CLEANSE CAPSULES

white paper provided by Archmore Botanical Research Group, LLC

A Dollar Coffee Club product

Cleanse Capsules

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- A technical overview outlining the safety and efficacy of Cleanse capsules, a dietary supplement designed to support the cleansing and rejuvenation of the digestive system including the intestines, bowels, liver and kidneys*
- This technical white paper will include:
    - Formulation breakdown
        - Synopsis of health benefits associated with the proprietary ingredients
    - Efficacy
        - Cellular, animal, and human trials demonstrating digestive system cleansing
        - A review of any negative outcomes found in clinical trials using the proprietary ingredients
        - Potential secondary health benefits outside the scope of digestive cleansing
    - Safety
        - In vitro and in vivo trials demonstrating safety of ingredients in Herbal Cleanse Capsules at recommended levels
        - A review of any adverse events associated with the ingestion of the proprietary ingredients
    - Recommended guidelines for use
        - Dosing recommendations for digestive system, liver and kidney cleansing
        - Potential adverse events and warnings

**These statements have not been evaluated by the Food and Drug Administration and are meant for research purposes only.*

Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

Overview

As we consume food, the body works to digest and convert these compounds into usable energy, namely sugars. Through the process of aging, digestion begins to lag in most people, making our bodies less efficient at breaking down foods and excreting waste from our system. This causes leftover particles of food, waste, excess sugars and cholesterol to build up along the intestinal walls, creating natural magnets to which other particles attach. This can lead to a toxic environment in the gut that may eventually lead to illness, fatigue, weight gain, and even disease.

Aging may also negatively impact other body systems and organs that are meant to help process and eliminate these toxins and waste particles from our bodies, namely the liver and kidneys. If these organs are not kept in check through periodic cleansing, they may weaken, leading to further build-up of detrimental compounds. This could impact one's ability to lose weight and stay active and healthy.

To rid the body of this build-up and help to create a healthy intestinal environment, periodic intestinal, liver, and kidney cleanses can be done. Since the times of Ancient Greece, man has sensed this need for cleansing and detoxifying his body to achieve optimal health. Many different methods have been used, including natural herbal remedies, juices, and high volumes of water. Although different, all of these types of cleanses are meant to help the body eliminate excess waste that builds up in the colon and intestinal walls, gathering toxins and posing a threat for disease.

Javita's Cleanse capsules were designed as a triple action formula, targeting (1)the digestive system, (2) the liver, and (3) the kidneys. It works to quickly and efficiently clean out waste particles from the intestines and colon, as well as eliminating toxins from the liver and kidneys.

It accomplishes this with a proprietary blend of herbs that act as both a laxative and diuretic; this helps remove toxins from the digestive system but also flush out toxins that may be building up in the liver and kidneys. What makes this formulation different from other "laxative-type cleansing products" is that it also includes herbs that will help ease the passage of these toxins and waste from the body, reducing the amount of physical distress common with stimulant laxatives. It also contains a unique blend of herbs meant to rebuild and strengthen the liver and kidneys. Together, these herbs clean, strengthen, and rejuvenate our valuable digestive systems.

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Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

Formulation

This proprietary formulation includes three categories of herbs targeting digestive cleansing, liver cleansing, and kidney cleansing. It also contains herbs designed to reduce discomfort often associated with bowel cleansing, as well as herbs shown to strengthen and improve the health of the digestive system and its supporting organs.

- Intestinal, Liver and Kidney Cleansing and Support
  - Senna Leaf Extract
  - Fennel
  - Dandelion Leaf Powder
  - Juniper Berry Powder
  - Milk Thistle Extract
- Reducing Discomfort Associated with Digestive Cleansing and Helping to Create a Healthier Digestive System
  - Marshmallow Root Extract
  - Chia Seed Powder
  - Slippery Elm Bark

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Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

Intestinal, Liver and Kidney Cleansing and Support

Intestinal Support

Both senna and fennel are included in the formula for their stimulating effects on the bowels, acting as laxatives to help push waste and toxins from the body. While this is mainly accomplished due to the anthraquinone content of the senna, primarily sennoside, it is enhanced by the fennel. Fennel relaxes the colon, reducing constipation and easing the passage of waste.

