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

WARNING LETTER

NOV 28 2000

VIA FEDERAL EXPRESS
VIA FACSIMILE

Dale M. Abadir, M.D.
Michelle C. Abadir, M.D.
Abadir Associates
90 South Ridge Street, #LL3
Port Chester, New York 10573

Re: Adatomed Silicone Oil OP5000
(a.k.a. AdatoSil 5000™), P910071

Dear Drs. Abadir:

The Food and Drug Administration (FDA) has reviewed a recent advertisement from your office titled, Fun Fall Ideas which includes statements related to a product identified as AdatoSil®. AdatoSil®, a registered trademark for AdatoSil 5000™, is manufactured by Chiron Vision Corporation (Chiron). The device was originally cleared as Adatomed Silicone Oil OP5000 and renamed in a supplemental application to the agency as AdatoSil 5000™. AdatoSil 5000™ is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

AdatoSil 5000™ was approved by FDA through the Premarket Approval process (PMA) on November 4, 1994, pursuant to section 515(d)(1)(B)(ii) of the Act. It is indicated for use as a prolonged retinal tamponade in selected cases of complicated retinal detachments where other interventions are not appropriate for patient management. Complicated retinal detachments or recurrent retinal detachments occur most commonly in eyes with proliferative vitreoretinopathy (PVR), proliferative diabetic retinopathy (PDR), cytomegalovirus (CMV) retinitis, giant tears, and following perforating injuries. AdatoSil 5000™ is also indicated for primary use in detachments due to Acquired Immune Deficiency Syndrome (AIDS)-related CMV retinitis, and other viral infections.

Your flyer, Fun Fall Ideas, promotes AdatoSil® for unapproved cosmetic procedures. The advertisement states, "Collagen and the newer Dermalogen® and Adatosil® can be used to fill in upper lip lines, those grooves around the mouth, even the circles around the eyes to revive and freshen your appearance. These are easy ways to polish your image."

Although physicians may use a legally marketed medical device to treat patients for any intended use that he/she desires within the bounds of his/her state licensing requirements, a licensed practitioner may not promote a medical device for use(s) for which they have not received FDA clearance.

Your promotion of AdatoSil® [sic] for cosmetic uses such as filling upper lip lines, filling grooves around the mouth, filling circles under the eyes, and/or “to revive and freshen your appearance” is a violation of the law. In legal terms, AdatoSil 5000™ 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 AdatoSil 5000™ is also misbranded within the meaning of section 502(o) of the Act, in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510(k), was not included in a list required by section 510(j), and a notice or other information respecting the device was not provided to the FDA as required by section 510(k).

This letter is not intended to be an all-inclusive list of deficiencies associated with the use of the AdatoSil 5000™. 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 center and/or medical practice. 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 the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

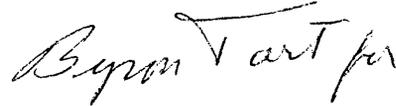
Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to 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 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.

Page 3 – Drs. Dale and Michelle Abadir, M.D.

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New York District Office (HFR-NE100), 850 Third Avenue, Brooklyn, New York 11232.

Sincerely yours,

A handwritten signature in cursive script that reads "Larry D. Spears". The signature is written in black ink and is positioned above the printed name.

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health