



final report

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PROOF OF CONCEPT DEVELOPMENT-BEEF THYROID CAPSULES

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Executive summary

Hashimoto's Disease is a form of hypothyroidism (Bernet 2018) and is diagnosed by an elevation of serum TSH (Thyroid Stimulating Hormone) caused by the pituitary gland over producing TSH (McAninch et al 2019). Hypothyroidism occurs in 8% of the population and often goes undiagnosed, is more common in women than men (Fatourechi 2009), especially those over 50 are more prevalent (Dr Victor Bernet Mayo Clinic Jacksonville). Symptoms include fatigue, weight gain, digestion, dry skin, low body temperature and mood swings.

A normal human thyroid gland produces thyroid hormones T4 (Thyroxine) and T3 (Tri-iodothyronine), the majority of T3 hormone comes from conversion of T4 to T3 in the liver and not a secretion of T3 from the thyroid. A T4:T3 ratio of 14:1 seems average for humans (Dayan & Panicker, 2018). Vitamin B12 deficiency (Benvenga et al 2019) and selenium deficiency are also thought to contribute to thyroid dysfunction (Sworczak et al 2011).

Hypothyroidism results when the thyroid gland fails to produce thyroid hormones T4 & T3 to regulate metabolism of carbohydrates, lipids and proteins, influencing every organ system and energy levels (Westminster Pharmaceutical LLC). Synthetic forms of LT4 only (levothyroxine) are available and recommended by most medical practitioners.

Natural Desiccated Thyroid (NDT's) are recommended by some Medical Practitioners along with Naturopaths and Complementary Medicine Practitioners and is popular with consumers turning to natural medicines (Harrah). NDT from animals has been used for centuries to support underactive thyroid. The majority of NDT has been sourced from pork thyroids (Harrah), however this is out of favour due to risk of African Swine Fever.

The global thyroid treatment market was valued at USD 1.97 Billion in 2016 with CAGR of 3.2% due to rising hypothyroidism awareness and diagnosis (source: www.grandviewresearch.com). Thyroid glandular supplements predominantly use New Zealand and Argentina beef products and are sold on line in Australia under various brands (Appendix C). NXGEN Wholefoods will be the first Australian made beef thyroid glandular supplement if commercialisation is achieved.

More than 60% of natural health products, including dietary supplements and complimentary medicines are sold as therapeutic goods by pharmacy's throughout Australia (Roy Morgan 2019). NDT's and their benefits are unknown by many Pharmacists and consumers. When competing in the market for Thyroid Supplements, containing natural Selenium, B Vitamins, Vitamin A, Pharmacists largely favour the bigger therapeutic brands.

Glandular supplements will become more popular once consumers and Pharmacists learn more about the benefits. Once sales meet \$200,000 a year for an SKU a large pharmacy chain is likely to want to stock the product. Until such a point though glandulars will mostly be sold online through specialty health stores and ecommerce platforms like eBay and Amazon.

Naturopaths, functional medicine, integrative and holistic health practitioners are aware of the benefits of glandular supplements and their vitamins, minerals, enzymes, cofactors, peptides and proteins provided by Beef Thyroid with Beef Liver.

Manufacturing desiccated Beef Thyroid is carried out by freeze drying and milling into a powder. Freeze drying results in yields of 25%. To dry 100kg of raw beef thyroid produces 25Kg. Each capsule of grass fed beef thyroid has 30mg of thyroid powder and 470mg beef liver powder. The cost to manufacture 1000 jars of beef thyroid capsules is \$18 per jar. The Wholesale Price is \$29.95. RRP is \$54.95.

Each head of cattle produces an average of 100 grams of beef thyroid tissue. It takes 1000 head of cattle to produce 100kg of desiccated raw material. The price of thyroid tissue is \$7/kg from the abattoir and a jar of grass fed bovine thyroid sells online for approximately \$54.95 (160 x 500mg capsules), resulting in a value multiplier of more than 8x the raw material price.

