Taiko Pharmaceutical Co., Ltd.

TEL(81) 6-6382-1041 FAX(81) 6-6319-2185 3-34-14, Uchihonmachi, Suita, Osaka, 564-0032, Japan



November 26, 2002

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740, U.S.A.

DEC 0 2 2002

Re: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

TAIKO PHARMACEUTICAL CO., LTD., 3·34·14 Uchihonmachi, Suita, OSAKA, JAPAN, who is the manufacturer of the following dietary supplement product, intends to make the following statement of support: "SEIROGAN Pills is a herbal dietary supplement to help regulate digestive system to maintain normal bowel functions." This claim is being made for Phellodendron Bark, Citrus Unshiu Peel, Gambir Leaves, Licorice Root, which are contained in Herbal Supplement SEIROGAN Pills. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the TAIKO PHARMACEUTICAL CO., LTD. and certifies that the information contained in this notice is complete and accurate, and that TAIKO PHARMACEUTICAL CO., LTD. has substantiation that the above statement is truthful and not misleading.

Yasuhide Nakagawa

General Manager of International Department

11266