



May 5, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2004-10

Mark G. Ganaban
Director of Finance
Hyalogic, LLC
P.O. Box 13736
Edwardsville, Kansas 66113-0736

Dear Mr. Ganaban:

An investigator from the Food and Drug Administration inspected your facility at 10601 Kaw Drive from December 18, 2003 to January 8, 2004. During this inspection, the investigator collected labeling for your product, Synthovial Seven. We have reviewed the collected labeling as well as your web site at www.hyalogic.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your product Synthovial Seven. You can find the Act and implementing regulations through links on FDA's Internet home page at: www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. The labeling of your product Synthovial Seven bears the following claims:

- Internet web site
 - "Hyaluronic acid (HA) has been proven by numerous medical studies to alleviate pain and suffering from arthritis of the knee and other joints Synthovial 7™ is an oral solution made from premium grade hyaluronic acid..."
 - "Patent Approved for... Arthritis and Fibromyalgia."
- Product package:
 - "Eliminate joint pain and enjoy...faster wound healing."

These claims cause your product to be drugs as defined in section 201(g)(1)(B) of the Act. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Your product is labeled as a dietary supplement; however, the labeling also contains claims that cause the product to be a drug. Even if the labeling for this product did not contain such claims, as a dietary supplement the product would violate other provisions of the Act. Under the Act, dietary supplements may be legally marketed with claims that they affect the structure or function of the body (structure/function claims), if certain requirements are met. The manufacturer of a dietary supplement containing a "structure/function" claim in the product's labeling must have substantiation that the claim is truthful and not misleading [Section 403(r)(6)(B) of the Act].

The labeling of your product Synthovial Seven bears the following structure/function claims:

- Internet web site:
 - "More cushioning and lubricating properties for the joints..."
 - "Other benefits may include: Increased Mobility..."
- Product package:
 - "As we age, the body produces less and less hyaluronic acid. The joints become stiff, the movement painful... [E]njoy the...anti-aging benefits of hyaluronic acid throughout the body: increased mobility..."

We have reviewed these claims and have concluded that they are not supported by reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Act. It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded.

This letter is not an all-inclusive review of the products that your firm markets and the claims you make in your product labels and labeling, including your Internet website, www.hyalogic.com. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against the manufacturers and distributors of those products. You should take prompt action to correct the violations identified in this letter. Failure to do so may result in enforcement action without further notice.

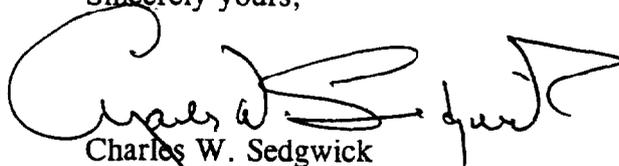
Please advise this office, in writing and within fifteen (15) working days of receipt of this letter, as to the specific steps that you have taken to correct any violations and to assure that similar violations do not occur. If corrective action cannot be completed within fifteen

Mark G. Ganaban, Director of Finance
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working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Joseph G. Kramer, Compliance Officer, at the above address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with a large initial "C" and a long, sweeping tail.

Charles W. Sedgwick
District Director
Kansas City District