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## MEDICAL ASPECTS OF ALOE

- 1. LITTLE HUMAN RESEARCH CONDUCTED UNTIL THE PAST FIVE YEARS
- 2. ISOLATION OF ACTIVE INGREDIENT (S) CARRINGTON
- 3. RECENT HUMAN CLINICAL STUDIES PROMISING CARRINGTON AND OTHERS
- 4 STUDIES IN PURE GEL CONFIRM ACTIVITY OF ACTIVES IN GEL
- 5. WHAT DOES THIS MEAN PHARMACEUTICALLY
- 6. TERRY LABORATORIES' PLAN TO DEVELOP PHARMACEUTICAL GRADE ALOE

The ability of Aloe Vera Gel to facilitate the healing of burns and wounds and to alleviate many internal complaints in humans has been accepted as fact by the general population for centuries. This acceptance has come as a result of Folklore and observed results rather than hard scientific proof. In the past few years considerable research has been done in an effort to isolate and investigate the medically active ingredient(s) in the gel of Aloe Vera. This research is now reaching the point of proving the medical value of Aloe Vera for a broad range of conditions requiring pharmaceutical intervention.

Current research worldwide is taking place in universities, private research corporations, and physicians medical practices to isolate and identify the active ingredient(s) of Aloe Vera Gel and the disease states or other conditions which are improved by exposure to these active ingredients. These studies are being conducted on the gel itself and also on a long chain polysaccharides which have been extracted from the gel and are considered the active elements in Aloe Vera.

All of this research points to the conclusion that Aloe Vera Gel does contain active ingredients which interact with the human auto immune system to enhance its' ability to fight off the invasion of foreign substances or viruses which attack people who are immunocomprimised. Evidence is mounting that the active ingredients in Aloe Vera increase both the number and activity of lymphocytes which are the first line of defense against invading pathogens. At least one of these actives has been identified and extracted. This active has been subjected to several human clinical involving immunocomprimised patients and has shown promise in alleviating symptoms and arresting the progress of the disease states involved. It has been postulated that this same enhancement of the immune response takes place topically in the treatment of burns and wounds with Aloe Vera Gel products.

Several initial new drug applications (INDA's) have been filed with the F.D.A. in regard to this identified active ingredient and are currently under review.

From a medical standpoint, Aloe Vera and it's active ingredients are about to enter into a totally new arena. This promises significant increases in the importance and usage of Aloe Vera and it's actives as a legitimate weapon against disease and infection.

#### PRESENT USES OF ALOE VERA GEL PRODUCTS

Aloe Vera Gel has been used for centuries around the world to treat burns and wounds and for it's moisturizing properties.

In the past fifteen years, Aloe has come in to favor in the cosmetic industry and in the over-the-counter first aid industry based on these same characteristics as a moisturizer and healing agent. Aloe manufacturers no sell Aloe Vera products world-wide to a variety of companies who formulate it into their product lines at varying percents.

It is widely used in first aid sprays, gels, creams and lotions. It is used in sunscreens, after sun and sunburn sprays, gels, creams and lotions. In addition it has been incorporated into practically any cosmetic product currently available and has also recently been formulated into Puffs tissues.

A serious research continues regarding Aloe Vera's healing properties, its uses will expand and take on increasing influence.

#### POTENTIAL USES FOR ALOE VERA GEL PRODUCTS

In the past five years there has been a significant amount of research conducted on Aloe Vera and various components of Aloe Vera which are considered to be its medically active components. As these studies and studies now in progress are validated and become accepted, the potential uses for Aloe Vera Gel will increase dramatically both in number and in scope.

At the present time, Aloe Vera Gel in any form, has not received approval by any regulatory agency including the F.D.A., for any type of medical effectiveness. This is because there have never been any human clinical studies done on Aloe Vera Gel of it's ingredients which conclusively prove the long held belief that Aloe Vera Gel is medically effective in the treatment of burns, wounds, and other medical indications. As mentioned earlier, recent and ongoing research, which is described in a separate section on the medical aspects of Aloe Vera Gel, will legitimize Aloe Vera Gel as a true medicament for the first time.