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1 Background

For more than 4000 years traditional cultures used the organs of healthy animals with the hope they would help support and treat the corresponding diseased organ in their body. The practice was so common traditional Chinese doctors would include it in their herbal medicine formulas (Mark Stengler, 2001). The theory behind Glandular Therapy is raw glandulars have nutritional benefits that support 'like for like' systems.

This project is aimed at making freeze dried beef thyroid with liver, available in an easy to take capsule, without any offensive after taste, that returns consumers to ancestral supplements. Supporting nose to tail eating, beef glandulars provide proteins, enzymes, cofactors, peptides and nutrients that nourish what the modern world has left out of most daily diets.

The over the counter (OTC) thyroid supplements market in Australia is estimated to be worth more than AUD120 million, with brands like ThyroPlex by Bioceuticals, Thyroid Manager by Caruso Natural Health, Thyroid Health by Cabot Health, being sold in pharmacy's and health stores. None of these products use Beef Glandulars.

A niche segment of this market is Glandular Supplements, a market segment where large brands can't compete due to the difficulty obtaining the raw material. Grass fed beef thyroids aren't a common purchase item at local butcher shops and many meat processors don't see any value in collecting them, preferring to discard the material to the rendering plant for use as meat meal or animal stock feeds.

With Australia providing the cleanest and healthiest beef in the world NXGEN Wholefoods seeks to find innovative meat processors to supply and collect beef thyroid, to provide health products for the nutraceutical market locally and internationally.

A healthy thyroid gland is important for health and wellbeing as it produces storage hormone thyroxine (T4). T4 is converted to active hormone T3 triiodothyronine. Active T3 is released into the blood stream and plays an important role in the regulation of metabolism, growth and development, intelligence fertility, kidney functions and cardiac functions.

According to the international thyroid society almost 20 million Americans suffer from some form of thyroid disease and more than 12 percent of the U.S. population will develop a thyroid condition during their lifetime. As such the benefits of maintaining a healthy thyroid is critical for healthy metabolic processes.

FEATURES OF AUSTRALIAN GRASS FED & FINISHED BEEF THYROID CAPSULES

Beef Thyroid from Grass Fed Pasture Raised Australian Beef with Liver is considered by Glandular Therapists, Naturopaths, Integrative and Holistic health Practitioners to be beneficial and help regulate production of thyroid hormones.

Direct market consumer feedback with practitioners revealed they would buy Natural Desiccated Thyroid (NDT) made from Australian ingredients and recommend these for their clients as opposed to using imported brands.

All NDT's are currently imported into Australia and purchased on line for between \$0.25 and \$0.36 per capsule. There is strong interest in Australian NDT because Australia is a trusted source of grass fed beef, BSE Free, raised without antibiotics and hormones, without use of herbicides & pesticides (free of Glyphosate) and are GMO free.

While many consumers and practitioners are loyal to a brand all the current products are generally being supplied beef thyroid powder from New Zealand. Australia offers a better value proposition since grass fed cattle are more widely available and a more competitive price can be offered since product is grown and made in Australia.



2 Project objectives

The objective of this project is to develop proof of concept minimum viable product for an Australian made over the counter beef NDT using lyophilised beef thyroid powder in capsule form, combined with liver. The project includes development of product costings, lab assays, specifications, label listing, nutritive values and provides market feedback from stakeholders on the concept and value propositions and involves a review of competitor analysis.

3 Methodology

Grass Fed Beef Thyroid was purchased from Greenham Pty Ltd, minced and freeze dried then milled into a powder. Beef Thyroid powder was then blended with Freeze Dried Organic Beef Liver Powder and encapsulated with 30mg NDT per capsule. No fillers, additives or binders were used. Samples of the beef thyroid powder was sent to a number of US companies to evaluate prior to encapsulating.

