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DATE: 4-18-03

FROM: Jim Barton

TO: whom it may concern

Dockets Management Branch
(hfa-305)
Food and Drug Administration
5630 Fishers lane
Room 1061
Rockville, MD.20852

FIRST I WOULD LIKE TO EXPLAIN THAT TERRY LABORATORIES IS A LEADING MANUFACTURER OF ALOE VERA POWDERS AND GELS AND A SUPPLIER TO THE DIETARY SUPPLEMENT INDUSTRY.

I AM WRITING YOU IN RESPONSE TO A RECENT ARTICLE IN NUTRACEUTICALS WORLD MAGAZINE ON THE SUBJECT OF THE PROPOSED RULE FOR DIETARY SUPPLEMENT cGMPs ON MANUFACTURERS.

MY QUESTION TO YOU IS, WILL THIS APPLY TO THE INGREDIENTS USED BY THESE MANUFACTURERS E.G (ALOE POWDER) AND IF IT DOES WILL IT COVER THE SUBJECT OF ADULTERATED INGREDIENTS.

WE TAKE PRIDE IN BEING A MANUFACTURER/SUPPLIER OF HIGH QUALITY **UNADULTERATED** ALOE VERA PRODUCTS AND GO TO GREAT LENGTHS TO INSURE THE QUALITY, PURITY AND CONTENT OF OUR PRODUCTS IS WHAT WE SAY IT IS.

OUR PROBLEM IS THAT ADULTERATION OF ALOE SEEM TO BE THE RULE NOT THE EXCEPTION AND THIS FACT PUTS US ON AN UNLEVEL PLAYING FIELD WITH OUR COMPETITORS.

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WE DO WHAT WE CAN TO COMBAT THIS ISSUE EVEN GOING AS FAR AS TO HAVE OUR PERSPECTIVE CUSTOMERS SEND US SAMPLES OF THE COMPETITIVE PRODUCT TO BE TESTED FREE OF CHARGE AND THE RESULTS VERIFIED BY AN INDEPENDENT TESTING FACILITY.

MANY TIMES WE HAVE DONE THIS AND HAVE BEEN TOLD THAT THE ISSUE IS NOT QUALITY BUT PRICE THAT MAKES THE DIFFERENCE IN DETERMINING WETHER THEY WILL PURCHASE FROM US OR OUR COMPETITORS.

ULTIMATLY WHAT THIS MEANS IS THAT THE CONSUMER/END USER WILL RECEIVE A PRODUCT THAT IS EITHER HIGHLY ADULTERATED OR HAVE NO ALOE AT ALL.

THE THOUGHT OF A CONSUMER USING A PRODUCT THAT IS SO HIGHLY ADULTERATED AND POTENTIALLY HARMFULL IS TO SAY THE LEAST DISTRESSING TO PEOPLE IN OUR INDUSTRY WHO REALLY CARE ABOUT MAKING SURE PEOPLE ARE GETTING WHAT THEY SHOULD BE GETTING.

ULTIMATLY MY QUESTION TO YOU IS ,WILL THEIR BE RECOURSE IN THESE PROPOSED RULE CHANGES TO TAKE ACTION AGAINST THOSE PEOPLE WHO CHOSE TO CONTINUE ADULTERATION OF THESE TYPES OF INGREDIENTS, AND WHOM CAN WE CONTACT TO DISCUSS THIS ISSUE.

WE WOULD WELCOME ANY GUIDANCE YOU CAN OFFER ON THIS SUBJECT.

Thank You
Jim Barton