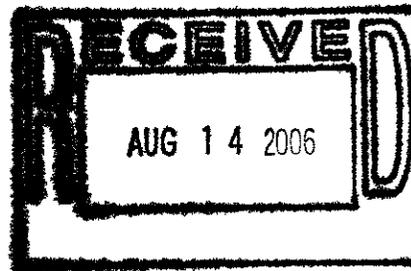


August 4th, 2006

DSHEA SUBMISSION/ Additional Info ENCLOSED

Sender: Michael G. Jeffers
JLM Marketing, Inc
700 North Walnut Street
Bloomington, IN 47404



Company: JLM Marketing, Inc.
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To: Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements, Center
for Safety and Applied Nutrition
Food and Drug Administration

RE: New Dietary Bulk Ingredient filing for Angelica gigas Nakai (Korean)
Extract (AGNE) as Bulk Manufacturing Ingredient and to be called
(Decursinol™)

Dear Sir/ Madame:

Pursuant to 21 CFR & 190.60 please be advised that JLM Marketing, Inc. of Tampa, FL, is hereby providing you with the notification if its intent to market a Bulk, New Dietary Ingredient, called Angelica gigas Nakai (Korean) Extract which is extracted from the root of the plant known as Angelica gigas Nakai. Enclosed with this original document are two additional copies of JLM Marketing, Inc's. submission and the attachments thereto.

Based on the following, JLM Marketing, Inc. respectfully submits that there are no safety issues relating to its intended marketing of Angelica gigas Nakai (Korean) Extract from the root of the Angelica gigas Nakai plant.

A) Name of the New Dietary Bulk Ingredient which we will call "Decursinol" in the US Market

- 1) Genus Name; Angelica
- 2) Author; Nakai
- 3) Family; Umbelliferae
- 4) Synonyms: Angelica cryptotaeniifolia-Kitag
- 5) Range; East Asia

2006-64576
ALMS

B) Description of the Bulk Dietary Ingredient

- 1) Source- Angelica gigas Nakai (Korean) Extract is derived from the plant called Angelica gigas Nakai. The extract is specifically derived from the root. The extraction process is Confidential and Proprietary and the extraction process is outlined as **Exhibit MP-A**. KFDA has approved the finished extract for the inventor, along with their finished product as defined in **Exhibit MP-B**. Chuncheon Bioindustry Foundation has validated the Manufacturing Sight for the manufacturing sight in **Exhibit MP-C**.
- 2) The key phytochemical components of Decursinol™ is decursinol and decursin. The quantitative analysis of two ingredients is performed in all commercial lots against the respective standards established in Exhibit SAG.
- 3) The Chemical composition is defined with CAS info. in **Exhibit AC**.
- 4) Composition of Matter- as defined by the following specification for Angelica gigas Nakai Extract or what we are calling “Decursinol™”, as **Exhibit SAG**.
- 5) Manufacturing Process of Decursinol™ Bulk Ingredient Extract.
Decursinol™ is manufactured from the extract of roots from Angelica gigas Nakai plants-grown on South Korea farms, and harvested after a minimum of 2 years of growth. A detailed manufacturing process can be found in Exhibit MP-A. The manufacturer has certification by KFDA for the Certificate of Free Sales, (**Exhibit KFDA-1**), and Certificate of Health in **Exhibit KFDA-2**.

C) Conditions of Use as an Bulk Dietary Ingredient

Dosage Rates from Human Clinical Studies:

- 1) To achieve 98% effectiveness suggested “ingredient” dosage rates to the recipient would be 250 mgs twice per day.
- 2) Response time to intake is projected at 45-90 minutes per the inventor, Scigenic Co., LTD of South Korea. This projection is based on the testimonials of users as well as the invitro pharmacokinetic study of AGNE (**Exhibit TS**).

Population Effect

- 1) Human clinical evaluations were conducted on a double blind study of 80 people with no negative results during consumption (RE: toxicity, etc.)
- 2) Angelica gigas Nakai Extract (Decursinol) as an “ingredient” has been used in commercial form in South Korea for over 2 years with no reports of side effects or toxicity in all genders and ages (per KFDA)

- 3) Historical Data surrounding the historical and cultural use of Angelica gigas Nakai as a holistic remedy in South Korea is posted in **Exhibit HD-EG**.

