

# Example Stage Gate

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Stage Gate Analysis  
Stage Gate Project Evaluation  
*FIBits*  
(Soy)

*Product / Project Description:*

FIBits provide a unique mechanism to deliver fiber and protein to children, while enhancing the flavor of what it is added to. Our product is a fiber and protein supplement which comes in four different flavors to pair with the consumer's favorite breakfast foods; mixed berry, blueberry, lemon, and maple.

The tiny spheres are great for adding extra flavor or enhancing a food item such as yogurt, oatmeal, muffins, or pancakes. They are colorful, unique, fun, and have an amusing texture which works well in a myriad of different applications. They can be added to liquids such as milk in your morning cereal, and are also heat stable and bake well into muffins, breaks, and pancakes.

The application for our product within a child's diet provides infinite possibilities to increase the amount of fiber and protein consumed. FIBits can be added to baked goods such as muffins, pancakes, or cupcakes, as well as dry foods such as cereal and oatmeal, and desserts such as cheesecake or ice-cream.

*Bench / Lab Production:*

A 50-50 fiber-protein blend is stirred into boiling water. Once a solution is formed, additional ingredients are added to provide texture, gelation, flavor and color. The viscous mixture is dropped through chilled oil to cool and establish structure. The formed product is extracted, rinsed, and chilled. The spheres are then placed in a -20°F freezer overnight, and then freeze dried.

*Product Functionality and Properties:*

FIBits have a fun shape and color coupled with a unique texture which appeals to our target market. The fiber utilized comes from the soy cotyledon and possesses benefits of both soluble and insoluble fibers, unlike other soy fiber on the market made from soy hulls. The soy protein used is an isolate which is essentially carbohydrate, cholesterol, lactose, and fat-free, making a great alternative to meat and dairy-based protein isolates while being economical.

The goal of our product is to provide an extra boost of fiber and protein in a child's diet in order to help reach the recommended daily value intake of approximately 24 g for children 3-12 years of age. Most children get 14g or less of fiber per day. The final goal of our product would be to incorporate at least 25% of the fiber not obtained by the average American child, or 2.5 g of fiber per serving. Using the 50-50 fiber-protein blend, we would also like to incorporate 2.5 g protein per serving as well.

Our finalized product will have a very stable shelf-life. The water activity, because freeze dried, will be low enough to not support the growth of bacteria, microbes, or mold.

*Freedom to Operate:*

Conclusions to a conducted patent search indicate that our product idea is novel to an existing market.

*Intellectual Property:*

Conclusions to a conducted patent search indicate that our product idea does not infringe upon any existing intellectual property rights of patent holders or applicants.

*FIBits*  
Preliminary Business Assessment

**The Market:**

Our target consumer is mothers of children age 3 to 12. These mothers will buy a product which both appeals to their children, and is beneficial for them. The current problem with a child's diet is that it lacks a sufficient amount of fiber and protein. Currently, there are products on the market that provide fiber or protein, but none offer both benefits targeted towards children. The interesting shape of our product will add visual appeal as well causing children to choose our product over competitors. Children's food is high in sugar to appeal to their tastes; therefore, children will add sugar to "healthy" food options in order to make it more appealing although the sugar does not provide any nutritional benefits. Additionally, the option of adding fruit, while nutritionally beneficial, is not appealing to our target market. Our product allows the consumer to continue with their routine diet while adding the benefit of fiber and protein as well as enhancing the flavor of their food. Mothers are the intended purchase target for this product; therefore, the product will appeal to the mothers' desires to provide nutrition along with appealing to their children.

**Market Size and Growth:**

The main target audience is mothers of children from ages 3 to 12. Children ages 3 to 12 encompasses approximately 20.2% of the US' total population. These mothers want to provide their families more fiber. Our product will appeal because it is versatile and has many applications. Once the product has established credibility, additional target consumers and markets may arise. The product could then be targeted to consumers such as geriatric patients, vegetarians, and the health-conscious young adult. For example, if the young adult population is attracted, this would increase our target audience by 21.1%. Because FIBits is not an expensive product, it can appeal to a wide range of consumers with varying economic statuses.