The process flow to make Beef Thyroid Capsules is as follows:

1. Pre mortem vet inspect animals
2. Process and post mortem vet inspection dressed carcass and offal
3. Collect human grade grass fed beef thyroids
4. Fast freeze in blast freezer
5. Transport to Freeze Drying facility
6. Knife trim any excess loose fat from product
7. Dice or mince product, pass through 'kill step' and load trays
8. Freeze dry to set temperature for holding period
9. Mill into powder
10. Sieve through 1000 micron vibratory screen
11. Pack freeze dried meat powder into 5 kg Mylar Bags
12. Pack bags into cardboard bulk bin and stretch wrap top of lid
13. Carry out QA microbial testing
14. Microbial results meet specification – release product
15. Transport to pharmaceutical company
16. Blend beef liver powder and thyroid powder
17. Encapsulate product and pack into jars



○ SOURCE OF T4, T3, T2, T1
 ○ SOURCE OF VITAMIN A (RETINOL), B12, AND IRON
 ○ HORMONE, PESTICIDE AND GMO FREE
 ○ NO FILLERS


Ingredients: Freeze Dried, 100% Australian Organic Grass-Fed & Finished Beef Liver & Beef Thyroid, Gelatin Capsule


Directions For Use: Adults: 1 capsule per day. Always consult your Health Practitioner prior to use.

Store in a cool dry place with lid properly sealed.

*These statements have not been evaluated by the TGA or Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Made & Distributed in Australia by
 NXGEN Wholefoods
 150 Hatfield Avenue
 Robin Hill NSW AUS 2786
www.nxgenwholefoods.com.au





Organic Beef Thyroid

**100% AUSTRALIAN
GRASS FED & FINISHED**

THYROID 130MG WITH LIVER STEMS

**180
CAPSULES
(500mg)**

EASY TO SWALLOW

FREEZE DRIED · WHOLEFOOD SUPPLEMENT

Supplement Facts

Serving Size	1 Capsule
Serving Per Container	180
Amount per Serving: % DV	
Bovine Thyroid Powder	130mg*
Bovine Liver Powder	370mg*
<small>*Daily Value Not Established</small>	
<small>100% additive-free. No stearates, lubricants, binders, fillers or flow agents.</small>	

4 Results

TRIAL #1

Beef Thyroid powder did not conform to the specification. The first trial met with three issues, high fat content, 60% instead instead of not more than 50%. The milling equipment was not suitable. Product was only able to be milled through a 5mm screen and friction from milling caused fat to melt and block the screen, resulting in cohesive and oily particles and preventing loose free flowing powder. Microbial results were also unacceptable for E.Coli and Total Plate Count caused by processing issues.

TRIAL #2

The specification was able to be achieved by making several changes to the manufacturing equipment and process. Fat content was reduced by trimming and removing fat. Product was minced then underwent a pathogen "kill step" prior to being placed onto freeze dry trays. Milling was carried out using cryogenic milling equipment. 1000 micron powder was able to be produced without blocking screens.

5 Discussion

There were several pain points associated with the development of the freeze dried grass fed beef thyroid powder manufacturing for encapsulation at a TGA licensed pharmaceutical company. The problems faced led to increased product concept development costs to be able to get to a minimum viable product.

The laboratory assays revealed high microbial results than normal, typical of raw organ meats and required changes to the handling and cold chain management to freeze product quicker. A positive microbial kill step was also implemented to improve quality.

The target fat content for the finished product is 46% and actual results were too high. The original material fat content started at 30%, after freeze drying and removal of 70% water, the fat content rose to 60%. A commercially viable method was found to remove excess fat tissue.

Milling 46% fat material to 1000 micron powder was unable to be carried out with standard milling equipment to make flowable powder fine enough for encapsulation. Suitable cryogenic milling equipment with a vibratory screen was developed to address this issue.

High fat freeze dried meat powders can oxidise and become rancid. A method was implemented to prevent this from happening and to provide a shelf life of 3 years from the manufacturing date.

It was difficult finding a meat processor who was willing to collect and supply beef thyroid product for the project as the collection can be labour intensive and low yield (approx. 100 gram per head).

