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August 19, 2003

**Documents Management Branch
Food and Drug Administration (FDA)
Department of Health/Human Services
5600 Fishers Lane, Room 4-62
Rockville, MD 20857**

**Re: Citizen's Petition (Addition) to Filings of March 16, 1998 Regarding
Labeling All Herbals, OTCs and Prescriptions Drugs for Adverse Drug
Effects and Drug Interactions**

Citizen's Petition Docket No. 98P-0169-CP1

Pharmacists Planning Service, Inc. (PPSI), a 501 C (3) nonprofit public health, consumer and pharmacy education organizations submits additions to its Citizen's Petition filed March 16, 1998, regarding the need for labeling the drug interactions and adverse drug events which are occurring when prescription drugs are mixed with herbal supplements. Herbal medicines can also alter test results by direct interference with certain immunoassays. Drug herbal interactions can result in unexpected concentrations of therapeutic drugs.

We would like to submit the enclosed two page document from US FDA Center for Food Safety and Applied Nutrition regarding dietary supplements, warnings and safety information on ten herbal and dietary supplement products including Aristolochic Acid, Comfrey, Ephedrine Alkaloids, Kava, LipoKinetix, PC SPES and SPES, St. John's Wort and Indinavir, Tiractricol, and Triax Metabolic Accelerator.

Also, Senate Bill 722 has been introduced in Congress to overturn the DSHEA Act which is the reason for our Citizen's Petition so that adverse drug events will be reported.

Sincerely,

Fred S. Mayer, R.Ph., M.P.H., President

98P-0169

SUP 3

U. S. Department of Health and Human Services
 U.S. Food & Drug Administration
 Center for Food Safety & Applied Nutrition

Dietary Supplements

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Warnings and Safety Information

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Alerts

- **Anthrax**
 - [Dietary Supplements Claiming to Prevent or Treat Anthrax](#) November 7, 2001
 - [FTC Cracks down on Marketers of Bogus Bioterrorism Defense Products](#) November 19, 2001
- **Aristolochic Acid**
 - [FDA Concerned About Botanical Products, Including Dietary Supplements, Containing Aristolochic Acid](#) April 11, 2001
- **Comfrey**
 - [FDA Advises Dietary Supplement Manufacturers to Remove Comfrey Products From the Market](#) July 6, 2001
- **Ephedrine Alkaloids**
 - see [Consolidated Information on Ephedrine Alkaloids](#)
UPDATED
- **Kava**
 - [Hepatic Toxicity Possibly Associated with Kava-Containing Products](#) (CDC MMWR Report, November 29, 2002)

The Food and Drug Administration (FDA) is advising consumers of the potential risk of severe liver injury associated with the use of kava-containing dietary supplements.

- [Consumer Advisory: Kava-Containing Dietary Supplements May be Associated With Severe Liver Injury](#) March 25, 2002
- [Letter to Health Care Professionals: FDA Issues Consumer Advisory That Kava Products May be Associated with Severe Liver Injury](#) March 25, 2002
- [Letter to Health Care Professionals about FDA Seeking Information on Liver Injury and Kava products](#) December 19, 2001

- **LipoKinetix: FDA Warns About Weight Loss Product**

FDA alerts consumers and health care professionals about LipoKinetix, a dietary supplement weight loss product. This product has been implicated in a number of serious adverse reactions related to several cases of liver injury.

- [FDA Warns Consumers Not to Use the Dietary Supplement LipoKinetix](#) November 19, 2001
- [Letter to Health Care Professionals on Hazardous Dietary Supplement LipoKinetix](#) November 19, 2001
- [Letter to Distributor on Hazardous Dietary Supplement LipoKinetix](#) November 19, 2001
- **PC SPES and SPES**
 - [MedWatch Safety Alert: Consumers Warned to Stop Using the Dietary Supplement/Herbal Products PC SPES and SPES](#) February 8, 2002
- **St. John's Wort and Indinavir**
 - [FDA Public Health Advisory: Risk of Drug Interactions with St. John's Wort and Indinavir and Other Drugs](#) February 10, 2000
- **Tiractricol**
 - [FDA Warns Consumers Against Consuming Dietary Supplements Containing Tiractricol](#) November 21, 2000
- **Triax Metabolic Accelerator**
 - [FDA Warns Against Consuming Triax Metabolic Accelerator](#) November 11, 1999
- **Other FDA Alerts**
 - [FDA Warns Public About Chinese Diet Pills Containing Fenfluramine](#) August 13, 2002
 - [FDA Recalls and Safety Alerts](#)
 - [FDA Import Alerts and Import Detention Reports](#)

Additional Safety Information

- [Products Consumers Inquire About:](#) Ephedra or Ephedrine; DHEA (dehydroepiandrosterone); Melatonin; Dieter's Teas; L-Tryptophan; Folic Acid; Gamma Hydroxybutyric Acid (GHB); Gamma Butyrolactone (GBL); and 1,4 Butanediol (BD)
- [MedWatch New Safety Information Summaries:](#) [2002](#) / [2001](#) / [2000](#) / [1999](#) / [1998](#) / [1997](#) / [1996](#)
- [Archived Information: FDA Warning Statements Issued from 1997 to January 1999](#)
- [Article on Herbal Products: Dangerous Combinations](#)
- [Illnesses and Injuries Associated With the Use of Selected Dietary Supplements \(1993\)](#)
- [Buying Medicines and Medical Products Online](#)
- [Other Sources of Safety Information](#) (such as NIH, USDA, etc.)
- [Letter to Stakeholders Regarding Contract on Dietary Supplement Safety Issues](#) December 15, 2000