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## **Focus Report (Deliverable 3)**

**Madagascar Business and Market Expansion Project  
November 2005**

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## **i. Table Of Contents**

<b>Section:</b>	<b>Page:</b>
<b>1.0 Focus Products</b>	<b>4</b>
1.1 Cinnamon ( <i>Cinnamomum verum</i> or <i>C. zeylanicum</i> )	4
1.2 Green Tea (and other bush teas--esp. organic or community produced)	5
1.3 Specialty Essential Oils	5
1.3.1 Katrafay EO ( <i>Cedrelopsis grevei</i> )	6
1.3.2 Ravensara Aromatica EO ( <i>Agathophyllum aromaticum</i> )	6
1.3.3 Niaouli EO ( <i>Melaleuca quinquenervia</i> )	6
1.3.4 Foraha or Tamanu oil ( <i>Calophyllum inophyllum</i> )	6
1.3.5 Ginger EO ( <i>Zingiber officinale</i> )	6
1.4 Cloves ( <i>Syzygium aromaticum</i> or <i>Eugenia caryophyllata</i> ) – Whole Dried Organic	6
1.5 Virgin Coconut Oil ( <i>Cocos nucifera</i> )	7
1.6 Handicrafts (various)	8
<b>2.0 Packaging Recommendations</b>	<b>9</b>
2.1 General Recommendations	9
2.2 Cinnamon ( <i>Cinnamomum verum</i> or <i>C. zeylanicum</i> ) water extract	10
2.3 Green Tea (and other bush teas--esp. organic or community produced)	10
2.4 Specialty Essential Oils	10
2.4.1 Katrafay EO ( <i>Cedrelopsis grevei</i> )	10
2.4.2 Ravensara Aromatica EO ( <i>Agathophyllum aromaticum</i> )	10
2.4.3 Niaouli EO ( <i>Melaleuca quinquenervia</i> )	10
2.4.4 Foraha or Tamanu oil ( <i>Calophyllum inophyllum</i> )	10
2.4.5 Ginger EO ( <i>Zingiber officinale</i> )	10
2.5 Cloves ( <i>Syzygium aromaticum</i> or <i>Eugenia caryophyllata</i> ) – Whole Dried Organic	10
2.6 Coconut Virgin Oil ( <i>Cocos nucifera</i> )	10
2.7 Handicrafts (various)	11
<b>3.0 Pricing Pointers</b>	<b>12</b>
3.1 General Recommendations	12
3.2 Cinnamon ( <i>Cinnamomum verum</i> or <i>C. zeylanicum</i> )	12
3.3 Green Tea (and other bush teas--esp. organic or community produced)	13
3.4 Specialty Essential Oils	13
3.4.1 Katrafay EO ( <i>Cedrelopsis grevei</i> )	13
3.4.2 Ravensara Aromatica EO ( <i>Agathophyllum aromaticum</i> )	13
3.4.3 Niaouli EO ( <i>Melaleuca quinquenervia</i> )	13
3.4.4 Foraha or Tamanu oil ( <i>Calophyllum inophyllum</i> )	13
3.4.5 Ginger EO ( <i>Zingiber officinale</i> )	13
3.5 Cloves ( <i>Syzygium aromaticum</i> or <i>Eugenia caryophyllata</i> ) – Whole Dried Organic	13

3.6 Coconut Virgin Oil ( <i>Cocos nucifera</i> )	13
3.7 Handicrafts (various)	14
<b>4.0 Labeling Primer</b>	<b>15</b>
4.1 Labeling Primer Key	15
4.2 Dietary Supplement Labeling	16
4.2.1 General Dietary Supplement Labeling Guidelines	16
4.2.2 Supplement Facts Box	17
4.2.3 Structure/Function Claims	17
4.3 Functional Food/Food Labeling	18
4.3.1 General Food Labeling Guidelines	18
4.3.2 Nutrition Facts Box	19
4.3.3 Functional Foods	19
4.4 Cosmetics/Personal Care Labeling	19
4.4.1 General Cosmetic Labeling Guidelines	20
4.4.2 General Essential Oil Labeling Guidelines	21
4.5 Handicrafts	22
<b>5.0 Marketing Plan Strategy Revisited</b>	<b>23</b>
<b>6.0 Key Objectives of Investigatory Trip to Madagascar</b>	<b>25</b>
6.1 Visits with Key Producers	25
6.2 Visits to Regions where Products are Produced	25
6.3 Educating Myself on the Selling Points and Story Associated with Products	25
6.4 Visiting with Research Institutions	25

## 1.0 Focus Products

Below is a list of focus products, represented by the most current market assessment from EthnoPharm, and from our understanding of what Madagascar has to offer. One of the major purposes of this investigatory trip to Madagascar is to understand the various products and selling points of these products that might differentiate Malagasy products in the market, and therefore open up more opportunities. I expect there will be several other promising products that will emerge as our understanding of these products evolves, and we are able to communicate this effectively to potential buyers.

### 1.1 Cinnamon (*Cinnamomum verum* or *C. zeylanicum*)

There has been a tremendous amount of interest recently in cinnamon extracts due to recent studies that demonstrate cinnamon has promise as a potential treatment for type II diabetes. Cinnamon may lower blood sugar levels in hyperglycemic patients according to a few recent studies. Many new supplement products now contain cinnamon either as a stand-alone or in combination with other nutrients.

Cinnamon also seems to be enjoying a rediscovery in functional food markets in a wide variety of applications. Tea and coffee consumption is on the rise, and cinnamon is being used as a favorite flavor, spice and functional ingredient in many tea and coffee products. Other beverage applications, nutritional bars, cereals and confectionery products are all now potential functional food delivery systems and cinnamon is becoming more popular as a flavor as well as a potential functional nutrient or nutraceutical. In addition to its potential benefits in lowering blood sugar, flavonoids and essential oils found in cinnamon are considered to have anti-bacterial and preserving qualities, as well as to enhance immune system function.

Essential oil products from cinnamon are being used in perfumery, candle and potpourri applications, in essential oil blends for topical use or in vaporizers. In food, cinnamon is still a commonly used spice. Traditional markets for cinnamon, which include spice, flavor, potpourri, candle and other related industries seem to offer sustained growth opportunity for cinnamon. These markets will not be the direct focus of this report.

The problem with cinnamon is that it suffers from a problem many natural products suffer from; cinnamon is subject to commodity-like pressures where price is the driving force in the marketplace. Cinnamon can be sourced in many places; there are many different species and varieties used as cinnamon and consumers are unlikely going to be able to distinguish the many differences available in the market.

The challenge, and consequently, the opportunity, for Malagasy cinnamon producers is to distinguish themselves by offering a superior quality cinnamon, and/or a sustainable story (like a Fair-trade or community-supporting story). This might be accomplished by understanding then disseminating what species and varieties there are in Madagascar as well as how they differ from other places; the differences in aroma, flavor and chemical

profiles. If there are small independent communities in Madagascar that produce cinnamon, then a community-supporting story and strategy may be created.

Sustainable cultivation and harvesting practices along with organic certification should help further differentiate cinnamon from that produced in other areas. There may be the possibility for growing or harvesting partnerships if we can package a quality and/or varietal difference along with organic, sustainable and fair-traded products. Should Madagascar not have the necessary means to manufacture (hot water extraction, filtration, concentration) and dry (spray, vacuum or belt dry) a cinnamon extract, a manufacturing partnership or supply relationship can be investigated with manufacturers, including ones that have the capacity to produce organically.

### **1.2 Green Tea (and other bush teas--esp. organic or community produced)**

The market for green tea in the U.S. is in some respects mature, but still offers significant growth potential as new applications arise and consumer awareness to the benefits of green tea continue to increase. Most of the green tea consumed in the U.S. comes from China, South East Asia and India. There are many products derived from green tea, but most are presented as either extracts (for supplement and functional food applications) or in beverages, many of which have functional claims.

There may be a niche market to supply green tea (cut and sift) for use in beverage applications (mostly tea products). However, there would have to be a distinguishing quality to green tea, like a unique and desirable flavor or aroma profile or if it is certified organic and produced in a sustainable manner (or socially responsible manner).

There may be further opportunities to develop brewed extracts of green tea in Madagascar, and either ship concentrates (which would require preserving) or soluble dry extracts (which would require drying capabilities). This of course, is contingent on available processing capabilities within country. Again, partnership or supply programs may be considered if there are distinguishing properties (aroma, flavor, organic certification) to the green tea produced in Madagascar.

Green tea is also a commodity, coming from fairly low value producing nations like China, which means that it is even more important to develop and promote the distinguishing qualities and properties of Malagasy green tea.

Another area of opportunity is in other tea products. There may be a market for tea and beverage herbs, other than tea (*Camellia sinensis*), should there be a convincing history of local or traditional use, an interesting flavor and aroma, as well as any distinguishing or health properties. An example of this might be Voafotsy (*Aphloia theaformis*), a tea that has an apparently rich tradition of use in Madagascar. Though little is known in the U.S. about Voafotsy or other types of teas, an educational project might be considered, to tell the story and tradition of other tea consumption in Madagascar. This kind of effort is likely to take some time to develop and may be beyond the scope of the work in this series of reports. However, there are many companies that have expressed interest in such

teas, as they could be one of the first on the market to offer them, and they are suitable for both dietary supplement and functional food industries.

### **1.3 Specialty Essential Oils**

One significant problem with developing business for Malagasy essential oils (EO) is that many EO products from Madagascar lack scalability. This is especially true for some of the endemic species and for less traded products. There are also consumer concerns regarding the quality and sustainability of many essential oil products. More education will be needed to inform the public about the benefits of trade in EO, especially from Madagascar, and that trade in EO actually promotes sustainability and helps community programs. The endemic, or primarily Malagasy essential oils that have the most promise for trade development are:

1.3.1 Katrafay EO (*Cedrelopsis grevei*)

1.3.2 Malagasy Ravintsara EO (*Cinnamomum camphora* or *Ravensara aromatica*)

1.3.3 Niaouli EO (*Melaleuca quinquenervia* or *M. viridifolia*)

1.3.4 Foraha or Tamanu oil (*Calophyllum inophyllum*)

1.3.5 Ginger EO (*Zingiber officinale*)

This is based on conversations with EO companies and traders. All the essential oils listed above have interesting properties. None of the essential oils though, with the possible exception of Ginger EO, are traded in large enough volumes to generate much money.

There is an opportunity for developing niche markets, especially with EO distributors and blenders, cosmetic companies and large retailing outlets (like Whole Foods, Williams Sonoma and so on). This is true if a story can be developed that differentiates EO products from Madagascar as being unique, exclusive, sustainable, organic and with a direct benefit to small and rural producers. A possible scenario would have a couple or a few Malagasy producers and exporters (like Phael Flor and HomeoPharma) link directly with clients in the U.S. and Europe, and have them establish the community programs on behalf of and with their clients.

Price and quality programs will need to be worked on and established. In the case of price, it will be important to demonstrate that prices and wages to small or rural growers, harvesters and producers are fair. At the same time, quality programs will need to be instituted that will offer clients standards of quality in traded products and assist in developing means for differentiating Malagasy EO products from those in other places.

### **1.4 Clove (*Syzygium aromaticum* or *Eugenia caryophyllata*) – Whole Dried Organic**

Cloves have a long and established place in the spice and flavors markets. It has long been used in a variety of different culinary applications, and no one in the U.S. could imagine a Thanksgiving treat of pumpkin pie without its most important spice.

Clove also has many nutritional applications. Clove is used as an anti-bacterial, anti-fungal and anti-vital, as well as to treat worms. However, it is most commonly used externally to treat toothache and mouth and throat inflammation. Similarly to cinnamon, clove may help regulate how the body uses insulin and thus blood sugar balance. It is also thought that clove is an antioxidant. Cloves are also prepared whole, ground, as extracts or tinctures and as an essential oil.

There may be an opportunity to supply whole cloves and clove EO if there is some means of differentiating the clove products through quality, EO quantity or quality, flavor, organic certification or sustainability program. As there is a lack of organic cloves on the market (according to a couple sources), this was assessed as an immediate opportunity. One program might be to develop a Malagasy Spice Rack, that can contain many favorite Malagasy spices, like cinnamon, cloves, basil, pepper, and so on. The spice rack might be packaged for a large-scale retailer and marketed using a story of supporting products, labor and trade for Madagascar. The spice rack idea can even be developed with a similar program for essential oils. Another possible outlet for these kinds of rack products might be a handicraft retailer, since these products can be easily and attractively packaged and are also mostly non-perishable. Yet another thought is to produce sachets and potpourri based on Malagasy spices and EO products and distribute as well through a handicraft or other retail outlet.

### **1.5 Virgin Coconut Oil (*Cocos nucifera*)**

Coconut and palm oils are produced in large-scale all over the world, and would not normally be considered a niche or high-value endeavor. Yet, there is a niche market developing for virgin coconut oil (see below for description of the difference between virgin and other oils). Virgin coconut oil is said to be nutritionally rich (including high content of lauric acid, a component of human mother's milk), and to have a positive effect on the immune system and on supporting energy levels. It is also touted as excellent for cooking and other food use, with an excellent flavor profile. A company based in the Philippines called Tropical Traditions ([www.tropicaltraditions.com](http://www.tropicaltraditions.com)) is selling a certified organic virgin coconut oil and seems to be doing quite well. The demand is growing and sellers command a premium for this product (see Section 3.6 for pricing pointers).

Opportunities may exist to work via culinary academies, specialty retailers (like whole foods) and restaurants to promote such a product. Selling virgin coconut oil also with a functional or dietary supplement application is also possible.

Virgin coconut oil is minimally processed oil from the ground (usually fresh but can be dried under low temperature) and crushed coconut meat. The milk is then separated (decanted) or fermented to separate the oil from water. The ensuing oil is clear and stable. The product is not exposed to high heat, chemical, hydrogenation nor any other harsh processes.

It is possible to develop an extraction program with a fairly small investment in Madagascar, making it a possible candidate for investment and further development. Again, this must be certified organic, sustainable, and/or fair trade based.

### **1.6 Handicrafts**

This group has already begun developing commercial links and opportunities for Malagasy handicraft producers to U.S. based traders. One such organization is World of Good, in California. They are very interested in continuing to develop the relationships with Madagascar. Other possible links may be with companies like Ten Thousand Villages. The response thus far has been very interesting. Companies and organizations seem to be very impressed with the quality of handicraft products from Madagascar, though there is some concern with pricing on certain lines.

There is a need to continue developing these opportunities and an even stronger need to be responsive to client interests, requests and requirements.



## **2.0 Packaging Recommendations**

### **2.1 General Recommendations**

The natural and nutritional products industry in the United States is undergoing a new phase of development and growth. One of the principal movements in the changing natural products industry is a movement toward defining quality in products. This is due to many factors, including commercial, regulatory and business cycle variations. The new laws regarding Bio-Terrorism and state laws like Proposition 65 in California have placed quality and safety issues ahead of most matters in the industry. One of the areas for quality concerns has to do with packaging and labeling. Yet, this is also an opportunity, as compliance with laws and regulations will be rewarded with more business. A cinnamon extract manufacturer recently reported that they lost business to other companies because their cinnamon extract, manufactured in China, had failed Proposition 65 requirements for heavy metals. An opportunity exists if Malagasy producers can demonstrate their products to be clean, safe and handled in appropriate conditions. This section will review some of the more important general, rather than product specific, packaging issues in the market currently.

**Raw Materials Handling** – The manner in which raw materials are handled is of vital importance. This is the first area of product quality, where serious issues like contamination and spoilage can be avoided. Raw materials should be handled, packaged and transported appropriately.

**Manufacturing** – Manufacturers and traders are typically the last to handle and package materials for export. As a result, their attention to packaging is of significant importance.

**Quality Control** – The responsibility for the packaging and quality of a product is usually with the manufacturer and/or a trading company. Defining and determining the quality of products is also important, as the shipper must usually attest to the fitness of the product for shipment.

**Packaging** – Some of the products covered in this report are powders, powdered extracts, or some other solid dosage form. These products are typically packaged in poly bags and placed into either food grade (cardboard) boxes, or fiber drums. The essential oils and liquids are typically packaged in food grade plastic (polyethylene or polypropylene) or glass; though glass is heavier and more fragile for transportation. Meanwhile the virgin coconut oil and bulk oils can be packaged in plastic drums or metal drums with plastic liners. In either case, the quality of packaging also affects short and long-term quality of the product. Due to the potential contamination of wood products, wood products should not be used anymore for shipment into the U.S., unless the wood products have been treated in advance. To read more about the quarantine requirements of wood products, go to: <http://www.aphis.usda.gov/ppq/wpm/import.html>.

Labeling Bulk – All products being imported into the U.S. must be accurately and completely labeled. All ingredients or components of the shipment must be declared and labels must be presented visibly.

Documentation – Export documents need to be compliant with all regulations, and exporters are required to register with and notify agencies like the FDA (Food and Drug Administration) of any shipment coming into the U.S.

Labeling consumer products – All products must conform with nutritional labeling, structure function claims, DSHEA and other regulations. This will be discussed in greater length under section 4.0 Labeling Primer.

**2.2 Cinnamon (*Cinnamomum verum* or *C. zeylanicum*)** – Cinnamon is either shipped as a whole, cut and sift, powdered extract, or essential oil. As a whole, cut and sift or powdered extract, cinnamon is likely best packaged in double, poly bags and inside a food grade box or fiber drum. Cinnamon, whole bark or pieces can also be shipped in sacks or totes, but special attention should be paid to potential contaminants. Cinnamon tincture and essential oil, however, must be shipped in bottles or drums that are protected from heat, moisture and light. Bottles made from polyethylene or polypropylene can be used for essential oils and plastic drums or metal drums with plastic liners can be used for larger scale EOs and Foraha oil. Glass is discouraged from use as it is expensive, heavy, and creates more fragility.

**2.3 Green Tea (and other teas)** – Green tea can be packaged in a manner similar to cinnamon, as its solid dose/serving forms are similar to cinnamon's.