Demand for Lyophilised Grass Fed Beef Thyroid powder is high amongst international customers, however export documentation has to be provided for exporting to these countries to meet the respective country biosecurity rules.

6 Conclusions/recommendations

It is commercially viable to make Beef Thyroid Powder and Capsules having validated the new product concept and manufacturing process. A minimum viable product is possible but requires support from a beef processor prepared to supply raw material to ensure reliable supply. 10,000 head of cattle will produce 1000Kg of beef thyroid tissue and yield approximately 250Kg of beef thyroid powder valued at more than US200 per Kg. The price for section of trachea with beef thyroid attached is AU\$7/kg. The price for a 90gram jar of Australian Beef Thyroid Capsules is AU\$44.95. Which contains 6% thyroid powder and 94% beef liver powder. NXGEN over the counter NDT's have no more than 30mg of NDT per capsule to maintain safe levels and avoid any higher dosage leading to hyperthyroidism.

7 Key messages

There is high demand for the smaller Grass Fed Beef Glands and Organs globally for use in nutraceuticals, provided beef has been raised free of any pesticides and herbicides. Many consumers want assurance that these smaller beef glands and organs are free of glyphosate chemicals and are GMO free. Consumers have heard of the ill effects glyphosate has on their health (New York Times 2020).

A number of meat processors were contacted to source Beef Thyroid Glands from and many of the Operations Teams unfortunately weren't able to provide material citing the product is not something they are set up to produce within their QA system and this was not something they wanted to produce due to the high labour costs and low yields.

One processor was eventually able to assist, they were able to provide a solution and suggest they can supply the Beef Thyroid Gland in tact and attached to the trachea section for removal at the drying facility.

Product Development staff from large complimentary medicine companies were contacted to see if they were interested in a private label NDT for their own brand but said there was no interest.

Meat Processors should be mindful of the value co products are providing for human health, in particular glands and organs are being produced in the US, Argentina and New Zealand for the global nutraceutical market. Australia meat processors have the potential to engage in new markets and channels similar to these other Countries. Hormone replacement therapy, glandular therapy and natural supplements from beef products are highly sought after.

8 Bibliography

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9 Appendices

APPENDIX A: PRODUCT SPECIFICATION

PRODUCT:	FREEZE DRIED BOVINE THYROID POWDER
PRODUCT CODE:	55433
SOURCE:	Grass Fed Beef
DESCRIPTION:	Edible Brown Freeze Dried Powder
PARTICLE SIZE:	< 1000 micron
BATCH:	20041

Proximate Analysis	Specification	Analysis
Loss on drying (Moisture) %:	NMT 6	2.3
Fat%:	NMT 48	47
Protein %:	NLT 30	34.2
Ash (Residue on Ignition) %:	NMT 8	7.6

Microbiological Analysis

Total Aerobic Count (TAC)		
(cfu per gram @ 35°c for 48 hours):	< 10,000 CFU	2,600
Clostridium perfringens (cfu per g):	< 10	< 10
Staphylococcus aureus (cfu per g):	< 10	< 10
Escherichia coli (mpn per g):	Not Detected	ND
Salmonella (per 25 gram):	Not Detected	ND

Beef thyroid is produced to an edible standard in DPI approved meat processing plants, frozen and packed in plastic packed in cardboard plastic lined meat cartons, then freeze dried, milled and sieved through a 1000 micron vibratory screen into a powder. All product is tested prior to release.

The actual microbial test results were not promising and required a kill step to be introduced to the process. The fat content was too high and required a fat removal step to be introduced.

APPENDIX B: MICROBIAL TEST RESULTS



Certificate of Analysis

NEXGEN WHOLE FOODS
150 HARTWOOD AVE
ROBIN HILL
NSW
, 2795

Attention: Leonard

Overall Description: Freeze Dried Beef Thyroid Powder
Our Ref No: FM2023287 Your Ref:
Project: Report Date: 26 Mar 2020
Samples Received: 20 Mar 2020
Testing Commenced: 24 Mar 2020

This report cannot be reproduced except in full, without written approval from the laboratory.
Samples tested as received into the laboratory.