As this happens, the cosmetic industry will be forced to take its usage of Aloe Vera much more seriously. The industry will realize the need to use Aloe Vera in its product line in quantities which are sufficient to provide the consumer a benefit. It will also be forced to become very careful in the marketing claims and benefits of products containing Aloe Vera Gel.

While Aloe Vera Gel is not used in significant amounts by the pharmaceutical industry at present, this will also change as research legitimizes Aloe Vera as a medically active compound. Aloe manufacturers who wish to compete in the pharmaceutical arena will have to be prepared to supply high quality Aloe Vera Gel on a consistent basis.

Aloe Vera has had a past history of peaks and valleys in terms of commercial usage and acceptance. This will change to a continuous upward curve as new uses and indications become accepted and approved.

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### TYPICAL COMPONENTS FOUND IN THE GEL OF ALOE VERA:

WATER URONIC ACID FRUCTOSE HYDROLYSABLE SUGARS ENZYMES (at least nine different enzymes) GLUCOSE (can be as high as 48%) MANNOSE (can be as high as 48%) GALACTURONIC ACID GALACTIN GLOCOMANN IN OVER 20 AMINO ACIDS LACTATE SODIUM **POTASSIUM MAGNES IUM** CALCIUM **ANTHRAQUINONES** VARIOUS OTHER TRACE MINERALS AND ELEMENTS

Percentages will vary due to the season the leaves are harvested in and the geographic location of the farm.

# HARVESTING MANUFACTURING AND HANDLING OF ALOE VERA GEL

Terry Laboratories' raw Aloe Vera Gel is obtained from our sources in the Caribbean. The leaves are harvested from the farm and are transported to the processing facility. At the processing facility the leaves are sanitized and filleted to remove the raw gel.

The pulp is then removed and the gel is lightly preserved, packed in 55 gallon drums, and loaded on refrigerated ships to be transported to Melbourne, Florida.

Upon receipt of a shipment of raw gel concentrate front the Caribbean it is stored in our walk-in coolers until we are ready to process it. The gel concentrate is then transported into our air conditioned and controlled Aloe processing room where it is pasteurized, preserved and processed into any of a variety of our finished products.

If it is destined to be one of our liquid products it is drummed and quarantined for Q.C. evaluation and approval. If it is to be freeze-dried or spray-dried, it is concentrated and drummed until the freeze or spray dryer converts it into powder.

Due to Aloe Vera's potential for contamination, all handling and processing of Aloe Vera Gel is done under BMP guidelines and with all sanitary requirements adhered to. Masks and hair nets are required at all times in the processing rooms and all finished product is quarantined until our Microbiology Department has certified it as meeting the minimum cfu's allowed, and our Quality Control Department has approved it for sale. We are subject to regular F.D.A. and State of Florida inspections and have been given an excellent rating.

Years of experience as Aloe manufactures allows us to provide you with a broad range of products manufactured under the most stringent controls possible.

#### NEW PRODUCT DEVELOPMENT

- \* New compounds and products will distinguish Terry Laboratories from the competition.
- \* Opportunity for profit greater in new product development versus Aloe sales alone.
- \* New products already developed and in some stage of release
  - A. Aloe-Moist
  - B. Aloe-Moist A
  - C. Aloe-Moist with Sunscreen (SPF 10)
- \* New products under development or in planning stage
  - A. Aloe-Moist and Chitoglycan
  - B. Aloe-Moist and Tiolisina
  - C. Other new products not based on Aloe-Moist
- \* New products under consideration for the Health Food Market
  - A. Aloe Vera Gel and Kera Gel (Sea Kelp derivative)
  - B. Aloe Vera drink flavored
  - C. Aloe Vera drink unflavored

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