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PRE MARKET NOTIFICATION

Extract of *Padina Pavonica* (EPP)

1. The name and address of the manufacturer of the new dietary ingredient:

Institute of Benthique Algae Limited
Unite F 24 Mosta Technopark
Valletta Road
Mosta MST 09
Malta

The name and address of the importer of the new dietary ingredient:

ExtractsPlus, Incorporated
3275 Corporate View Drive
Vista, CA 92083

The name and address of the encapsulator into dietary supplement:

SSI
5800 Newton Drive
Carlsbad, CA 92008

Distributor of the dietary supplement containing new dietary ingredient:

Perfect Equation
3275 Corporate View Drive
Vista, CA 92083

2. Name of the new dietary ingredient

The name of the new dietary ingredient is EPP, an extract of the algae *Padina pavonica*.

3. Description

The description of the new dietary ingredient is as follows: EPP is a natural marine extract from the *Padina pavonica* brown algae; a member of the *Pheophyceae* genus. EPP is an off-white to tan, odorless, fine powder that will be presented for use as a hard gel capsule. This new dietary ingredient represents a whole extract of the plant.

4. Level of the new dietary ingredient in the dietary supplement and conditions and range of use on labeling:

Each hard-gel capsule will contain 200 mg of dry EPP. Adults should take 1 capsule by mouth, daily.

5. Safety:

Local divers handpick the algae throughout the year and deliver the plant to a dedicated laboratory on the Island of Malta. The dry Padina is active but activity varies with harvest site, season, depth, water temperature, light, and currents. I.B.A. applies its proprietary extraction process, outlined in Exhibit A, using strict guidelines to assure the safety and efficacy of the product. After extraction, testing by biological titration ensures the efficacy of the final product. This testing consists of a measure of the calcium fixation by osteoblasts in cell culture for each harvested batch to ensure consistency among batches and maximum efficacy.

Following European law CEE/67/548, EPP was tested for safety on rats and has been found to be non-toxic and safe for ingestion. In each of the following reports the test material is EPP, the same material as the ingredient we are seeking to offer for sale in the United States. Exhibit F contains letter by Gilles Gutierrez, pharmacist, certifying that the tested materials are identical to the new dietary ingredient, EPP. See the Chrysalis Report #944/007 of December 30, 1997 attached as Exhibit B. EPP is non-toxic or mutagenic per Ames II Assay. See the Xenometrix Report #BIO-1097 of October, 1997, attached as Exhibit C. Toxicity studies in animals show dosages of > 2000 mg/kg without toxicity, attached as Exhibits D and E.

In Asia, *Padina pavonica* is used as a food according to the United Nations Organization for Nutrition and Agriculture (Exhibit G). In addition, for more than a generation, people in Mediterranean countries have eaten the algae.

Since January, 2001, EPP, the same ingredient we seek to sell in the United States, has been for sale in Europe. During this time, there have been no reports of any unusual events or side effects. In addition, in November, 2002, the Malta Standards Authority, Medicines Regulatory Unit has approved the sale of EPP as a food supplement (Exhibit H).

Based upon the information summarized above and the attached Exhibits, we have concluded that the dietary supplement containing this new dietary ingredient is reasonably expected to be safe.