Sample Details: Test Description	Results	Units	Site
001 Freeze Dried Beef Thyroid Powder			
FC0009.	Total Fat	60.1 g/100 g	VIC
FC0018.	Water Activity	0.31 Aw @ 20oC	VIC
001 Freeze Dried Beef Thyroid Powder			
FC0001.	Moisture	2.3 g/100g	VIC
FC0003.	Ash	7.6 g/100 g	VIC
FC0086	Protein (Dumas)	34.2 g/100g	VIC

Signatories

This document has been electronically signed by the authorized signatories indicated below. Electronic signing has been carried out in compliance with procedures specified in 21 CFR Part 11.

Signatories	Position	Accreditation Category
Karl Kusko	Laboratory Manager	Food Chemistry
Stacey Lim	Laboratory Supervisor - Chemistry	Food Chemistry

General Comments

N/D = Not Detected, < = Less than, > = Greater than, cfu = colony forming unit, MPN = Most Probable Number, PN = Probable Number, Y = Yeast, M = Mould, ~ = Estimate



Certificate of Analysis

NEXGEN WHOLE FOODS
150 HARTWOOD AVE
ROBIN HILL
NSW
, 2795

Attention: Leonard

Overall Description:	Freeze Dried Beef Thyroid Powder	Your Ref:	
Our Ref No:	FS2014625	Report Date:	03 Apr 2020
Project:			
Samples Received:	18 Mar 2020		
Testing Commenced:	18 Mar 2020		

This report cannot be reproduced except in full, without written approval from the laboratory.
Samples tested as received into the laboratory.

Sample Details: Test Description	Results	Units	Site
001 Freeze Dried Beef Thyroid Powder (NATA Accredited)			
FM0003E	Salmonella spp	N/D	in 25g NSW
FM0011	Standard Plate Count	78,000	cfu/g. NSW
FM0013	E.coli	23	MPN/g NSW
FM0023	Coag Positive Staph	<100	cfu/g. NSW
FM0029	Clostridium perfringens	<100	cfu/g. NSW

*NATA accreditation does not cover the performance of this service.
Measurement of Uncertainty values for your compliance are available at <https://www.alsglobal.com/au/services-and-products/food-safety/laboratory-downloads/client-downloads>.

Signatories

This document has been electronically signed by the authorized signatories indicated below. Electronic signing has been carried out in compliance with procedures specified in 21 CFR Part 11.

Signatories	Position	Accreditation Category
Kylie Raven	Microbiologist	Food Microbiology
Kumudini Dissanayake	Microbiologist	Food Microbiology

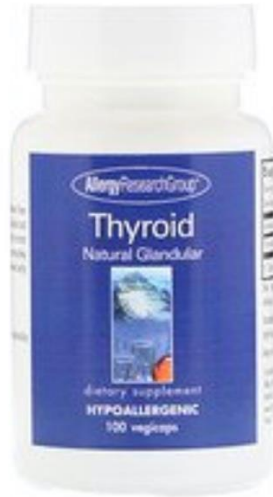


General Comments

N/D = Not Detected, < = Less than, > = Greater than, cfu = colony forming unit, MPN = Most Probable Number, PN = Probable Number, Y = Yeast, M = Mould, ~ = Estimate

Where a result is required to meet compliance limits the associated uncertainty must be considered. Please contact ALS Signatories for details.