Senna: Senna is a powerful herbal laxative product that is approved by the US Food and Drug Administration (FDA) as a non-prescription drug. Both the leaves and fruit (pods) of senna are stimulant laxatives, which function by anthraquinone cathartic action and are generally well tolerated in the adult population. There is some scientific evidence to support the use of senna for the treatment of chronic constipation or constipation induced by childbirth or pharmaceutical drugs. Senna may be one option for adjunct therapy for patients on drugs (opioids, tricyclic antidepressants, phenothiazines) that cause constipation as an adverse effect. Approximately 80% of terminal cancer patients who are taking opioids for pain relief require laxatives, and senna has been shown to be as equally efficacious and safe as lactulose for these patients. [1-11].

Fennel: Fennel is a flowering member of the carrot family, with tall leafy stalks jutting out from a bulbous white stem. This stem is often eaten as a vegetable, since it has a similar flavor profile to anise or licorice and can be found in many Mediterranean and Indian dishes. Fennel is often touted for its high vitamin C and antioxidant content, with studies showing benefits ranging from immune response to anti-cancer treatments. While some of this evidence is anecdotal, there are many in vitro and in vivo studies showing its benefit for digestion. In fact, it is part of a standard treatment in Brazil for constipation, which has been substantiated by modern clinical trial [12]. But perhaps more importantly, fennel has demonstrated growth inhibition of Helicobacter pylori (H. pylori). H.pylori is a bacteria that can proliferate in the digestive system and is the causative agent of acute and chronic gastritis. This antibacterial property makes fennel a recommended agent for gastrointestinal problems and an ideal component for an intestinal cleansing regimen [13].

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Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

Liver and Kidney Support

The liver is an organ that detoxifies the body from various metabolites and aids in digestion. It produces bile which helps with the breakdown of fats. If the liver is not functioning properly or at all, serious health concerns arise, including in extreme cases death. The kidneys process and filter approximately half a cup of blood each minute, helping to eliminate waste and excess water from the body. Dandelion and juniper berries can help keep the liver and kidneys healthy by toning and strengthening the organs themselves but also by maintaining healthy fluid levels entering and leaving these organ systems. This will help facilitate the elimination of toxins through these valuable organs. Milk Thistle is a powerful liver cleansing natural product with significant scientific support for its use in this capacity.

Dandelion: Dandelion has been used for centuries by traditional healers throughout regions of the world. In Western Palestine, where herbal naturalists function as medical doctors, dandelion continues to be used for treating GI conditions and kidney stones [14]. These uses have been backed by more modern means of validation, including cellular and animal trials. In these trials, dandelion has demonstrated hepatoprotective benefits, possibly due to targeted antioxidation. In animals administered sodium dichromate, a common environmental toxin, serious liver damage occurred, including necrosis of hepatocytes and DNA fragmentation. However, in those animals pretreated with doses of dandelion, a significant reduction in liver damage was seen. Researchers concluded that dandelion may provide liver protection against serious oxidative damage [15]. A similar protection of the kidneys was observed when dandelion was administered to animals treated with carbon tetrachloride. Not only did the dandelion protect from kidney damage, in those animals where damage already occurred, dandelion returned the affected cells back to normal levels [16].

In addition to being a powerful antioxidant in the liver, dandelion also improves kidney function. Dandelion contains a powerful compound called taraxasterol, which has been shown to positively change serum and urine parameters in animals while still maintaining the antioxidant environment shown to protect these organs. Additionally, it reduces crystal deposition and improves the excretion of small deposits from the kidneys, thus reducing the chance of them being retained in the urinary tract as kidney stones [17]. Further investigation into the treatment of kidney stones has shown that dandelion may have a disinfectant action, helping to

Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

dissolve stones already formed due to its basifying action [18]. This action was tested in another trial to determine if it is only this compound, taraxasterol, or the whole herb that is having the positive benefits for reducing calcification of kidney stones. When tested head to head, researchers showed that it was actually the more complete plant product that produced greater benefits than the taraxasterol alone. They concluded that there must be synergies within the herb itself which provide the benefits [19].

