

December 22, 1967

REGULATORY LETTER
CHI-431-86

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Namir Kim, Owner
Modern Pharmacy
3432 W. Lawrence Ave.
Chicago, Illinois 60625

Dear Mr. Kim:

This letter is in regard to your marketing the products Heart Tonic, Gastro Intestinal Pills, Hiya Kiogan Silver, Tian Ma Hu Ku Pien, Peking Jen Tang, Po Chai Pills, Euberin, We Chung San Fine Granules, Ryukaku - San Powder Expectorant and Pien Tze Huang. Labeling distributed by your firm makes numerous claims for the products including, but not limited to, the following:

Heart Tonic: dyspnoea, angina pectoris, infarct of myocard.
Gastro Intestinal Pills: diarrhea, food poisoning, pain caused by dental caries.

Hiya Kiogan Silver: nervousness, convulsion, vomiting, diarrhea.

Tian Ma Hu Ku Pien: headache, rheumatic pains, numbness of limbs.

Peking Jen Tang: tranquilizes nervous strain, expectorant, delirium, vertigo.

Po Chai Pills: diarrhea, vomiting, influenza, gastro-intestinal disorders caused by intoxication.

Euberin: backache, pain.

We Chung San Fine Granules: gastric distress, heartburn, gastritis.

Ryukaku-San Powder Expectorant: cough, phlegm, throat discomfort.

Pien Tze Huang: hepatitis, otitis, inflammations.

Because such labeling includes statements which represent and suggest that the articles are intended to affect the structure or function of the human body or to diagnose, cure, mitigate, treat or prevent disease conditions, these products are considered drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

We are unaware of substantial scientific evidence which demonstrates that the composition of these drugs is generally recognized as safe and effective therapy for any such intended uses. Distribution of these products is a serious violation of the Act as follows:

SECTION

BRIEF DESCRIPTION

502(a)

The articles of drug are misbranded in that their labeling is false and misleading by representation and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the conditions specified in their labeling.

502(c)

The article of drug, Euberin, is further misbranded in that words, statements, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

502(f)(1)

The articles of drug are further misbranded in that their labeling fails to bear adequate directions for use for the conditions for which the articles are represented or suggested, and they are not exempt from this requirement under Regulation 21 CFR 201.115 since the articles are new drugs within the meaning of Section 201(p), and no approval of applications filed pursuant to Section 505(b) are effective for the said article of drug.

505(a)

The articles are new drugs within the meaning of Section 201(p) of the Act, and no approvals of applications filed pursuant to Section 505(b) of the Act are effective for such drugs.

The violations and products listed above are not meant to be all inclusive. It is your responsibility as a drug distributor, to ensure that all of your present products as well as any similar products intended for further distribution are the subject of approved new drug applications wherever appropriate and that the products are properly labeled for their intended uses.

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We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions provided under the law. These include seizure and/or injunction.

Please notify us within ten (10) days of the steps you have taken to correct these violations. Your response should be directed to Larry E. Ormsbee, Director, Compliance Branch, Food and Drug Administration, 433 W. Van Buren, Chicago, IL 60607.

Sincerely yours,

Raymond V. Mlecko
District Director
Chicago District

RVM/CLR/klc

cc: HFR-5150
cc: HFN-300
cc: HFN-304
cc: HFA-224
cc: HFI-35
cc: CHI-DO
cc: CLR
cc: LEO