**2.4 Specialty Essential Oils** – The essential oils should be packaged in bottles or drums that are protected from heat, moisture and light. Bottles made from polyethylene or polypropylene can be used for essential oils and plastic drums or metal drums with plastic liners can be used for larger scale EOs and Foraha oil. Glass is discouraged from use as it is expensive and creates more fragility. Focus products that this applies to are the following:

2.4.1 Katrafay EO (*Cedrelopsis grevei*)

2.4.2 Malagasy Ravintsara EO(*Cinnamomum camphora* or *Ravensara aromatica*)

2.4.3 Niaouli EO (*Melaleuca quinquenervia* or *M. viridifolia*)

2.4.4 Foraha or Tamanu oil (*Calophyllum inophyllum*)

3.4.5 Ginger EO (*Zingiber officinale*)

**2.5 Cloves (*Syzygium aromaticum* or *Eugenia caryophyllata*)** – Whole Dried Organic – Cloves can be packaged in a manner similar to cinnamon, as its solid dose forms are similar to cinnamon's.

**2.6 Virgin Coconut Oil (*Cocos nucifera*)** – The coconut virgin oil should be packaged in tins or drums with liners. The tins can be offered in a variety of sizes (1 or 5 gallons for

instance). It is important to protect the coconut oil from exposure to heat, light and moisture.

**2.7 Handicrafts (various)** - There are no major guidelines for packaging handicraft products as they vary so much in types, styles, materials and so on. However, it makes sense to package products in such a way as to protect the products from breakage, contamination or other exposures. Again, please no wooden crates.

### 3.0 Pricing Pointers

#### 3.1 General Recommendations

As the family of natural, health and wellness products continues to develop and grow, there is a movement toward commoditization of products. Products are too easily substituted and buyers shop for products based on price almost exclusively. This is partly due to the difficulty the industry has in establishing proprietary and added value products, as well as accepted standards in the dietary supplement and functional food industries. The major opportunities for differentiation and adding value may come through the development of partnerships, vertical integration, organic and science based products. Further differentiation with clean products that are solvent, residue and heavy metals free will also help sellers distinguish themselves and add value.

Pricing and value work like an inverse pyramid with most of the value captured at the top of the pyramid and little with the producer. One of the aims of projects like these is to reshape the pyramid slightly so that it is not so wide on the top and so narrow on the bottom.

Most of the recommendations for products have to do with increasing value (and consequently, price) through differentiation techniques like improved raw materials, improved handling or processing techniques, organic certification, sustainability, better quality control, pure and clean products and so on.

**3.2 Cinnamon (*Cinnamomum verum* or *C. zeylanicum*)** – The cinnamon extracts used for diabetes products (usually standardized to 8% polyphenols) have an estimated import price into the U.S. of \$25.00 to \$30.00 per kg and a wholesale price of around \$65.00 per kg. Extraction ratios are said to be between 10 and 15:1. The extracts mostly come from China. The retail value of cinnamon extracts is described below:

- New Chapter Cinnamon Force – 60 X 140 mg softgel capsules of a combination *Cinnamomum aromaticum* and *C. verum*. It is a blend of 94 mg water/ethanol extract at 8% polyphenols and 46 mg of supercritical CO2 extract at 35% cinnamaldehyde. Price is \$17.97 per bottle
- Gaia Herbs Liquid Phyto-Caps Cinnamon Bark. 1 bottle of 60 capsules (per 2 capsules: Cinnamon bark, supercritical CO2 extract (*Cinnamomum burmanii*) 50 mg; cinnamon Bark, ETOH Extract (*Cinnamomum burmanii*) 200 mg—standardized to 33.75 mg total cinnamaldehydes and 16mg total phenol). Retail \$ 21.99 1 bottle.
- Gaia Herbs Cinnamon Bark Liquid extract. Same extraction procedures as above with 65% pure grain alcohol USP and spring water; standardized to 7.5 mg total total cinnamaldehydes and 2 mg mg total phenol. Retail \$ 10.99 1 bottle.
- Diabeticine – 60 X 300 mg. Includes, Banaba, Guggle, Bitter Melon, Licorice extract, Cinnamon herb powder, Gymnema sylvestre, Yarrow, Cayenne, Juniper berries, Huckleberry, and Vanadyl sulfate. Price for 1 bottle - \$74.95, 10 bottles - \$374.95

- *Cinnamomum zeylanicum* – 625 mg capsules powdered cinnamon. 30 count - \$6.38, 60 count - \$10.18, 350 count - \$39.32
- Wonder Labs – 350 X 600 mg Cinnamon powder - \$24.95
- Planetary Formulas Cinnamon extract – 120 X 200 mg tablets of *Cinnamomum aromaticum* 10:1 at 8% flavonoids for \$13.50 per bottle
- FutureBiotics Cinnecare – 125 mg of CinnulinPF® (*Cinnamomum aromaticum*) extract 20:1, plus Chromax®, Activin®, Fenugreek, Vanadium and Bioperine (Black Pepper). Price is \$21.25 per bottle
- CinnaBetic II – 60 X 125 mg capsules of *Cinnamomum* extract. Retail price is between \$19.99 to \$24.99 per bottle
- HerbPharm – Cinnamon tincture – *Cinnamomum zeylanicum (verum)* – 1:5 ratio
- Cinnamon Essential Oil - \$2.00 for 1 oz. – Indonesia
- Nature’s Sunshine Cinnamon Leaf EO – 1/6 fl oz (5 ml) - \$7.95

### 3.3 Green Tea (and other bush teas)

Since there is an immediate opportunity for the possible sale of certified organic green tea (cut and sift, for use in tea), we will attempt to determine those values per client negotiation, depending on quality. Green tea pricing is highly variable, and can be anything from wholesale \$ 20-120/k. Green tea that is packaged as individual tea bags is also highly variable, and can range from \$2.49/box of 20 tea bags (retail) to close to \$8/box. Traditional Medicinals offers one of the highest quality lines of tea on the market, and they consistently charge about \$ 5/box of 16 teabags (see samples).

### 3.4 Specialty Essential Oils

Below are some broad retail and wholesale values for the focus product essential oils:

**3.4.1 Katrafay EO (*Cedrelopsis grevei*)** – Retail - \$ 18.00 per oz – Wholesale - \$185.00 per kg

**3.4.2 Malagasy Ravintsara (*Cinnamomum camphora* or *Ravensara aromatica*)** EO – Retail - \$ 8.00 per oz – Wholesale - \$122.00 per kg

**3.4.3 Niaouli EO (*Melaleuca quinquenervia* or *M. viridifolia*)** – Retail - \$ 4.00-12 per oz – Wholesale - \$48.00 per kg; in perfume roller (jojoba oil) application, retail \$11.59 for 5 ml.

