



WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 27, 2001

WL-21-02

Laura L. Wochner, President and CEO
Island Kinetics, Inc.
6002 S. Ash Avenue
Phoenix, AZ 85283

Dear Ms. Wochner:

During an inspection of your Phoenix, Arizona cosmetic and drug manufacturing firm conducted between the dates of September 7 and September 20, 2001, our investigator documented serious deviations from Current Good Manufacturing Practice Regulations (CGMPs) found in Title 21 of the Code of Federal Regulations, parts 210 & 211 (21 CFR § 210 & 211) for those of your products which are deemed drugs within the meaning of Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). Such drug products include, but are not limited to, such products as sunscreens, acne products, eczema/psoriasis products and products claiming to be anti-inflammatory or anti-microbial. These deviations cause your drug products to be adulterated within the meaning of Section 501 (a)(2)(B) of the Act. For example:

1. Failure to establish a written procedure for production and process control designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess. Specifically, our inspection disclosed that with the exception of the unsigned product formula sheets for each product your firm manufactures, there are no approved, formal written procedures governing the production of drug products at your firm, and that as you indicated to our investigator, many aspects of production are handled "verbally". [21 CFR 211.100(a)].
2. Failure to establish master production and control records for each drug product, including each batch size, which are prepared, dated and signed by one person and independently checked, dated and signed by a second person. Such records must also include the requirements set forth in 21 CFR 211.186(b). Specifically, the unsigned product formula sheets for each drug product your firm manufactures are deficient in a number of respects:

- The product formula sheets have typed names of individuals, but are not signed, and bear no indication as to having been independently reviewed and checked.
 - The product formula sheets lack such basic requirements as statements of theoretical weight or measure at appropriate phases of processing; statements of theoretical yield including the maximum and minimum percentages of theoretical yield beyond which investigation is required; a description of the drug product containers, closures and packaging materials including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling; and complete manufacturing and control instructions including sampling and testing procedures.
3. The product formula sheets, when used as batch production and control records, fail to adequately meet the requirements set forth in 21 CFR 211.188. For example, the product sheet for batch T0G1101, Acme Treatment, does not reflect that each significant step was done (some lines are crossed through, others are not); is not dated; lacks the weights and measures of components used in the course of processing; has no mention of in-process or laboratory results; bears no statement of actual vs. theoretical yield; lacks a description of any labeling control records; does not describe the drug product containers and closures; does not indicate if any sampling was performed; does not identify the persons performing and directly supervising or checking each significant step; and is altered with the words "not used" written alongside one of the ingredients with no explanation.
 4. Laboratory controls are insufficient; other than recording of pH readings on the batch records, there is no documentation for raw material, in-process and finished product testing to assure conformance to appropriate written specifications, and that appropriate stability testing is performed according to a written program designed to assess the stability characteristics of the finished drug products [21 CFR 211.160 through 211.166]
 5. Your firm lacks written procedures describing the handling of all written and oral complaints regarding a drug product. A formal complaint file is not maintained, although there are indications that complaint records exist. For example, our investigator was advised, in relation to an injury complaint received on a custom formulation product made for an individual customer, that the file was kept at home and not regarded as a product quality issue, but rather as a legal issue. A written record of each complaint is to be maintained in a file designated for drug product complaints, at the establishment where the drug was manufactured.

We note further, with respect to the drug products, that you are required to register as a drug manufacturer with the FDA in accordance with Section 510 of the Act. During the inspection, you were provided with information on how to obtain the appropriate forms on drug registration and listing.

The above-described violations are not intended to be an all-inclusive list of those conditions existing at your firm. As was explained to you, this inspection focused on your firm's overall quality system approach to the manufacturing of drugs, and as such, was focused principally on quality and production systems. The CGMP's for human drugs represent an established systematic

and documented approach to the manufacture of drug products, to assure they are not adulterated or misbranded within the meaning of the Act, and you are responsible for all sections within 21 CFR 211 which apply to your drug products, not solely the sections referred to above. At the close of the inspection, our investigator provided you with a copy of the regulations in Title 21 CFR which deal with the CGMP's for human drug products. It is your responsibility to ensure that all requirements of the Act and promulgated regulations are being met.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes, but is not limited to, seizure and/or injunction. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

Please note that we have not undertaken a review of product labeling at this time; we shall advise you separately of any labeling violations after we complete our review of the labels and labeling collected during the inspection.

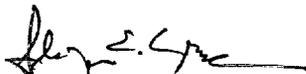
You should also notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you plan to take to assure that each of the noted violations will be corrected. Your response should also include an explanation of the specific steps that will be taken to prevent the recurrence of similar violations.

This case has been assigned to compliance officer Barbara J. Rincon at the Los Angeles District office; should you need clarification concerning the content of this letter, you may contact her at (949) 798-7739.

Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612

Sincerely,



Alonza E. Cruse
District Director

cc: Linda J. Walker, Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief