project," said Michael Lelah, PhD, technical director for NOW Foods, based in Illinois. Earlier in 2013, NOW Foods approached Capsugel and discussed the importance of a third-party verification as an endorsement of their self-certification. "Consumers want to know that the products they consume are non-GMO, and as a leading manufacturer of natural products, we have been an early adopter and advocate for participation in the Non-GMO Project. Our partnership with Capsugel is an example of how suppliers and manufacturers can work together to meet consumer needs."

No doubt part of the reason Whole Foods Market gave until 2018 for companies to comply with its GMO-labeling rules was to give time to supplement companies to get their supply lines zipped up. Having a GMO-free option already on the market for encapsulated supplements gives supplement makers relief that at least that part of their challenge is taken care of.

With the numbers only increasing for the values-choice shopper - environmentalist, organic, enviro-friendly packaging, Kosher- or Halal-certified - by the time Whole Foods Market's 2018 GMO labeling edict rolls around, it is expected that most independent natural-foods retailers will follow suit. Softgels are well-received but they come up against the GMO issue and will get knocked out unless they can come up with a non-GMO gelatin that can get certified. To date, that's not on the radar.

STUDIES CONFIRM: CONSUMERS PREFER CAPSULES

Another issue that is of keen interest to supplement makers is the consumer experience of swallowing nutrients. Known as "pill fatigue," it's been the reason why alternative delivery systems have gained recent sway (though they still represent less than one out of 10 supplement servings), from gummies for adults to effervescent satchels and tablets.

A great deal of consumer research has been done on swallowability of different pill forms. The idea germinated from pharmaceutical drug trials wherein compliance is always an issue - if a patient does not take the drug in its prescribed time frame they will not receive the benefit. The results, though, align perfectly with popping supplement pills.

The "mature" market in particular reports greater difficulties in swallowing tablets than younger people. In a 1999 Norwegian study among such patients aged 65 to 88



TOP PREFERRED SUPPLEMENT DELIVERY FORMS

% supplement users indicating they would prefer to use supplements in the following formats if they were available



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years old, 44 percent reported general swallowing problems. Issues ranged from tablets scratching the esophagus during passage to tablets with a bad taste or smell.

In a study from 2001, Dutch researchers investigated the swallowability and the patient preferences of tablets and capsules with different sizes, shapes, surfaces and colors. Among 331 patients in the study, 278 were aged 23-64 years old, and 53 patients were older than age 65. Also, 156 patients took fewer than 10 pills a day and 175 swallowed 10 or more.

The results showed that about two-thirds of patients most easily swallowed gelatin capsules, while 18 percent preferred coated tablets and only 4 percent preferred uncoated tablets. The difficulty to swallow tablets increased with increasing size of the pills. Benefits ascribed to capsules included the smooth, glossy shell of capsules, as well as their rounded, narrow shape.

"Everybody I've ever talked to would prefer capsules every time," said Cornerstone's Pedersen. "Some will say it's the corners and edges of tablets, but for the most part it's the way we swallow: capsules float and tablets sink. If you put them in water, capsules float and tablets sink. That ability to float keeps capsules from lodging in the throat and sticking. Because it floats it stays away from the edges of the throat as it's going down."

Researchers in Tennessee found similar results with gelcaps compared to tablets - 18 out of 20 patients said gelcaps were easier to swallow tablets.

These differences should not be downplayed, concluded these researchers. "When taking into account the number of concomitant medications being given for other conditions associated with this population, any improvements that can be made for these patients should be viewed as positive," they said in the study.

IMPROVED PRODUCT INTEGRITY

Once the supplement gets down the gullet, consumers can also suffer from issues with digestion and absorption of the nutrients. Tablets in particular, because of the way they are manufactured - with so much compression and heat, and binders to



hold it all together - can suffer from nutrient degradation as well as either breaking apart inside the pill bottle or, alternately, not breaking apart once in the body.

"Every once in a while you come across certain tablets that people don't absorb and the tablets might end up in stools," observed Raji Labs' Vallabhaneni. With capsules, the breakdown starts within 8 minutes, so you get a higher absorption rate of the nutrients, and that's something that makes a lot of sense but not a lot of people appreciate."

