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No purging needed



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2329M

JAN 21 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Huan-Chen Li, M.D., Ph.D.
Hon-Tech Foundation for Medical Technology
P.O. Box 400956
402 Rindge Avenue 17H
Cambridge, Massachusetts 02140

Re: Li's Itch Stopper, K963824

Dear Dr. Li:

The Food and Drug Administration (FDA) has reviewed your web site for the Itch Stopper at the internet address: <http://www.itchstopper.com>. This product is manufactured by Xiangfen Dai-You Medical Devices, China, is distributed by Hon-Tech Foundation for Medical Technology (Hon-Tech) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Itchstopper has been cleared under section 501(k) of the Act and is intended for the prompt, temporary stopping for up to 24 hours of skin itching due to insect (mosquito) bites.

Hon-Tech's web site makes claims for the Itchstopper which have not been cleared by the agency i.e., treatment/cure of poison ivy, eczema, psoriasis, herpes, acne, and the cure of acute skin problems.

Under the provisions of Title 21, Code of Federal Regulations, Part 801.4 [21 CFR 801.4], the intended use of a device [objective intent] may be shown by the circumstances surrounding the distribution of the product. This objective intent may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by labeling claims that the article is, with the knowledge of such persons or their representatives, offered and used for purposes for which it is neither labeled nor advertised. Hon-Tech's web site for the Itchstopper clearly establishes the intended use of the product as being used for the treatment/cure of the above mentioned medical conditions.

Claims for the treatment/cure of poison ivy, eczema, psoriasis, herpes, acne,

the intended use of the device as described under 21 CFR 807.81(a)(3)(ii) and requires the submission of a new 510(k) prior to marketing the device with such claims.

The Itchstopper is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Itchstopper is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

The agency requests that you submit data to support the following statements which appear on your web site: (1) "may cure acute skin problems in one day;" (2) "temporarily stops the degranulation process of skin mast cells and in some situations, destroys endogenous or exogenous toxins in the skin;" (3) "works by activating the healing genes and by destroying toxins in your skin;" (4) "does not cause DNA damage or skin cancer;" (5) "more effective than UV at activating stress genes;" and, (6) "destroys toxins below the surface of the skin."

This letter is not intended to be an all-inclusive list of deficiencies associated with your Itchstopper. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within

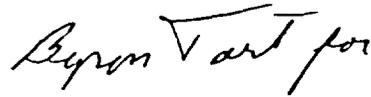
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15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New England District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New England District Office (HFR-NE200), One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health