Juniper Berry: Throughout regions of the world where herbal remedies are prescribed by healers as medicine, such as Nepal, juniper berries are given for kidney health and the reduction of kidney stones. The berries of this tree have kidney protecting benefits, most likely through antioxidation, but also improve functionality. Modern science has confirmed these traditional uses through in vitro and in vivo trials [20]. In one animal trial, rats were treated with a kidney toxin called tacrolimus. This toxin produces vasoconstrictive metabolites of the prostanoid pathway, which can lead to renal ischemia and ultimately the pathogenesis of chronic allograft nephropathy. Juniper can reverse and prevent this by producing vasodilatory prostanoids in the renal-cell membrane. Although unclear if these results are translatable to humans, these researchers believe the evidence was significant enough to warrant human trials [21]. This beneficial action was seen with other plant part tinctures as well. In an animal trial, juniper leaf extracts showed a remarkable effect in enhancing liver and kidney functions [22].

Juniper also has significant benefits for the liver. Liver disease is a leading cause of death due to the vital role of the liver in the overall functionality of the body. In cellular trial, the compound hinokiflavone was isolated from juniper and administered to cellular cultures damaged by oxidative toxins. Hinokiflavone protected liver cells, indicating an antioxidative mechanism of action [23]. This antioxidation reduced cell death in the liver by 75% and improved the hepatic microcirculation in livers undergoing oxidative stress [24].

Diabetes, although a blood sugar disorder, can negatively impact the functionality of the liver and kidneys. In an animal trial, researchers attempted to determine if juniper berries could provide protection for these organs even while stressed from diabetes. They demonstrated that diabetic rats fed juniper extracts decreased blood glucose levels and lipid peroxidation in liver

and kidney tissues. They concluded that juniper does offer liver and kidney protection for those suffering from diabetes [25].

Cancer of the liver is one of the most serious forms of liver disease. While several natural products have shown cytotoxicity in liver and colon cancer cell lines, most are not yet commercially available. Juniper berries are commercially available, and they have shown strong potential benefits for destroying these cancer cells [26]. These same benefits were seen in vitro when juniper fractions were tested in animals suffering from liver tumors. Juniper-treated mice showed tumor reductions of 40% and had a prolonged survival rate [27].

Milk Thistle: Milk thistle (*Silybum marianum*) is an herbal product that is widely used in western society for the prevention and treatment of liver problems. It is often standardized for silymarin content. Silymarin is a complex mixture that contains a number of structurally-related flavonolignans, taxifolin, and a number of other constituents, with flavonolignans making up approximately 1.5-3% of the dry fruit weight of milk thistle [28]. It is this complex that has shown impressive hepatoprotective benefits both in cellular as well as human trials. Cellular trials demonstrated a strong propensity toward anti-oxidation as well as anti-inflammation within the liver itself, which has led to improved vitality of liver cells even when alcohol abuse is present. Since alcohol is cleared from the system via the liver, extensive damage can occur when large quantities of alcohol are consumed for long periods of time. Milk thistle extract has the potential to reverse and protect from this damage [29].

It is not just alcohol that can damage the liver. Several drug therapies are also cleared through the liver, such as those treating HIV and some cancer therapies. Milk thistle extract has been shown to protect from potential damage caused by these drug therapies [30].