**3.4.4 Foraha or Tamanu oil (*Calophyllum inophyllum*)** – Retail - \$ 6.00 per oz – Wholesale - \$85.00 per kg

**3.4.5 Ginger EO (*Zingiber officinale*)** – Retail - \$ 20-35.00 per oz – Wholesale - \$300.00 per kg

### 3.5 Clove (*Syzygium aromaticum* or *Eugenia caryophyllata*) – Whole Dried Organic

There is not much information on the wholesale or retail prices for clove based products.

- Morton & Basset, Whole cloves (not organic, I think) 1.3 oz bottle-\$ 8.79
- Wholesale prices for clove EO are around \$70.00 - \$75.00 per kg.

### **3.6 Virgin Coconut Oil (*Cocos nucifera*)**

There is not much information on the wholesale or retail prices for virgin coconut oil.

- Jungle Products Extra Virgin Organic Coconut Oil 16 OZ -\$ 13.99
- Organic coconut oil unrefined (for medium heat) 14 FL OZ- \$ 6.99
- Organic coconut oil refined (for medium heat) 14 FL OZ- \$4.99
- Tropical Traditions retails a gallon of virgin coconut oil for about \$65.00

### **3.7 Handicrafts (various)**

Handicrafts can vary considerably in price depending on the item, quality, quantity, and sale channel. One of the potential clients, World of Good, focuses only on Fair Trade products, and is very interested in creating a relationship with Madagascar. However, they say that for their customer base rarely will pay more than \$30 per item. With a mark up of about 6 X the FOB price, this means that the items from Madagascar need to be in the \$5-6 range. We are currently exploring these possibilities. There may be higher end vendors that can pay higher prices but lower volumes, but this clientele has not yet been developed.

## 4.0 Labeling Primer

### 4.1 Labeling Primer Key

The first step in labeling finished products for the US market is to decide which into market the product will be sold and what regulations apply to the specific product, it will be labeled as either: a dietary supplement (see Section 4.2), a food or functional food (they are both labeled as foods; see Section 4.3); a cosmetic care/personal care product (see Section 4.4); or a handicraft (see Section 4.5).

To decide which market your product fits, use these questions as your guide:

- Is your product “a product, other than tobacco, intended to supplement the diet that bears or contains one or more of the following 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 of the aforementioned dietary ingredients; and is intended for ingestion in the form of a capsule, powder, softgel or gelcap, is not represented as a conventional food or as a sole item of a meal or the diet (Section 201 (ff), FD&CAact)?” If the answer is “Yes,” see Section 4.2. If you are not sure, for clarification, what is commonly referred to as a “herbal medicine” is regulated as a dietary supplement in the U.S. If your product is an herbal tea that has a structure/function claim associated with it, then it is considered a dietary supplement (go to Section 4.2). If it is a beverage tea with no claims, then it is a food (go to Section 4.3). See Examples. If you answered “No” to the above questions, then go onto the next question.
- Is your product “articles used for food or drink for man or other animals, chewing gum, and articles used for components of any other such article (21 CFR 102.5(a))?” If the answer is “Yes,” see Section 4.3. If you answered “No” to the above question, then go onto the next question.
- Is your product an “article intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions? Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product. Soap products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body are not considered cosmetics under the law.” If the answer is “Yes,” see Section 4.4. If your product is a pure essential oil or a fragrance, fragrance blend or perfume, see Section 4.4. If you answered “No” to the above question, then go onto the next question.
- Is your product a craft or other item that is not intended for consumption or topical use on the skin? If the answer is “Yes,” see Section 4.5. If you answered “No” to the above question, then return to the top of Section 4.1 and review the questions again.

## **4.2 Dietary Supplement Labeling**

The FDA (Food and Drug Administration; <http://www.fda.gov/>) is broadly responsible for ensuring compliance with the law for dietary supplement, including the law known as DSHEA (Dietary Supplement Health and Education Act of 1994; <http://www.fda.gov/opacom/laws/dshea.html>). This law governs, among many other things, labeling and permissible claims for dietary supplements. The FTC (Federal Trade Commission; <http://www.ftc.gov/>) also regulates dietary supplements from a consumer protection point of view. Therefore, when companies make outrageous claims on how their herbal or dietary supplements can cure disease, it is not only the FDA that can prosecute, but also the FTC that may prosecute companies. Often times, the heaviest punishments that are given to manufacturers regarding false claims come from the FTC.

Among the focus products that may be subject to dietary supplement labeling regulations are cinnamon extracts (for use as a dietary supplement) and herbal teas, possibly such as green tea and voafotsy.

### **4.2.1 General Dietary Supplement Labeling Guidelines**

The finalization of dietary supplement labeling had been a controversial topic in the US, with much concern as to the types of claims that can be made for a product. The labeling regulations are very specific about font sizes and placement of certain items on the label, and these topics will not be covered by these guidelines. Instead, refer to the CD-ROM called “Dietary Supplement Labeling Compliance Review” for technical aspects of specific labels.

Dietary supplement labels must contain the following:

- **An Identity Statement**  
This statement is essentially the wording “Dietary Supplement,” or other similar term that is placed on the front panel of the label, and must be the second most prominent (meaning the font is as large or the next size smaller to the name of the product or other larger font) type on the label.
- **An Ingredient Statement & Nutrition Labeling**  
Dietary supplements are required to list all the ingredients on the labels, and this is usually done in a Supplement Facts Box. Small label exemptions to apply, but not if there is a structure/function statement made. The common name of all herbs is used, as specified by the Herbs of Commerce, 2<sup>nd</sup> Ed. For more specific information on the Supplement Facts Box, see Section 4.2.2. In the case of excipients (or ingredients present at less than 2%), these are referred to as “Other ingredients,” and listed directly below the Supplement Facts Box.
- **Name and Address of the Place of Business**



The name and place of business of the manufacturer, packer or distributor is required on dietary supplement labels in a conspicuous manner. If it is not manufactured by the business, then qualifying words, such as “Manufactured for...” or “Distributed by...” may be placed on the label. The street address, city, state, and ZIP code is required. If the business is listed in a current city or telephone directory, the street address may be omitted.