Other limitations become apparent with certain ingredients. Probiotics, for example, are among the largest, fastest-growing healthy ingredient class. But the heat processing of coated tablets - about 45C for between 45 and 60 minutes, according to Pedersen - would physically kill the beneficial bacteria that are probiotics. And that's why probiotics are always found in capsule form when they come as pills. (Probiotics, of course, are in a wide swath of food and beverage products from yogurt to chocolate and teas.)

Beta-carotene is another. Most beta-carotene comes in beadlets, explained Pedersen, and because of the processing conditions inherent in tablets, the beadlets get crushed. In response, manufacturers put in as much as 200 percent of the actual amount with overage, "and then you hope it doesn't oxidize because the beadlet is

compromised," he said. "You don't have to worry about that in capsules."

Calcium is another challenging nutrient to work with. That's because with all the inactives used to hold the mineral together, and the inherent humidity, tablets are often bound together so well that there become problems with disintegration, "the problem with tablets is it won't break apart and dissolve," said Pedersen,

Another aspect of ingredient integrity is appearances. That is, clear capsules offer consumers the ultimate in transparency – nutrients that can be as close to the natural, unprocessed material as can be. Whether it's flecks of various green botanicals or a uniform brown powder, shoppers can see what they're about to swallow. That, and the simple visual confidence that nothing unnecessary has been added to the capsule

ENHANCED PRODUCT INNOVATIONS

Capsules have been around as long ago as the ancient Egyptians. Today, capsules offer dosage form innovations that allow greater opportunities for manufacturers.

For one, capsules offer **superior protection against ingredient oxidation**. They protect nutrients to a greater degree compared to nutrients compressed in tablets. In fact, the heat that occurs upon tablet compression is the reason probiotic bacteria are housed in capsules and not tablets.

In the case of Capsugel, its Plantcaps offer **the best oxygen barrier** of all plant-based products, masking pungent odors and protecting sensitive ingredients. Organic supplement manufacturers in the United States using Plantcaps benefit from "Made with Organic Ingredients" labeling when delivering organic ingredients.

The low-moisture Vcaps® Plus is a HPMC capsule that is a **leading vegetarian offer** in Health and Nutrition and is ideal for moisture-sensitive ingredients and dry herbal products. It is made from only HPMC and water with no additional additives or gelling systems and offers a high-gloss appearance, color choices, and quick dissolution – 100 percent in 30 minutes or less.

Capsugel's DRcaps line are **well-suited for pro-**

biotics because the capsules have a low moisture level of 4-6 percent in 50 percent relative humidity compared to gelatin at 12-14 percent. This helps keep the probiotics stable in the package before ingestion. But humidity is only one concern. The other is pH conditions throughout the gastrointestinal tract that can affect probiotic survivability.

"Customers told us they needed capsules with not only lower moisture, but one that provided a better way to protect probiotics so they would be released in the intestinal tract rather than the stomach," said Mark Vieceli, director of sales, marketing and business development at Capsugel.

In the case of Capsugel, its Licaps® liquid capsules enable nutrients to be **absorbed directly by the body** without having to go through the breakdown stages that include tablet disintegration into granules or aggregates, deaggregation into fine particles, and dissolution of the active ingredient in a solution.

Licaps® offer other benefits. After the capsule is filled with the liquid, it is flushed with nitrogen to eliminate oxygen from the final sealed product, evidenced by a nitrogen bubble visible through the transparent capsule. Because the capsule has no plasticizers, it provides an effective barrier to oxygen transmission. The robust seal further enhances the barrier to oxygen. This is particularly important for nutrients with short half-lives, such as the red wine molecule, resveratrol.