Non-alcoholic fatty liver disease is the build-up of excess fats in the liver that is not caused by excess alcohol consumption. Although it can be a genetic condition, most cases are caused by high cholesterol, obesity, and metabolic syndrome. In the United States, it is the most common form of chronic liver disease most likely because of poor dietary habits. Silybin, a major component of milk thistle extract, reversed the damage done by these excess fats in the liver cells in cellular trials. Researchers identified multiple complimentary mechanisms of action,

Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

including increasing the mitochondrial size and function in the liver cells, stimulating mitochondrial fatty acid oxidation, and rescuing the cells from cellular death caused by fatty acid signaling and oxidative stress [31]. These results have been confirmed in multiple human trials. In a meta-analysis of more than 580 patients with non-alcoholic fatty liver disease, milk thistle extract showed significant benefits for reducing transaminase levels, an indicator of liver damage [32].

Not only is milk thistle extract highly effective for clearing and protecting the liver, it also may reverse damage already done through normal use and aging. In animal trials, milk thistle stimulated the production of hepatic stem cells, rejuvenating the liver and reversing signs of aging within the organ [33]. By rebuilding these vital cells, liver functionality may be significantly improved.

Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
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Soothing abdominal discomfort and Improving the Intestinal Environment

Unfortunately, stimulating the gastrointestinal tract (GI) to excrete waste can be uncomfortable. An increase in gas, bloating, and cramping may result. To help alleviate some of this distress, several herbs were included to relax and calm the GI tract while allowing the waste to be eliminated. Marshmallow root helps to soothe tissues throughout the intestines and colon while increasing moisture throughout this body system. It lubricates intestinal walls, easing the passage of waste and reducing strain. With this increase in moisture comes an increase in urination, an added benefit for intestinal and kidney cleansing. As urination increases, so does the amount of fluids processing through the kidneys. This will help flush out the kidneys, strengthening this organ system as well. Slippery Elm Bark works synergistically with Marshmallow root since it contains high concentrations of mucilage. This is a polysaccharide substance that lubricates the walls of the intestines, helping waste to flow freely during elimination. Chia Seed rounds out this trio, providing powerful anti-oxidant protection for these delicate body systems. Inflammation in the digestive system has been shown to cause bowel diseases, leading to pain, distress, and even death. By reducing inflammation throughout the intestines and bowels, Chia Seed can help reduce the risk of pain and discomfort that sometimes accompanies bowel cleansing.

Soothing Abdominal Discomfort

Slippery Elm bark : Slippery Elm (*Ulmus davidiana*) is a tree native to the eastern United States. The bark of this tree has been used in OTC remedies to relieve inflammation and irritation. In Korea, it has been prescribed for relieving chronic inflammation in the GI system associated with various GI and bowel disorders. Medical researchers believe this is due to the immunomodulatory role slippery elm may play in intestinal homeostasis. To test this hypothesis, the small intestinal lamina propria, spleen, and mesenteric lymph nodes of mice were analyzed after being fed a diet of slippery elm bark for 14 days. Based on changes in various levels of immune cells (i.e. B- and T-lymphocytes, dendritic cells, macrophages, etc.), researchers concluded that slippery elm bark regulates these immune cells in such a way as to promote homeostasis and ultimately reduce inflammation in the intestines [39]. This is especially promising for those suffering from serious bowel and GI disorders, such as IBS, IBD, and Crohn's disease. Unfortunately, these conditions are on a rise, with the fastest rate found in the elderly population of the United States [40]. Through the use of Slippery Elm Bark, these inflammatory

Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

conditions may be reduced, while will help with abdominal pain and discomfort associated with bowel cleansing.

Improving the intestinal environment

Once cleansing is complete, nutrients that benefit a healthy GI environment should be consumed. This will allow for proper function of the GI tract including the bowels, kidneys and liver. Healthy microbiota will also thrive, and detrimental viruses and parasites will have a harder time surviving. Several nutritional ingredients may help in this capacity which are included in Javita's Cleanse formulation. These include marshmallow root extract and chia seed.