**Competition:**

The competitors are industries that make health benefit products, particularly products which provide fibers and proteins. The following products are potential competitors of FIBits: Metamucil fiber capsule, Vitafusion fiber gummy, Rainbow Light, Fiber Garden Gummies, GNC wellbeing be-BUFF protein and fiber complex mix, and Whey Weight control protein. Another competitor would be products that are food additives which also have health benefits, such as Splenda with added fiber. These products do not directly compete because they are not independent use items and are not added to different food items already in the consumer's diet, especially children. Therefore, the most likely competitor would be dried fruits and vegetables for similar use in breakfast foods. However, these do not appeal to children and also do not provide the added protein benefit.

## Strengths:

Novelty contributes a great strength to FIBits. It is an inexpensive breakthrough mechanism to provide fiber and protein to children while enhancing the flavor of what it is added to.

The aesthetics of our product have a greater appeal to our target market, children ages 3-12, more than other fiber and protein sources. FIBits have a fun shape and color coupled with a unique texture.

The versatility of application for our product within a child's diet provides infinite possibilities to increase the amount of fiber and protein consumed. FIBits can be added to baked goods such as muffins, pancakes, or cupcakes, as well as dry foods such as cereal and oatmeal, and desserts such as cheesecake or ice-cream.

There are many opportunities for expansion of the FIBits brand including flavors, colors, and applications.

## Threats:

Competitive fiber and protein supplements such as gummy vitamins and other nutritionally fortified final products may pose a threat.

FDA approval could potentially pose a problem. Microbial threats may exist in the final product. However, with the final product being freeze-dried, the water activity is so low that it cannot sustain microbial or bacterial growth. All other ingredients are food grade, and FDA approval should not be a huge concern.

## Weaknesses:

Formulation, in order to provide an appropriate balance between an appealing texture and a significant amount of fiber and protein, may be difficult.

Another weakness is the unfamiliarity of the product to parents. Parents will be the ones purchasing the product for their children and may initially be hesitant to choose FIBits over a familiar item such as freeze-dried fruits.

The price of freeze-drying is rather high, and will drive the price of our final product up.

Even though we have many different tastes for our products, there could be an off taste to some consumers.

It is difficult to obtain uniform shapes for our products because of the production method we chose to use. It depends on the temperature and viscosity of the paste and the size of the opening of the dropper.

## Opportunities:

Childhood obesity is becoming more prevalent in the media as consumers become more aware of the detrimental effects of a diet high in fat and low in fiber and protein. Studies and research focusing on the benefits of adequate amounts of fiber and protein in one's diet has increased. This could lead to a growing consumer base.

Once the product has established credibility, additional target consumers and markets may arise. The product could then be targeted to consumers such as geriatric patients, the health-conscious young adult, and vegetarians. Additionally, established industries could use FIBits within their final products to increase the nutritional benefits such as cereals, oatmeals, etc.

*FIBits*  
Preliminary Development Plan

**Key Research Questions:**

For sensory analysis, see "FIBits Questionnaire" attached.

Other important questions:

- Can we get 25% daily value fiber in one serving? 25% daily value protein?
- Can we improve the taste?
- What other flavors are desirable?
- Can we improve the texture?
- Can we increase shelf-life?
- Does amount of fiber increase or decrease appeal?
- Does amount of protein increase or decrease appeal?

**Milestones:**

- Formulating our product
- Working in significant amounts of fiber and protein into our product
- Perfecting flavor/color/shape
- Preservation and texture through drying
- Sensory analysis

**Product Specifications:**

Specification checklist for Fibitz:

- Have the raw ingredients arrived with a certificate of analysis?
- Does the foreign object detection and work and have been used?
- Are the ingredients well packaged when it is delivered?
- Are the ingredients stored in a cold temperature room (prevent damaged by the humidity)?
- Is the water heated to boiling point during production?
- Has the mixture of the ingredients and the water reached 80-95 degrees Celsius?
- Is the viscosity of the mixture paste acceptable?
- Is the color of the products within specification?
- Has the mixture cooled down to 30-40 degrees Celsius?
- Is the oil at -5 to 6 degrees Celsius?
- Is the oil constantly being filtered?
- Is the cold water bath 15-20 degrees Celsius?
- Is the size of the products within specifications?
- Is the temperature of the freeze dryer running in the given cycle?
- Is the moisture content of the FIBits acceptable?
- Does the product pass the sensory test and microbial testing?