D) Comparison of AGNE (Decursinol™) as a Bulk Ingredient to the Commercial Form known as Joinwell which is manufactured and distributed in South Korea.

- 1) The Bulk Ingredient called Decursinol™ (AGNE) is suggested in dosage rates of 250 mg, twice per day, per human clinical evaluations (**Exhibit HCS**).
- 2) During the human clinical evaluations of AGNE “GWB78” was used as the clinical trial code name during the research phase of the Angelica gigas Nakai Extract. This is the same Angelica Gigas Nakai extract in this submission, but the inventor used the code name of GWB78 in the lab. Inventor information is posted in **Exhibit MSL**.
- 3) The finished COMMERCIAL form (capsules) which includes the plant extract Decursinol™ (AGNE) was developed in South Korea by Scigenic, LTD. Manufacturing and Distribution information is posted in Exhibit MSL.
- 4) The Commercial finished formula provided by Scigenic is a two piece capsule and includes 320 mg of Decursinol (AGNE) along with additional excipients such as Glucosamine Sulfate, Vitamins and various flow agents. The Commercial formula for Joinwell is listed in **Exhibit FF**. The Joinwell label in English and Korean is listed in **Exhibit FF-1**.
- 5) This COMMERCIAL form called Joinwell established market share upon approval by KFDA (Exhibit MP-B), and after full review of the AGNE by KFDA. Joinwell has been selling and thriving in the South Korea commercial sector for almost three years. Consumption includes all age groups and gender but the distributor in South Korea does not have 24 month Commercial “tracking data” as to which specific ages are consuming the Joinwell.
- 6) The phytochemical content of Jointwell™ and Angelica gigas Nakai Extract (AGNE or Decursinol™) being submitted as a bulk manufacturing ingredient are quantitatively and qualitatively equivalent. The inventor of the ingredient extract, (Exhibit MSL), is also the marketer of the finished form, Jointwell™, which is being marketed in South Korea as nutritional supplement.

E) The Safety of the Bulk Ingredient called Decursinol™, or AGNE (Angelica gigas Nakai Extract)

Pre-clinical clinical animal toxicology studies have found that AGNE has a good safety profile up to 2 gram/Kg (of body weight) dose level. The toxicology study report is shown in **Exhibit HCS**.

- 1) The Human Clinical evaluations did not show any indications of addictive properties, or gastro problems as identified in Exhibit HCS.
- 2) Negative results were found on Acute Toxicity, Genetic Toxicity, and Subacute Toxicity evaluations as identified in Exhibit HCS.
- 3) Stability Data is defined in **Exhibit SD** showing the long-term stability and effectiveness of AGNE under acceleration and temperature progression evaluations.
- 4) KFDA evaluated Angelica gigas Nakai Extract and found the use and human consumption of AGNE acceptable for South Korea as outlined in Exhibit KF-D.
- 5) The Specification of Decursinol™ is included as Exhibit SAG, and the MSDS Sheet for Decursinol™ is included as **Exhibit MS**.

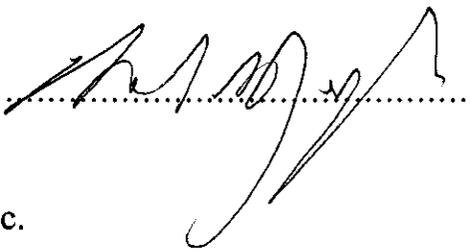
F) Literature as Points of Reference are posted in the human clinical evaluations

G) Summary

- 1) Based on the foregoing we believe that FDA should accept this filing on behalf of JLM Marketing, Inc. as providing sufficient evidence that Decursinol™ (AGNE), as a Bulk, New Dietary Ingredient, extracted from the root of the Angelica gigas Nakai plant, when used as suggested in the dosage rates defined in the Human Clinical Evaluations (as Exhibit HCS), can reasonably be expected to be safe for human consumption.
- 2) In support of this we have included all appropriate Exhibits defining the purity, safety, stability data, toxicity results, manufacturing protocols and specifications, animal studies, and human studies, of Decursinol™, or Angelica gigas Nakai Extract.

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If you have any further requirements for additional data please direct all correspondence to the undersigned.

Signed:.....

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