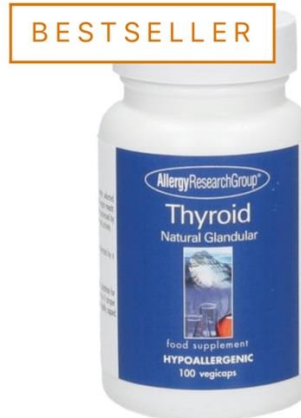
APPENDIX C: IMPORTED NATURAL DESICCATED BEEF THYROID BRANDS



Allergy Research Group
Thyroid, Natural
Glandular, 100

★★★★★ 27

AU\$28.48



**Allergy Research
Group**
Thyroid
100 capsules

€ 23,99

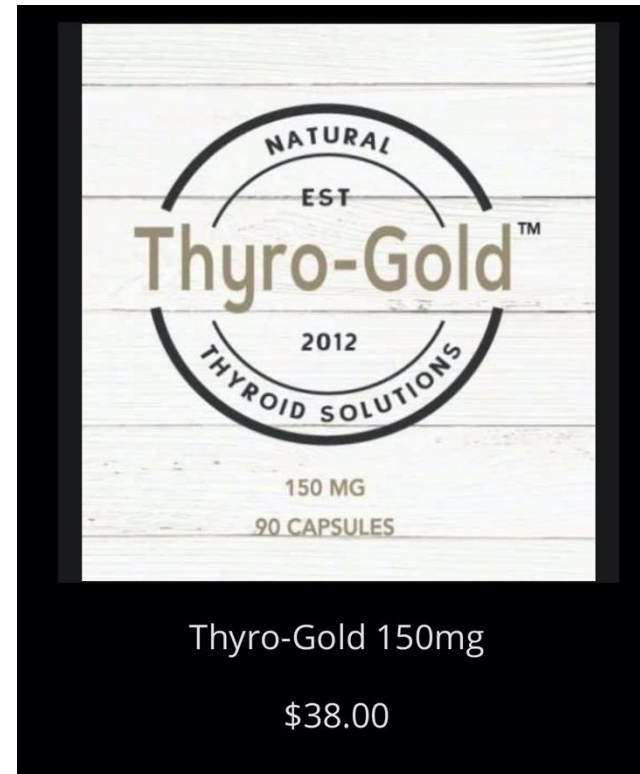
In stock

★★★★★ 4.8 (79)



Thyrovanz (NZ) 25mg

\$23.95



Thyro-Gold 150mg

\$38.00

Nutri-Meds Bovine Thyroid 65 mg

Freeze-dried bovine thyroid tissue

BESTSELLER

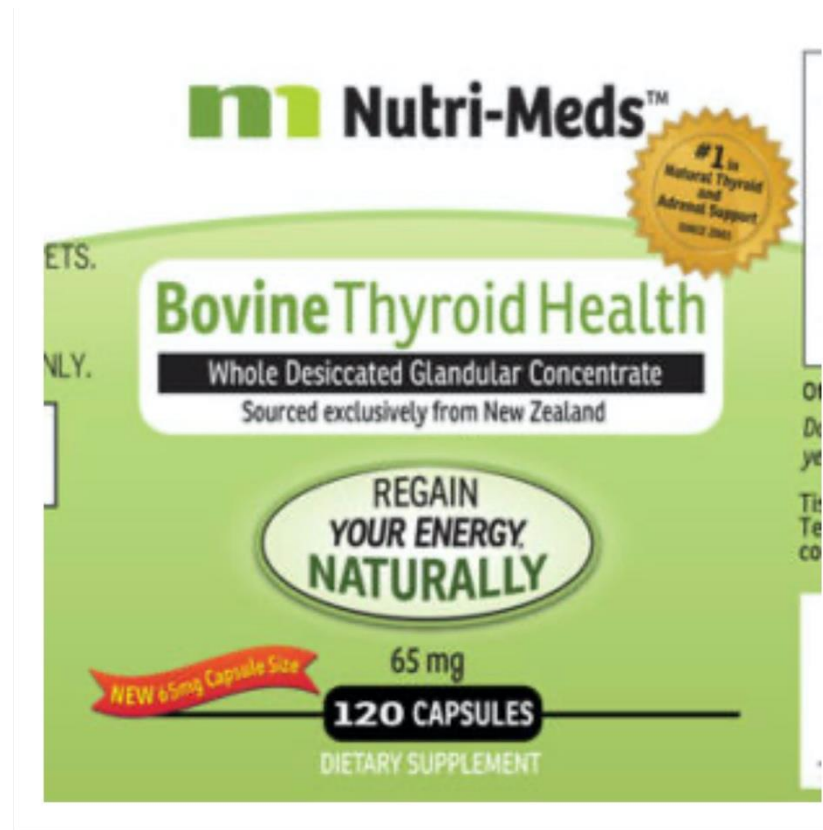


8 Customer Ratings

€ 42,99 (€ 85,98 / 100 g)