According to section 201 (ff) of the Federal Food, Drug and Cosmetic Act, “a product (other than tobacco), intended to supplement the diet, that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any ingredient described above. A dietary supplement is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such a form, is not represented for use as a conventional food or as a sole item of a meal or the diet and is labeled as a dietary supplement. A dietary supplement also may not contain an article that is an approved drug or that is authorized for investigation as a new drug, and for which substantial clinical investigations have been initiated and have been made public, unless that article was marketed as a food or a dietary supplement prior to its approval as a new drug or authorization as an investigational new drug.”

The FDA also specifies that “a comparability protocol is a comprehensive plan that describes the specific tests and validation studies and acceptable limits to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality, purity, or potency of the product, as they may relate to the safety or effectiveness of the product.”

It is important that our analysis test qualifies to make the health claim or nutrient content claim contained on the product label (Area of Emphasis No. 4).

Specific tests that need to be performed:

According to the FDA, “for the comparability protocol we need to include a plan for the stability studies that will be performed to demonstrate the comparability of the pre- and postchange product. The comparability protocol should provide: (1) information that is typically provided in a stability protocol, such as the number and type of batches that will be studied, test conditions, and test time points, or (2) a reference to the currently approved stability protocol. You should specify the amount of stability data that will be collected before the product made with the change is distributed. The plan for evaluating stability could vary depending on the extent of the proposed change, type of product, and available manufacturing information. In some cases, no stability studies may be warranted or a commitment to report results, when available (e.g., annual report), from stability studies postapproval can be sufficient. If you don’t plan to conduct stability studies, we recommend that you state this clearly and provide justification for not doing so.”

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm071547.htm>

[www.fda.gov/downloads/Drugs/.../Guidances/ucm070262.pdf](http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070262.pdf)

*FIBits*  
Economic Assessment

<b>Economic Calculations</b>				
<b>Raw Ingredients</b>		<b>Vendor/ Source</b>	<b>Kg/ Year</b>	<b>\$ / Per Year</b>
Fiber	2.15 /kg	Solae	112100	\$ 241,015.00
Protein	5.2 /kg	Solae	112100	\$ 582,920.00
Water	0.000396 /kg	www.fcwa.org/story_of_water/html/costs.htm	23150	\$ 9.17
Sucralose	90 /kg	Beijing Hezhong-Huimei International Trading Co., Ltd.	44012	\$3,961,080.00
Flavor	35.59 /kg	Firmenich	124450	\$4,429,175.50
Citric Acid	0.8 /kg	Dalian Chem Imp. & Exp. Group Co., Ltd.	42050	\$ 33,640.00
Agar - Agar	47.69 /kg	www.BulkFoods.com	42050	\$2,005,364.50
Coloring	2.612946 /kg	Webstaurant Store	88.00	\$ 229.94
<b>Operating Costs</b>			<b>H2O / Year</b>	
Refrigeration	0.65 kW/kg H2O	Handbook of Industrial Drying (Mujumdar, 2007)	421000	\$ 19,155.50
Vacuum Pump	0.36 kW/kg H2O	Handbook of Industrial Drying (Mujumdar, 2007)	421000	\$ 10,609.20
Freeze Drying	15 /kg			\$1,185,000.00
				Total for 12 oz.
				\$ 8.84
				Selling price:
				\$ 11.50
<b>Assumptions:</b>	1. Annual Production is 500 Metric Tons (500,000 Kgs) of "Wet Product" ≈ 79,000 Kgs of Final Product			
	2. Values based on current market price and will not change extremely during calendar year			
	3. Plant operates 350 days/ year			
	500,000			
	4. Assumed Energy Cost of \$0.07 / kWh for Indiana			
	5. Selling price was calculated assuming 25% mark-up			