- **Net Quantity of Contents Statement**  
The net quantity of the contents shall be stated on the front display panel of the label, and shall be expressed as either weight (if solid or semi-solid), fluid measure (for fluids), or numerical count (or maybe a combination of weight and numerical count).
- **Nutrient Content Claims & Health Claims**  
There are certain claims that can be made on labels of dietary supplements for dietary substances that have an established Daily Value, but only if they conform to the regulation for the meaning of that term. Example for a nutrient content claim is “healthy,” a food product that has the word *healthy* on it has to conform to the specific implied nutrition content claims for as specified by law, the same is true for the words “high” or “low”.

Specific health claims are also allowed, and there are less than 20 that have been approved. These health claims only refer to food substances.

- **Other Claims as may Be Provided for by the FD&CA and 21 CFR Part 101**  
Other claims that are allowed on dietary supplements are referred to as “structure/function” claims because they are statements that are not disease claims (otherwise they would be regulated as pharmaceuticals), but rather statements that do not explicitly or implicitly claim an effect on a specific disease or health condition, but may alter a structure or function of the body. For more information see Section 4.2.3.

#### **4.2.2 Supplement Facts Box**

See example Supplement Facts Boxes for the format, font sizes and example boxes for different products. In general, the supplement facts box may contain one or two sections of ingredients. If the product has nutritional contents (i.e. calories, fat, carbohydrates) or ingredients with daily values (the major vitamins and minerals), then those will be listed first in the order as specified by the FDA. If there are ingredients that do not have daily values, such as herbs or other dietary supplement products (like glucosamine sulfate), then those would be listed in the next section in descending order. If there are no products with daily values or nutritional content, then that section may be omitted.

#### **4.2.3 Structure/Function Claims**

Whenever a structure/function statement is made, there should be a premarket notification that is filed with the FDA. Also, there needs to be an asterisk next to the

statement and then a bolded and boxed disclaimer (at the bottom of the same page or panel where the statement appears) that reads: “\* 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.” See examples of Structure/Function Statements.

### **4.3 Functional Food/Food Labeling**

The FDA (Food and Drug Administration) is broadly responsible for ensuring compliance with the law, as well as labeling. Foods and drugs are covered under CFR (Code of Federal Regulations) Title 21. Most functional food and traditional food manufacturers only use ingredients that are considered GRAS (Generally Regarded As Safe) or are on an “Approved Food Additives” list. The FTC (Federal Trade Commission) also regulates functional foods from a consumer protection point of view.

The labeling regulations are very specific about font sizes and placement of certain items on the label, and these topics will not be covered by these guidelines. Instead, refer to the CD-ROM called “Food Labeling Compliance Review” for technical aspects of specific labels. Also see example Nutrition Facts Boxes.

One of the focus products that is labeled as a food, and may also be considered a functional food is Virgin Coconut Oil. See sample product for labeling. Other focus products that may be subject to food labeling are green tea (and other beverage teas), whole or processed cloves and cinnamon.

#### **4.3.1 General Food Labeling Guidelines**

Like dietary supplement labeling regulations, the food regulations are complex, more due to the wide variety of foods and package forms on the market. Functional foods are a marketing term, and as such do not have a specialized regulatory body that governs them. All “functional foods” are considered foods by the US regulations, and are governed as such (see more on this in Section 4.3.3). In general, the food or functional food label should contain the following items:

- **Identity Statement**  
The common name or usual name of the food shall be placed on the most prominent panel of the label, along with any appropriate descriptive term. In the case of “imitation” products, this must also be stated.
- **Designation of Ingredients & Nutrition Labeling**  
Ingredients shall be listed in an ingredient statement if there are two or more ingredients present in the product. Ingredients should be listed in descending order of predominance by weight. Spices, flavorings, colorings and chemical preservatives may be declared as specified by 21 CFR 101.22. In this regulation, the word “spice” can be used as a blanket identity statement for the usual spices, including cinnamon and cloves. For more on Nutritional Facts Boxes, see Section 4.3.2.

- **Name and Place of Business**  
The same regulations for listing the name and place of business for dietary supplements apply to foods (see Section 4.2).
- **Net Quantity of Contents**  
Similar regulations on stating the net quantity of contents for dietary supplements apply to foods (see Section 4.2).
- **Nutrient Content Claims & Health Claims**  
Similar regulations on nutrient content claims & health claims that were stated for dietary supplements also apply to foods (see Section 4.2).
- **Statements about the Structure or Function of the Body**  
The label of a conventional food may bear a structure/function statement, similar to those discussed for dietary supplements. The difference, however, is that for a food, it must be able to produce this effect through the nutritive value of the food, otherwise it is regulated as a drug. See more about this in Section 4.3.3.

#### **4.3.2 Nutrition Facts Box**

See example Nutrition Facts Boxes. Generally, the Nutrition Facts Boxes only contain nutritive information about the food in the package and daily value information for the major vitamins and minerals.

#### **4.3.3 Functional Foods**

As stated previously, functional foods are not regulated as such by the FDA. The term “functional food” is a marketing term that does not have any relevance or meaning to the FDA. However, what is commonly referred to as a functional food is a “food or food ingredient that has been shown to affect specific functions or systems in the body.” Functional foods may take the form of conventional foods, such as yogurts that enhance digestive function, or still conventional but more innovative forms such as beverages with herbs (that are Generally Recognized as Safe) added. One of the characteristic differences with what are commonly referred to as functional foods may be the use of structure/function statements on the label. These are the same as those used by dietary supplements, except that disclaimers are not generally required.

#### **4.4 Cosmetics/Personal Care Labeling**

The definition of cosmetic under the law varies slightly between countries, but in general terms “cosmetic” means any article intended to be used by means of rubbing, sprinkling or by similar application to the human body for cleaning, beautifying, and for maintaining health of the skin and hair, provided that the action of the article on the human body is mild. The regulatory agency for cosmetics in the US is the Food and Drug Administration (FDA). The FDA does not require pre-market approval for cosmetics. The cosmetic product name and details of its ingredients are voluntarily

reported to the FDA within 60 days of marketing. With the exception of color ingredients that require authorization for use, the FDA does not approve the use of any cosmetic ingredient, unless a safety problem arises after it has been put on the market, in which case the FDA can take action. The FDA's budget for cosmetic safety surveillance is less than 1%.