from 2 only € 40,99 / piece **-5%**

Price shown includes 10% VAT. Excludes delivery costs

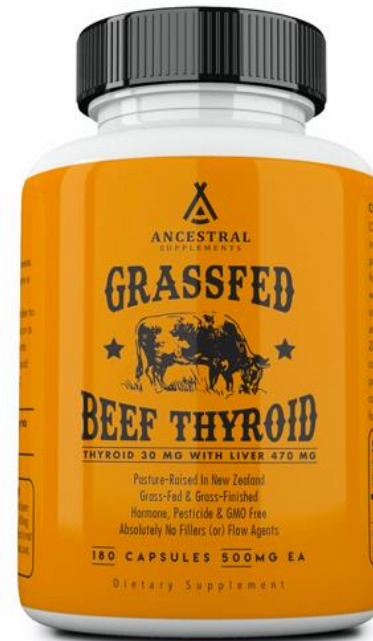
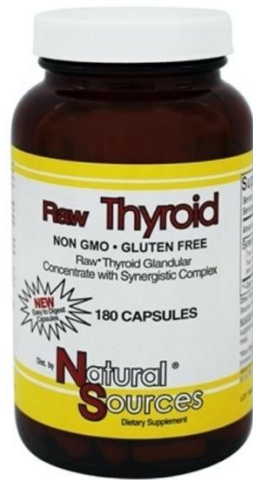


Bovine Thyroid Health Capsules 65mg



\$25.95

[\$56]



Thyroid, 180 capsules
Price: \$59.95

APPENDIX D: BUSINESS MODEL CANVAS

<p>Key Partners</p> <p>1. Meat processors are able to source grass fed cattle 2-3 years old or younger</p> <p>2. Contract Freeze dry company is able to further process frozen offal with high standards of hygiene practices to mince, dry, mill and pack product successfully.</p> <p>4. Contract Pharmaceutical Company is able to encapsulate and pack.</p>	<p>Key Activities</p> <p>Beef thyroid removal is possible from the trachea in the offal room.</p> <p>Freeze drying, milling & encapsulation equipment is needed to be able to mill to 1000 micron powder for encapsulation or tablet.</p> <p>Processes need to meet</p>	<p>Value Proposition</p> <p>Manufacturers of over the counter natural desiccated thyroid is in short supply in EU and US markets. Beef thyroid with liver provides natural vitamins and minerals to support healthy thyroid function.</p> <p>Traditional cultures believe grass fed beef glandulars provide 'like for like' health support. Eating glandular tissue from a healthy animal could help nourish what's missing.</p>	<p>Customer Relationship</p> <p>Customers will be found by online sales, collaborating with naturopaths, functional food experts and integrative medicine practitioners, health food stores and select</p>	<p>Customer Segment</p> <p>The target customer are people of all ages wanting natural vitamins to support thyroid health and function.</p>
<p>Cost Structure for 100Kg (1000) Jars</p> <ul style="list-style-type: none"> > Freeze Dried Grass Fed Beef Thyroid 6Kg \$120/Kg. \$720 > Freeze Dried Beef Liver 94 Kg \$45/Kg. \$4,230 > Pharmaceutical packing \$6,000 (includes labels, testing, packing) > Distribution & Shipping \$2,000 > Administration & invoicing \$1,000 		<p>Revenue</p> <p>> 1000 Jars at a wholesale price of \$29.95</p> <p>TOTAL REVENUE \$29,950</p>		