Marshmallow root: Marshmallow root (*Althaea officinalis*) grows throughout marshy regions of the world and is a member of the Asteracea family of flowering plants. When extracted, marshmallow root yields high concentrations of polysaccharides with known antioxidant properties [34]. One of these polysaccharides, glucuronoxylans, has even shown significant inhibition of peroxidation of fat cells in vitro [35]. This may help prevent peroxidation of fat in liver cells, a cause of non-alcoholic fatty liver disease. It protects the intestines and bowels from free radical damage, and has been used historically as a powerful antibacterial agent. Modern science has confirmed this benefit, citing a recently published study which reveals its powerful cytotoxicity for harmful bacterial strains, including *Streptococcus mutans* [36].

Chia seed : Chia is one of the many edible plants in the mint family. The seeds are considered a pseudocereal product because of the way they can be consumed: as a whole seed product or ground into a flour or meal. The nutritional content has allowed chia seeds to gain enormous popularity throughout the United States and Mexico. This includes the essential fatty acid, alpha-linoleic acid (ALA). ALA is an omega-3 fatty acid that provides cardiovascular benefits in the body. In an animal trial, ALA was fed to rats who were on a high-carbohydrate, high-fat diet. Chia seed was added to their drinking water at a 5% level for 8 weeks. At the end of the trial period, those animals fed chia seed had improved insulin sensitivity and glucose tolerance, reduced visceral adiposity, decreased hepatic steatosis and reduced cardiac and hepatic inflammation and fibrosis without changes in plasma lipids or blood pressure. Researchers

concluded that chia seeds, and in particular the ALA, help to redistribute lipids, benefiting both the heart and the liver [37].

Another reason for the rise in popularity of chia seeds is their high fiber content. Fiber is an essential tool for helping to clean the GI system and therefore must be consumed in significant quantities on a daily basis. However, fiber can also help produce a healthier environment in the gut by changing the contents of the gut itself. This allows for a better environment to support the growth of healthy microbiota, which will improve functionality of this complex body system. In addition, human clinical trials have shown improved satiety when chia seeds are consumed, possibly due to the bulking action of chia seeds in the GI tract. Chia seeds also reduced blood glucose levels and prolonged the time to reach peak glucose levels, benefiting those individuals concerned with their blood sugars [38].

Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
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Safety

As nearly all of the herbs in Javita's Cleanse capsules have been used for centuries by traditional and Ayurvedic medicines, they have substantial history of use with minimal safety concerns, usually only in select populations of individuals with specific concerns. These are outlined for each herb individually. In general, Cleanse capsules should not be consumed by pregnant or lactating women nor children.

Senna: Senna is generally well tolerated in the adult population, but when taken at doses much higher than recommended or when used chronically (laxative abuse), adverse effects may occur (i.e., hypokalemia, metabolic alkalosis, renal tubular damage, etc.) [41]. Sennocide is a potent laxative compound found in senna. When administered for long period of time in cellular cultures, sennocide has been shown to induce apoptosis (cell death) of colonic epithelial cells, resulting in shorter intestinal glands. Longer intestinal glands seem to protect from colorectal cancer; therefore, by shortening them, it is hypothesized that the risk for colorectal cancer could be increased. This was shown to occur only with long term use and is still under investigation; however, short term use of this product would be strongly recommended [42].

In an in-depth review of all available published scientific papers, researchers established the safety and potential warnings surrounding the use of senna for laxative purposes. Although senna is generally safe for the majority of the adult population looking for relief from constipation, including the elderly, women after childbirth, and cancer patients suffering from opioid-induced constipation, it does carry warnings for specific segments of the adult population [43]. Caution should be exercised in these specific populations as outlined below.