Essential oils (EOs) are the volatile, odorous oils that occur in certain plants. EOs are widely known for their scents and flavors, making the food flavor and fragrance (F&F), aromatherapy (including body care and cosmetics) industries among the largest users.

In addition to the federal regulations set by the FDA and FTC (see <http://www.cfsan.fda.gov/~dms/cos-206.html>; and <http://www.cfsan.fda.gov/~dms/cos-hdb1.html>), the body care and cosmetics manufacturers also work with industry associations to provide additional guidelines and standards. The CTFA (Cosmetic, Toiletry and Fragrance Association) for example, works with manufacturers on developing safety and quality control standards that exceed those of the federal government. Industry associations like these have independent researching, testing and reporting capacity. Industry members are likely to abide by and uphold these standards, as they are the commonly accepted way to do business

Among the focus products that may be subject to these labeling guidelines are: Katrafay EO (*Cedrelopsis grevei*), Ravensara Aromatica EO (*Agathophyllum aromaticum*); Niaouli EO (*Melaleuca quinquenervia*); Foraha or Tamanu oil (*Calophyllum inophyllum*); and Ginger EO (*Zingiber officinale*).

#### **4.4.1 General Cosmetic Labeling Guidelines**

[The following text is excerpted from an FDA Guidance Document at <http://www.cfsan.fda.gov/~dms/cos-labl.html>:]

Under the [Food, Drug, and Cosmetic Act](#) (FD&C Act) and the [Fair Packaging and Labeling Act](#) (FPLA), certain information must appear on the labels of cosmetic products.

All cosmetics, whether they are sold on a retail basis to consumers or marketed exclusively for salon or workplace use, are subject to the FD&C Act. This law and regulations enacted under its authority require the cosmetic label to state the name and place of business of the manufacturer, packer or distributor; an accurate statement of the quantity of contents; and any appropriate directions for safe use and/or warning statements. This information must comply with additional regulatory requirements. It must be prominent and appear in the proper location on the label.

Regulations enacted under the FPLA require ingredients to be listed on the labels of cosmetics sold on a retail basis to consumers -- even if the label states "For professional use only." Consumers can use the ingredient declaration to identify ingredients they wish to avoid. Ingredients are listed in descending order of predominance, that is, with the

ingredient present in the greatest amount listed at the beginning and those present in the smallest amounts listed at the end.

Special rules apply to the ingredient declaration on products that are [both cosmetics and over-the-counter drugs](#). An example of such a product is an anti-dandruff shampoo: A shampoo is a cosmetic, while an anti-dandruff treatment is a drug. Regulations enacted in 1999 require such combination products to have the drug ingredients listed separately as "Active Ingredients," in alphabetical order, followed by the cosmetic ingredients, which are listed as "Inactive Ingredients" in descending order of predominance.

In addition to the immediate label, FDA regulates all cosmetic product "labeling." The definition of labeling includes all written, printed, or graphic matter that appears on the product, its containers, or its wrappers, as well as any such matter that accompanies the product. Typically, materials such as promotional literature, product catalogs, and flyers fit this definition of labeling. FDA also has considered promotional statements appearing on Internet sites to constitute labeling, especially on those sites where the promoted product can be purchased. However, unfair or deceptive advertising that appears in magazines, in newspapers, or on television generally falls under the authority of the [Federal Trade Commission](#).

Cosmetic firms should refer to FDA's [Cosmetic Labeling Manual](#) (<http://www.cfsan.fda.gov/~dms/cos-lab1.html>) and the [regulations related to cosmetics](#) (<http://www.cfsan.fda.gov/~dms/cos-cfr.html>) for more detailed labeling information.

#### **4.4.2 General Essential Oil Labeling Guidelines**

Essential oils may be regulated, and thus labeled, as cosmetics if they are included in lotions or other product delivery forms that fit within the cosmetic regulations (see Section 4.1). If essential oils are sold as fragrances or fragrance blends, however, the regulations are much less specific. In order to be perceived as a supplier of good quality essential oil, certain information should be included on the label, as follows:

- *The Latin Binomial*  
As there are many common names for essential oils and the plants from which they are derived, to avoid confusion and to show the consumer that this is a quality product, the label should contain the Latin binomial (a two word scientific botanical name) for the plant that the oil was derived from. According to Christoph Streicher, aromatherapy expert (<http://www.spiritualminds.com/articles.asp?articleid=6305>), "All Eucalyptus oils are not alike. Eucalyptus Globulus is a great decongestant and antibacterial oil, but it is too strong to use in a baby's room. Eucalyptus Radiata is wonderful and safe for keeping your baby's nasal passages clear, so you both can have a good night's sleep. Eucalyptus Citriodora is a good insect repellent. Thyme, Pine, and Chamomile are several commonly used oils that have different subspecies."
- *How it was grown*

Whether a plant source for an oil was organically grown, wildcrafted or fair-trade/community supporting should be listed on the label. The source location and even region may be excellent ways of distinguishing your essential oil, and can be included on the label.

- *Toxic Oils*

As a few oils are considered toxic, there should be cautionary statements listed on the label, and should listed for use only by trained aromatherapists. A few of the oils that are considered toxic are White Birch, Sassafras, Thymus zygis, Hyssop, and Camphor.

#### **4.5 Handicrafts**

Handicrafts and craft products do not have a consolidated agency for regulation of labeling (unless it is a child's toy). Standards and criteria for handicrafts may arise as a result of an interest in trading under sustainable practices and the desire to carry a seal or certification of some kind. As in the case of the Sustainability Markets, certifiers establish standards based on social, environmental and economic principals and benefits.

One area for attention regarding crafts and arts is that any product that may be used or seen as a child's toy, must conform to regulations set up by the FTC (Federal Trade Commission) and the CPSC (Consumer Product Safety Commission). Mostly, these agencies are concerned with protecting children from toys and crafts that may cause safety problems. Some toys require age appropriate labels for example, to inform adults of the possible risk of exposing toys to younger children these toys need to be labeled with recommended minimum ages and safety information. It is important for exporters to work with their American clients to ensure the products comply with these important safety measures.