Market surveys conducted by Capsugel show consumers prefer Licaps® because the liquid inside the capsule gives the impression the nutrients are already dissolved for better performance.*

FORM SALES % GROWTH

Specialty Gourmet Channel

year over year 2013-2014

Gummy	+ 25.6%
Vegetable Capsule	+ 21.2%
Powder	+ 11.6%
Capsule	+ 1.0%
Chewable Tablet	+ .5%
Lozenge	- .2%
Liquid	- 1.2%
Caplet	- 1.6%
Tablet	- 3.2%
Softgel	- 3.8%

*<http://www.naturalproductsinsider.com/articles/2001/05/capsugel-launches-licaps-system.aspx>

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PRICE VS. VALUES

For marketers or brand managers of supplement lines, capsules offer an element of time-efficiency that can make or break a fledgling brand. "We really recommend for those wanting to get to market quickly to start with capsules and move to tablets as you move to larger markets," counseled Cornerstone's Pedersen, who said he gives potential clients prices for both capsules and tablets. "There's a break point. If you're going to make 50,000 bottles per quarter, that's the break point. At some point tablets become cheaper than capsules. But with capsules you don't have to conduct stability testing or disintegration testing because it won't fall apart. So I can get you to market more quickly. You'll lose three months in the market in tablets so capsules will get you three more months of profits."

From the perspective of today's new supplement consumers, price points come at a price and per-

sonal values trump all. So what price can you put on a supplement bottle that's been verified by the Non-GMO Project? What price on a transparent encapsulated supplement? What price on a vegan or vegetarian supplement? Do clean labels matter? Look at, for example, gluten-free products, which command a price premium of some 55 percent over glutinous foods, and organic foods that can be twice the price of conventional.

New trends are being set across market sectors, driven by the younger, values-based shoppers. And that's why vegetarian, non-GMO encapsulated supplements are not just a quick-hit fad in the supplements aisle - these products are, instead, a harbinger of a cultural shift across all industries and market segments.

For these new consumers, there is a value to be put on values. As long as they can perceive a benefit that resonates with their ineffable sense of worth, the price is well worth the value.

Natural supplement shoppers prefer capsules over all other dosage forms. **WANT TO KNOW WHY?**

Capsule use is on a dramatic rise, and it's being led by the vegetarian option. Today's natural shopper selects vegan and vegetarian capsules as an extension of their personal values. Let us count the Top 10 reasons:

- ① **PURE AND SIMPLE.** Capsules offer whole foods delivered simply, without additives.
- ② **PROTECTION AGAINST DAMAGE.** No degradation of nutrients as can happen with compression and heat of tablet manufacturing.
- ③ **GMO-FREE.** Increasingly important, not only to the natural shopper, but to general consumers too.
- ④ **VEGETARIAN OR VEGAN.** Four out of ten supplement users expect it and are willing to pay more for it.
- ⑤ **CLEAN-LABEL PROMISE.** No pollutants like excipient binders, fillers or disintegrants found in tablets.
- ⑥ **SOURCE IS CLEAR.** The need for transparency on the label is on the rise.
- ⑦ **CERTIFIED TRUSTWORTHY.** Capsugel Vcaps® and Plantcaps™ are Non-GMO Project Verified, have GRAS status, Kosher and Halal certifications and are approved by the Vegetarian Society.
- ⑧ **INTEGRITY.** That's because nutrients remain closer to their whole selves inside capsules.
- ⑨ **FLAVOR SEALER.** Capsules seal in potential flavor off-notes that come along with some nutrients.
- ⑩ **SWALLOWABILITY.** Capsules are easy to swallow and don't get caught in the throat like some tablets.

Source: NMI 2013 survey of 2,000 DS shoppers

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Lonza Inc. – Capsugel

Following the closing of the Capsugel acquisition, Lonza further strengthened its position as one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. Lonza harnesses science and technology to create products that support safer and healthier living and that enhance the overall quality of life.

Lonza Consumer Health & Nutrition combines expertise in high-quality, science-backed ingredients with formulation know-how and industry-leading capsule and encapsulation technologies to create innovative solutions for consumer health and nutrition companies. Our deep clinical knowledge supports specialty ingredients with proven performance, enabling customers to address consumer health concerns via new, differentiated health products.

We apply consumer market insights and our extensive experience in pharmaceutical delivery science to help our customers improve bioavailability, targeted delivery, swallowability, taste and odor masking of their nutritionals. Our technology enables unique combination products and provides visually appealing dosage forms that meet the expectations of today's health-conscious consumers.

We also bring exceptional service capabilities, global regulatory expertise, and expert technical service to support our customers in quickly delivering differentiated nutritional products to market.

For additional information please visit solutions@lonza.com

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