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October 20, 2003

First Fishery Development
9484 Chesapeake Drive 802
San Diego, CA 92123

File No. 1003271

Attn: Mr. Richard Lentz

RE: **MICROBIAL CHALLENGE STUDY**

A. Nasal Pray w/Baptisia tinctoria 4X (Homeopathic Control)
Lot No. (none stated) - Received in small amber bottles.

B. Olive Leaf Nasal Spray 1 fl. oz
Lot No. 3T37 8/05 - Received commercial retail unit with nasal pump spray

Received: 10-14-03

INITIAL MICROBIAL SCREEN	
SAMPLE	**STANDARD PLATE COUNT CUF/ML**
A. Baptisia tinctoria	>570,000
Retest 10/17	>570,000
B. Olive Leaf	<1
The Baptisia have too high of an initial microbial load to perform the challenge study.	

Reported By:
ANRESCO, INC.

Laila Lam
Microbiologist

LL:G-Micro\1003271

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January 21, 2004

First Fishery Development
9484 Chesapeake Drive 802
San Diego, CA 92123

File No. 1003271
FINAL REPORT

Attn: Mr. Richard Lentz - FAX: 858-279-7040

RE: **Preservative/Effectiveness (P/E) Study**
A. SEAGATE NASAL SPRAY W/BAPTISIA NACL- Received in plain amber bottle
B. SEAGATE OLIVE LEAF NASAL SPRAY (30 ml Lot No. 3Y37 8/05) - Received commercial retail unit.
Received: 10-14-03

Two samples of nasal sprays were submitted to determine the effectiveness of the antimicrobial agent. Prior to inoculating the samples with known organisms, the initial microbial load of each was determined. The presence of viable organisms prior to inoculation is already an indication of it's antimicrobial effectiveness. The nasal spray w/baptisia had viable organisms present which disqualifies this sample for the study. The Olive Leaf Nasal Spray (Lot No. 3Y37 8/05) did not have any viable organisms present. Therefore, this sample was subjected to the P/E Challenge Study.

SAMPLE PREPARATION

According to USP 24 Reference Method <51>, E. coli ATCC 8739, Ps. aeroginosa ATCC 9027, Staph. aureus ATCC 6538, Candida albicans ATCC 10231 (Yeast) and Aspergillus niger ATCC16404 (Mold) will be inoculated to the Olive Leaf Nasal Spray to yield approximately 1×10^5 to 1×10^6 organisms per ml of sample.

0.3 ml of each inoculum was aseptically added to 30 ml of sample and immediately shaken to evenly distribute the organism in solution. For Time 0, 6hr and 24 Hr, the samples were plated at 1:100, 1:1000 and 1:10,000 dilution in anticipation of the survival of the designated organisms. In addition, a 30 ml of sterile saline was also inoculated to run in parallel with the sample. This will determine the viability of each organism throughout the study.

The inoculated sample was plated again at Day 7, Day 14, Day 21 and Day 28. The results are listed in Table I - Table III in the following page.

OBSERVATIONS

The initial number of organisms for E.coli, Staph, Pseudomonas and Candida were detectable immediately after inoculation at levels ranging from 10^2 to 10^4. The same organisms were undetectable by 6 Hr til the end of the study. The saline blank for each organism is within the expected range of 1×10^5 and 1×10^6 organisms per ml.

The Aspergillus remained detectable throughout the study but at very low levels.

CONCLUSION

The submitted sample met the requirements for antimicrobial effectiveness as stated in USP 24 <51>. The criteria are as follows:

Bacteria (E. coli, Pseudomonas and Staph)	*Not less than a 1 log reduction from the initial calculated count at Day 7 and not less than 3.0 log reduction from the initial count at Day 14 and no increase from Day 14 to Day 28*
Yeast/Mold (Candida & Aspergillus)	*No increase from the initial calculated count at Day 7, Day 14 and Day 28.*

Reported By:
ANRESCO, INC.

Laila Lam
Microbiologist

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Table I - Media

MEDIA	Manufacturer	Lot No.	Expiration
Trypticase Soy Agar	Difco	0179000	7-01-05
Sabouraud Extrose Agar	Difco	0157000	7-01-05

Table II - Challenge Organisms

Organisms	ATCC No.	Inoculum CFU/ml	Estimated Initial Sample Concentration CFU/ml
E. coli	8739	8.3×10^8	8.3×10^6
P. aeruginosa	9027	1.2×10^8	1.2×10^6
S. aureus	6538	5.2×10^8	5.2×10^6
C. albicans	10231	6.0×10^7	6.0×10^5
A. niger	16404	5.8×10^7	5.8×10^5

0.3 ml of each inoculum to each 30ml sample

ATCC = American Type Culture Collection
CFU = Colony Forming Units

Table III - INHIBITION SCREEN

DILUTIONS

	1:1	1:10	1:100	1:1000
E. coli	No Growth	Growth	Growth	Growth
Ps.	No Growth	Growth	Growth	Growth
Staph	No Growth	Growth	Growth	Growth
Ca	No Growth	Growth	Growth	Growth
Asp	No Growth	Growth	Growth	Growth

Samples were plated with 1 ml of each of the dilutions. Agars were seed with each organisms and poured to each sample. Reactions were recorded base on Growth and No Growth

Inhibitory properties are detected in 1 ml sample

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Table IV - Microbial Load over 28 Days

	Initial	6 Hr	24 Hr	Day 7	Day 14	Day 21	Day 28
E.COLI	6.1×10^3	<10	<10	<10	<10	<10	<10
	4.1×10^3	<10	<10	<10	<10	<10	<10
Saline	9.4×10^6	6.5×10^6	*	1.7×10^6	1.4×10^6	1.5×10^6	2.0×10^6
STAPH	1.9×10^4	<10	<10	<10	<10	<10	<10
	2.6×10^3	<10	<10	<10	<10	<10	<10
Saline	2.2×10^7	1.4×10^7	*	9.4×10^6	4.1×10^6	5.0×10^6	3.8×10^6
PSEUDO	900	<10	<10	<10	<10	<10	<10
	<100	<10	<10	<10	<10	<10	<10
Saline	6.7×10^6	5.0×10^6	*	1.0×10^7	8.6×10^6	4.0×10^6	5.2×10^6
CANDIDA	1.5×10^4	<10	<10	<10	<10	<10	<10
	1.0×10^4	<10	<10	<10	<10	<10	<10
Saline	3.8×10^5	2.1×10^5	9.7×10^5	4.7×10^5	2.0×10^5	4.7×10^5	6.7×10^5
ASPERGILLUS	3.0×10^4	2.0×10^3	**	30	40	40	50
	3.1×10^4	1.6×10^3	**	20	30	20	40
Saline	8.0×10^5	9.0×10^5	**	1.0×10^6	1.6×10^5	1.6×10^5	1.0×10^5
Sample Blank	<10	<10	<10	<10	<10	<10	<10

** Analyst forgot to perform count on Saline controls.*
*** Unable to perform 24 hour count due to lack of media*
<10 = Less than 10