Links for toys - FTC <http://www.ftc.gov/bcp/online/pubs/buspubs/thread.htm>  
Child Safety Protection Act of 1994 - <http://www.cpsc.gov/businfo/frnotices/fr94/94-56387.html>

<http://www.cpsc.gov/cpscpub/pubs/282.html>

## 5.0 Marketing Plan Strategy Revisited

Our market plan is still best summarized as a "three pronged" approach. First we will be looking for general distributors that can handle Madagascar essential oils, spices, possibly other botanicals, and handicrafts. We are specifically looking for the distributors that will make an effort or take a larger interest in Madagascar, and not just selling its products as commodity items. We may need as little as two distributors, and as many as four to cover the range of market channels we are interested in entering. The distributors that have the highest potential for covering the markets are Frontier Natural Products Co-Op, The Lebermuth Company Inc., RFI Ingredients, Pharmline, PharamChem, Lemur International, Tri-K Industries, Ecotrend, Trout Lake Farm, BDS Natural Products, and World of Good. These distributors are well positioned in the functional food, dietary supplement, cosmetic and skin care, as well as craft markets. Further negotiations are needed to narrow down this list or carve out areas of sales territories (or products) for effective promotion of the Malagasy products.

The "second pronged" approach is to develop direct relationships with either a) large or established and innovative companies that might be interested in developing a "Madagascar-themed" product line in the medium to long-term, or b) other companies that are interested in carrying one or more product from Madagascar as a stand-alone product in the short-term. An example of (a) might be a line of Aveda body care and cosmetics that features Malagasy essential oils and tells the story of Madagascar and the sustainable promotion of its products; or (b) any size company that sees an immediate need for a stand alone product from Madagascar, such as the "focus products" that are recommended with this report. Examples of companies that fit this approach are Aveda or Estée Lauder, Access Business Group (Nutrilite and Amway), Frontier Natural Products Co-Op (through Simply Organics or Aura Cacia), Aubrey Organics, GNC, Whole Foods (introduce a branded line of functional spices and essential oils), Williams Sonoma, Exalted Extracts, and Threshold Enterprises. Negotiations with these companies are in very early stages, and will need more time to develop. Shorter-term relationships and sales may be formed once samples and introductions are made, or perhaps after meetings at the Natural Products West conference.

The "third pronged" approach is what I have been referring to as developing "fair deal" or direct-to-community relationships. The idea is to find smaller companies or product innovators in the natural products and handicrafts industry and help them to make direct relationships with a community (or more than one) from Madagascar that is similar to Fair-trade (provides higher prices or living wages to farmers or suppliers), and/or may provide other socioeconomic benefits to the community (such as building roads, schools, etc). This is becoming a popular marketing strategy in the U.S. that can also help to alleviate poverty and possibly create longer-term (rather than those based on price) relationships than the usual supplier relationship. An added benefit is that the larger consuming public may become educated and the awareness of Madagascar may increase, helping other sectors of business. An example of a company that has done this successfully is HonesTea, who support a South African community with their ready to

drink (RTD) iced teas. Other companies that may have similar interests are Traditional Medicinals, HerbPharm, Young Living Essential Oils, and World of Good.



## **6.0 Key Objectives of Investigatory Trip to Madagascar**

During this investigatory trip to Madagascar, I hope to accomplish certain goals that will be crucial in my ability to establish business relationships with US companies and Malagasy producers.

### **6.1 Visits with Key Producers**

One of the key purposes for this first trip to Madagascar is to meet with a few of the key producers with which we hope to work. Hopefully, I will be able to meet various producers that represent the variety of products that are available in Madagascar, along with specific producers with whom we are already working, such as the handicraft producers, Homeopharma, and Phaelflor. During these visits I hope to personally meet the people with whom we will be communicating, and who will be responsible for sending sample, answering emails, etc. for each producer. I also hope to see their current products, and gather samples and/or take pictures (that I can post on our website), as appropriate. I also would like to gain an understanding of the production capacity of each producer. In this regard, I would like to know the following types of questions:

- What is the volume they can produce of each product, and at what times of year do they produce?
- What is their understanding of potential applications for their products?
- What other production capacities do they have—do they have manufacturing machinery to add value to a product like in the bulk handling (drying and handling of herbs), drying capabilities (spray drying, vacuum drying, etc.), and any other scalable capabilities that they have?
- Do they have quality control procedures in place, and if so, what kind?
- What is the optimal type of relationship they would like to form with a US company?

Of course, as I am looking for the producers to help me understand the answers to these questions, I will also be happy to meet with each producer and answer questions about the marketplace from my understanding and the potential I see for their products. I am also happy to give feedback on labeling and other specific technical questions when I can.

### **6.2 Visits to Regions where Products are Produced**

I am hoping to also get an opportunity to visit the various producing regions for the key products or other potential products we are working with, as well as meeting with growers and grower cooperatives. As part of the strategy for creating successful long-term value added products out of Madagascar includes telling the story, or creating a perceived higher value through “community-supporting” products, it is essential for me to know these regions. In a visit to a region I hope to understand what about that region of Madagascar is special for producing a higher quality (or ethnic) product, and to get to know the peoples with whom such relationships might be possible. One example might be the Malagasy Magic Fingers cooperative. I will also hope to bring home pictures of

the peoples and lands with which we might find business linkages in the US, for posting on the [www.madagascarnatural.com](http://www.madagascarnatural.com) website.

### **6.3 Learning about the Selling Points and Story Associated with Products**

I am constantly asked from potential clients, “What from Madagascar is interesting? Can they compete on price with products from India or China, or are there products that are unique to Madagascar in quality or identity?” I need to gain a thorough understanding of what Madagascar has to offer, and why businesses should pay a premium (value added or even just the extra shipping costs) that are associated with doing business with Madagascar.

### **6.4 Visiting with Research Institutions**

A few of the businesses that I have been talking with would like to explore the possibility of working in tandem with research institutions in Madagascar to help develop the science and/or quality of products out of Madagascar. Additionally, I believe often times these type of research institutions have already performed certain scientific studies, application work or have prospected plants (along with creating relationships with traditional healers) that could be very useful for our work in developing the markets in the US. Therefore, if it would be possible to arrange a meeting with key researchers or institutions in Madagascar so that I can help to promote relationships with them, and also learn from them what products are promising, I believe it would be very useful. An example of such an institution is the IMRA (Institut Malgache de Recherches Appliquées).