

Section III:
Manufacturing methods

1. Manufacturer

The new dietary ingredient is being produced by Global Cancer Strategies Ltd., Preventive Health Division Vancouver, British Columbia, Canada, intended to be distributed in the United States. It is manufactured by Central Pharmaceutical Co. Ltd., a Chinese GMP pharmaceutical manufacturer, addressed at 1 Fujin Avenue, Beichen District, Tianjin, China.

The product trade name of ACAPHA has been created by Global Cancer Strategies Ltd. for the North American market. The Chinese trade name is called Zeng Sheng Ping (ZSP), 增生平 or 抗癌乙片¹ (photo see appendix 1).

2. Name of the New Dietary Ingredient

The name of the new dietary ingredient is ACAPHA. Its Chinese name is Zeng Sheng Ping. The Binominal Latin names of the herbs used in the preparation of ACAPHA are:

Latin name: *Sophora tonkinensis* Gapnep
Family: leguminosae
Plant parts used: dried roots and taproot

Latin name: *Polygonum bistorta* L.
Family: polygonaceae
Plant parts used: dried rhizome

Latin name: *Prunella vulgaris* L.
Family: labiatae
Plant parts used: dried flower stem

Latin name: *Sonchus brachyotus* DC
Family: valerianaceae
Plant parts used: dried whole plant

Latin name: *Dictamnus dasycarpus* Turcz
Family: rutaceae
Plant parts used: dried root bark

Latin name: *Dioscorea bulbifera* L.
Family: dioscoreaceae
Plant parts used: dried rhizome

Sophora tonkinensis is considered the major ingredient in ACAPHA

3. Description of ACAPHA

ACAPHA is a traditional Chinese herbal supplement, prepared from six herbs in accordance with Chinese GMP regulations. Historically, it has been used in traditional Chinese medicine for its beneficial effects on epithelial tissues in association with the GI and respiratory tract.

3.1 Known Major Chemicals in Each Botanical

<i>Sophora tonkinensis</i>	<i>Polygonum bistorta</i>	<i>Prunella vulgaris</i>
/	/	/

<i>Sonchus brachyotus</i>	<i>Dictamnus dasycarpus</i>	<i>Dioscorea bulbifera</i>
/	/	/

3.2 Physical and Chemical Characteristics

The known major bio-active chemical compounds (and their respective natures) present in ACAPHA are listed in the table below.

Compound	Nature

13 PAGES TOTAL

REDACTED IN ITS
ENTIRETY

CONTAINS
TRADE SECRET
CONFIDENTIAL
COMMERICAL
INFORMATION

4. Level of Ingredients in ACAPHA

Each 600mg tablet of ACAPHA is represented by

<i>Sophora tonkinensis</i>	~~~~~
<i>Polygonum bistorta</i>	————
<i>Prunella vulgaris</i>	~~~~~
<i>Sonchus brachyotus</i>	————
<i>Dictamnus dasycarpus</i>	~~~~~
<i>Dioscorea bulbifera</i>	————

4.1 Recommended daily dose

The recommended total daily dose is 1.8g, 3 x 600 mg tablets/day.

4.2 Administration recommended

The tablets should be consumed three times, one tablet at a time orally with water or liquid, before meals.

4.3 Suggested labeling of new dietary supplement

The film coated tablets are packed in amber HDPE bottles, the top sealed with aluminum foil seal and closed with white plastic cap at 80 tablets per bottle and put in a carton box. The tablets are to be stored at ambient temperature between 15-30 degree Celsius. The product will be labeled as a dietary supplement for healthy cellular and respiratory function and for a healthy aerodigestive function. It will be targeted towards adults who are concerned with the increase in environmental pollutants in water, food and air.

4.4 Recommended Conditions of use

The product is intended for use by healthy adult males and females who are seeking to supplement their diet with herbal supplement to support the health of their epithelial tissues such as the oro-pharyngeal and respiratory tissues, i.e., support normal respiratory function in a smoke-rich environment, support respiratory health for those exposed to second hand smoking, support body's ability to cope with a polluted environment, may help minimize the risks to long-term health posed by exposure to environmental toxins.

5. List of appendices

1. Photos of the product of ACAPHA
2. Sanders, D.J., Minter, H.J., Howes, D., Hepburn, P.A., The safety evaluation of phytosterol esters. Part 6: The comparative absorption and tissue distribution of phytosterols in the rat. *Food & Chemical Toxicology* 2000;38:485-91
3. Heinemann, T., Axtmann, G., Von Bergmann, K., Comparison of intestinal absorption of cholesterol with different plant sterols in man. *European Jnl of Clin Investigation* 1993;23:827-831
4. Manufacturing records of ACAPHA
5. Drug stability testing results and conclusion/batch consistency and stability
6. Stability Testing