June 29, 1990

REGULATORY LETTER
CHI-512-90

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Charles B. Ingersoll, President
Ingersoll & Associates
227 Oswald Avenue
Batavia, IL 60510

Dear Mr. Ingersoll:

This letter is in reference to the marketing of Harmony Lecithin Triple-Strength Capsules, Harmony Lecithin Granules, Harmony Lecithin Powder and Harmony Lecithin Keylex Granules by your firm.

Promotional material (labeling) distributed with these products states or suggests that by virtue of their lecithin content these articles can treat senile behavior; prevent and treat heart disease and atherosclerosis; and are useful in the treatment of Alzheimer's disease, tardive dyskinesia, manic depression, memory loss, acne and aging skin.

Because such labeling includes statements which represent and suggest that these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial scientific evidence which documents that these drugs are generally recognized as safe and effective for the above referenced disease conditions or any other disease conditions. The drugs are therefore, new drugs within the meaning of Section 201(p). Accordingly, marketing of these drugs is a violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION 502(a)

The articles of drug are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the treatment of the above listed disease conditions.
The articles of drug are misbranded in that their labeling fails to bear adequate directions for use in the treatment of the above listed disease conditions for which the articles are represent-ed 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 any application filed pursuant to Section 505(b) are effective for these drugs.

The articles of drug, Harmony Lecithin Triple-Strength Capsules, Harmony Lecithin Granules, Harmony Lecithin Powder and Harmony Lecithin Keylex Granules are further misbranded in that their labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which they are offered are not amenable to self diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for the purposes for which they are intended.

The articles, Harmony Lecithin Triple-Strength Capsules, Harmony Lecithin Granules, Harmony Lecithin Powder and Harmony Lecithin Keylex Granules, are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug, and Cosmetic Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approvals of any applications filed pursuant to Section 505(b) are effective for such drugs.

In addition, the labels for Lecithin Triple-Strength Capsules, Lecithin Granules, Lecithin Powder and Lecithin Keylex Capsules are in violation of the following food labeling provisions of the Act:

The products identified as Lecithin Triple-Strength Capsules, Lecithin Granules, Lecithin Powder 25%, and Lecithin Keylex Capsules bear declarations of lecithin components according
to potency which may mislead consumers to believe that lecithin and/or its components are essential nutrients, whereas, there is no known dietary requirement of lecithin for humans, and there is no U.S. RDA established for choline.

Additionally, the statements "...Harmony Lecithin Granules are a natural food supplement..." and "...Harmony Lecithin powder is a natural food supplement..." on the left panel of the respective labels falsely represent these products to be essential nutrients for which U.S. RDA's have been established.

On "Lecithin Triple Strength capsules" and "Lecithin Keylex Capsules" label statements concerning "brain biochemists and cardiovascular researchers" represent and suggest that the products have special nutritional value in promoting brain and cardiovascular health, which representation and suggestion are false and misleading, because they are contrary to fact.

The labels (all) make nutritional claims but fail to bear nutrition labeling in accordance with 21 CFR 101.9.

The ingredient statement and the name and address (all labels) of the manufacturer, distributor or packer are not declared in a size type of at least 1/16 of an inch in height as required by 21 CFR 101.(2)(c).

The labels (all) fail to bear the name and address of the manufacturer, packer or distributor together on the information panel with the nutrition information.

The triple strength capsules and Keylex capsules products are fabricated from two or more ingredients, but their labels fail to declare each ingredient by its common or usual name.

The net contents statement (all labels) is not in a size of type established in relationship to the area of the principal display panel as required by 21 CFR 101.105.(i).
We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of these products. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

Your response should include:

1) An estimate of the quantities of the drugs manufactured or received within the past twelve (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amounts of the drugs that are in inventory under your control and your estimate of the amounts in distribution channels outside your control.

4) The date of discontinuance in the event that you have already discontinued marketing these drugs products.

5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to Jerome Bressler, Director, Compliance Branch.

Sincerely,

Raymond V. Mlecko
District Director