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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

Richard Koo
President
Helio Medical Supplies, Inc.
606 Charcot Avenue
San Jose, California 95131

Re: AcuGlide Acupuncture Needles

Dear Dr. Koo:

The Food and Drug Administration (FDA) has reviewed promotional materials for the AcuGlide Acupuncture Needles. These products are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The AcuGlide brand Acupuncture Needle has been cleared for marketing via premarket notification (510(k)) K012583, and is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

In our previous letters of September 14 and November 26, 2001, we cautioned you about claims made for the then-uncleared/pending AcuGlide needles. We cautioned you that any representations you may make in the labeling of a device that are false or misleading with respect to another device may render your device misbranded in accordance with 21 CFR 801.6.

We have recently reviewed a product advertisement entitled "Innovation, Quality & Value." Claims made include the following:

"AcuGlide The Finest Acupuncture Needle Ever Engineered," "We are proud to introduce the finest acupuncture needle ever developed," "There is no silicone on the needle When there is a better alternative, Why take the silcone (sic) risk?**,", "This results in a surface far smoother than any other needle, including those with a silicone coating," and "...we have produced a needle safer, smoother and more comfortable than any silicone coated needle, without the risk of silicone exposure to your patients.* AcuGlide is the finest needle available on the market today!"

The asterisked material refers readers to the following, “Silicone granuloma on the entry points of acupuncture, venepuncture (sic) and surgical needles’ Journal of Cutaneous Pathology 2000:27:301-305”

The AcuGlide premarket submission was found substantially equivalent to other acupuncture needles already on the market. We have previously advised you that any legally marketed silicone-coated acupuncture needle has been cleared or approved by the Center for Devices and Radiological Health’s (CDRH) Office of Device Evaluation (ODE). ODE has not determined that the use of silicone coating is unsafe. Representations that the AcuGlide is safer, painless, and more comfortable than silicone coated needles render your device misbranded in accordance with 502(a) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 801.6. The AcuGlide Acupuncture Needles are misbranded within the meaning of section 502(a) of the Act, in that the labeling for the device contains statements that are false and misleading.

This letter is not intended to be an all-inclusive list of deficiencies associated with your devices. 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 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 Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

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A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,



Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health