Individuals suffering from the following conditions should be advised not to use senna:

- Patients who have had an obstruction of the gastrointestinal tract [44]
- Individuals with hemorrhoids, stomach ulcers, irritable bowel conditions, or gallstones should seek expert medical advice before beginning any laxative regiment [45]
- Individuals already using another diuretic or laxative due to potential additive potassium depletion from over exposure [46]
- Patients using anticoagulant and antiplatelet agents due to the potential for excessive bleeding to occur [47]

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Fax: 713-583-8615
archmorebotanical@gmail.com
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- Individuals with an allergy or hypersensitivity to senna [48]
- Children should not use this product due to the lack clinical evidence [49]
- Pregnant and lactating women

In general, all stimulant laxatives have been hypothesized to cause structural changes in the bowels, such as "cathartic colon" or enteric nerve damage, which could result in dependency on the product for bowel movements. Although, this causal link is not well established, it is recommended to only use stimulant laxatives, such as Cleanse capsules sporadically to avoid any potential dependency [50; 51].

Fennel: Fennel is a vegetable commonly consumed throughout the world, particularly in Mediterranean and Indian dishes, and is therefore Generally Recognized As Safe, or GRAS, by the US FDA [52].

Dandelion: In several studies evaluating the efficacy of dandelion for kidney health, no adverse events were reported [53]. While it may be well tolerated by animals and humans, researchers have warned of potential kidney drug interactions with dandelion. Therefore, they have advised that care should be exercised if individuals are on kidney medications, particularly the CKD/ESRD population. Consult your primary care physician before beginning any cleansing regimen if you are currently on medications.

Juniper Berry: In a study evaluating any potential toxicity of an herbal formula including both juniper berries and dandelion, among other herbal ingredients, researchers found no pathological effects even at significantly high doses (20mg/kg in mice) and no changes from control for all biochemical measurements [54]. When toxic results are cited for juniper, they occur when the wood and branches from the J. oxycedrus species are used to create a product called Cade oil. This does have detrimental effects and carries warnings; however, this is not the product used in Cleanse capsules by Javita. Javita sources only the berries for this product which are not associated with adverse event reports.

Milk Thistle: This herbal extract has been widely used for benefits on the liver with minimal adverse events. In a study to evaluate cytotoxicity of the active compound, silymarin, researchers showed that concentrations up to 100 µM have neither a cytotoxic nor genotoxic effect on blood platelets, PMBCs and A549 [55].

Marshmallow Root: The root of the marshmallow plant is considered safe for humans when ingested by mouth at appropriate doses [56]. There have been some reports that marshmallow root may potentially decrease blood sugar levels. However, the only published research in this area is on a different member of the same genus. This research was done on the flowering part of that plant, and is not indicative of marshmallow root. However, should blood sugar levels fall when taking marshmallow, care should be exercised.

Slippery Elm Bark: The bark from this tree is generally considered safe for human consumption when taken orally. In human clinical trials, it was well tolerated with minimal to no adverse events reported [57].

Chia Seed: Chia is a food product and is therefore exempt for government ruling on its safety. In a letter from the FDA, chia has been cited as having no known safety concerns.

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Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

Usage Guidelines

Stimulating laxatives should only be consumed for short periods of time, as they could cause dependency. Therefore, it is recommended to consume Cleanse capsules once daily for 7 days, and then abstain for at least three weeks. This can be done cyclically, i.e., when beginning a new nutritional program, seasonally, or based on your personal needs. As there may be some gastrointestinal distress associated with an intestinal and colon cleanse, it is advised to consume the capsules at night before bed. This will allow you to sleep through some of the discomfort, should you experience this. Smaller doses than recommended may also be consumed should discomfort occur. A single capsule per day for the first cycle may still produce the desired results and allow your body to become accustomed to the cleansing process.

It can be expected that normal side effects from a laxative can be expected. These could include cramping and bloating. However, should these symptoms become severe, discontinue use and contact your healthcare professional immediately.

Due to the nature of the product and the desired effects, at least eight glasses of water should be consumed daily while taking this product.

This product should not be used by pregnant or lactating women, nor those women looking to become pregnant. It should also not be used by children, as studies have not been conducted in children to determine safety.

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Fax: 713-583-8615
archmorebotanical@gmail.com
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Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com

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Phone: 281-360-7282
Fax: 713-583-8615
archmorebotanical@gmail.com
www.archmorebotanical.com