



Rakesh M. Amin, LL.M., R.Ph.

Direct (312) 327-3382
rakesh@amin-law.com

ASSOCIATES
Shannon McGarrah
Brian D. Grubb
Radna Kurra, LL.M.
Gokul Kishan, LL.M.

OF COUNSEL
Michael L. Clerkin, LL.M.

July 19, 2004

Division of Standards and Labeling Regulations
Office of Special Nutritionals (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RECEIVED
JUL 26 2004
BY: AB/FDA

Re: New Dietary Ingredient Notification

Dear Sir/Madam:

In accordance with 21 C.F.R. §190.6, Amin Law, on behalf of its client, Ztis, Inc., hereby notifies the U.S. Food and Drug Administration that the company intends to market the new dietary ingredient *Clematis mandshurica* and hereby submits the following information in support thereof.

An original and two copies of this notice are submitted pursuant to 21 C.F.R. §190.6(a). Please confirm receipt of this notice and maintain confidentiality of these submitted materials pursuant to 21 C.F.R. 190.6(c) and (e), respectively.

Thank you for your attention in this matter. Please call me if you have any questions at 312-327-3382.

Sincerely,

Rakesh M. Amin

89046



RECEIVED
Feb 10/20/2004

Rakesh M. Amin, LL.M., R.Ph.

Direct (312) 327-3382
rakesh@amin-law.com

ASSOCIATES

Shannon McGarrah
Brian D. Grubb
Radna Kurra, LL.M.
Gokul Kishan, LL.M.

OF COUNSEL

Michael L. Clerkin, LL.M.

October 18, 2004

Division of Standards and Labeling Regulations
Office of Special Nutritionals (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: New Dietary Ingredient Notification: *Clematis Mandshurica*

Dear Sir or Madam:

In response to the New Dietary Ingredient Notification that we submitted on behalf of our client, SK Pharma Co, Ltd, dated July 26, 2004, we ask that the following information be kept confidential pursuant to 21 C.F.R. §190.6(e) as it is considered proprietary information:

1. General Description, Section 2.1, page 4;
2. Product Description, Section 2.2, page 4;
3. Product Labeling Information, Section 2.3, page 4;
2. Summary of all Testing Results, Chapter 3, pages 5-7,
3. Certificate of Analysis, Chapter 4, page 8;
4. Phase III Clinical Trials, Section 4.3, pages 11-13;
5. 26-Week Toxicity Study, Section 5.3, pages 29-31; and
6. Original references included in the submission:
 - Jung et al., *A Four-Week, Randomized, Double-Blind Trial of the Efficacy and Safety of SKI306X, a Herbal Anti-Arthritic Agent Versus Diclofenac in Osteoarthritis of the Knee*
 - FINAL REPORT, JOINS™ (SKI306X), Twenty-six Week Oral Repeated Dose Toxicity Study with Four-Week Recovery Period in Rats, Study No. B03006.

We respectfully request that any and all information referenced to these studies which may not be included herein also be considered confidential.

Please note that the client information was incorrectly listed on the cover letter included in the NDI submission as Ztis, Inc. but the manufacturer/submitter was correctly identified on page 3 of the submission as SK Pharma Co, Ltd. and should be referenced as the client information in future communications. Thank you.

Sincerely,

Rakesh M. Amin