



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 9, 2001

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-20

Mr. M. Yamamota, President
Uni-Heartous Pet Products, USA, Inc.
FSD Bldg. 7-20-9, Nishi Gotanda, Shinagawa0Ku
Tokyo 141-0031 Japan

WARNING LETTER

Dear Mr. Yamamota:

On September 21, 2000, an Investigator from our office performed an inspection of your pet food manufacturing facility located at 144 North Canal Street, Seattle, Washington. During this inspection, we determined your firm introduced animal food into the United States interstate commerce that was misbranded as defined by Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Section 501.15(c)(1). This regulation states, in part, "all words, statements, and other information required [on a pet food label] by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language". The product you manufactured and offered for sale in interstate commerce was labeled fully in what has been determined to be the Japanese language.

On November 15, 1999, your firm sold [REDACTED] cases of this pet food bearing no English language to [REDACTED] and on March 16, 2000, the product was shipped in interstate commerce. You informed our Investigator that you had obtained a verbal agreement that the product would be relabeled in English prior to being offered for sale to consumers in the United States.

According to 21 CFR 501.100(d)(2), any agreement concerning labeling of an animal food product at the location not controlled by the manufacturing firm must be written, signed by the person responsible for the labeling operation and meet specific criteria. The label for this food may also lead the consumer to believe it is a human food, and not meant as pet food, without a label bearing the English language.

As a manufacturer of animal food, you are responsible for assuring that your entire operation and practices and the food products are in compliance with the Act and applicable regulations.

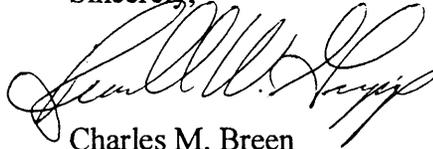
Mr. M. Yamamoto, President
Uni-Heartous Pet Products USA, Inc., Tokyo, Japan
Re: Warning Letter SEA 01-20
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You should take prompt action to establish procedures to prevent a recurrence of this violation. Failure to do so may result in regulatory action without further notice.

You should notify this office in writing within 15 (fifteen) working days of the receipt of this letter of the actions you have taken to comply with the Act. You may wish to include in your response documentation, or other useful information that would assist us in evaluating your corrections.

If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer at (425) 483-4913 or via e-mail at leland@ora.fda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen". The signature is fluid and cursive, with the first name "Charles" being the most prominent.

Charles M. Breen
District Director

Enclosures:

21 CFR PART 501
Section 403 of the Federal Food, Drug, and Cosmetic Act

cc: Perry S. Davids, General Manager
Uni-Heartous Pet Products USA, Inc.
144 North Canal Street