



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94619d

FEB 12 2004

WARNING LETTER

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

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Sergio Finkielsztein
President
Marine Polymer Technologies, Inc.
107 Water Street
Danvers, Massachusetts 01923

Re: Syvek NT Patch, K972914, K984177

Dear Mr. Finkielsztein:

The Cardiovascular and Neurological Devices Branch (CNDB), Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed labeling and promotional materials for the Syvek NT Patch, submitted to our office on August 6, 2003, by [REDACTED], your legal representative. The Syvek NT Patch is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This review reveals that your company is promoting the Syvek NT Patch for a new intended use for which you have not received premarket clearance or approval.

Marine Polymer Technologies (MPT) received two substantial equivalence determinations (510(k)'s), permitting marketing of the Syvek NT Patch as follows:

-K972914, cleared as a medical adhesive tape and bandage for Over the Counter (OTC) use under product code KGX, December 22, 1997. The intended use is: "intended for the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy."

-K984177, cleared as a hydrophilic wound dressing for both prescription and over the counter use under product code KMF, December 18, 1998. The intended use under the direction of a healthcare professional is identical to K972914, i.e., "intended for the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy," but also adds the following: "for use in the local management of bleeding wounds such as vascular access site, percutaneous catheters or tubes, or surgical debridement."

The materials you submitted demonstrate that MPT is marketing the Syvek NT Patch for intended uses that do not fall within these existing clearances. These materials include three advertisements bearing the heading "vascular access site hemostasis." Two of these

advertisements include color diagrams with captions illustrating the application of the Syvek NT Patch, with pressure, at the skin surface, and then documenting vasoconstriction, resulting in a cessation of bleeding from the vessel itself. These diagrams illustrate formation of a clot at the point of vessel puncture, extending up through various tissues, to the skin surface.

One of these advertisements bears the heading "Rapid Hemostasis at Hand." It states:

- "Faster than traditional compression. Less risk of infection, fewer complications, and less expensive than percutaneous devices. Syvek NT accelerates the progression of hemostasis."
- "Total relief in just minutes of compression"
- "no contraindications"
- "no risk of infection"

The other advertisement bears the heading "Accelerate Hemostasis without Complications." Under the heading of "Problem", it states:

There is a need for a better way to manage bleeding at the vascular access site. Manual compression is safe, but it is also time consuming and expensive in terms of labor costs. Percutaneous devices provide speed; however studies document complications such as more frequent hematoma and increased need for vascular surgical repair at the access site. A method that offers speed and safety would be ideal.

Under the heading of "Solution," the advertisement states,

Syvek NT actually accelerates the progression of hemostasis. Applied externally, it eliminates the complications of invasive devices, yet matches their speed. Syvek NT requires just minutes of compression.

Syvek's third advertisement does not illustrate use of the device but states that Syvek NT is "Faster than traditional manual compression."

These three advertisements thus compare the use of the Syvek NT Patch to "traditional manual compression" and to the use of percutaneous devices, both of which are used to achieve primary closure of a puncture in a blood vessel, thus ceasing bleeding from the vessel itself. Your graphics specifically illustrate this effect. Achieving proper hemostasis at this location is of significant importance to human health. Failure to achieve hemostasis of arterial punctures can result in significant complications which include puncture site bleeding requiring transfusion, late puncture site bleeding (i.e., following hospital discharge), puncture site hematoma greater than or equal to 6 cm, tissue ischemia, and tissue compression injury (such as nerve compression injury) due to hematoma compression of adjacent tissue.

By comparing the use of the Syvek NT Patch to manual compression alone and to the use of percutaneous devices, the purposes of which are well-known, you have indicated that the Syvek NT Patch may be used for the same purpose, of closing the vascular puncture site and stopping bleeding from the vessel itself. (In fact, you indicate that the Syvek NT Patch is superior to other existing methods of stopping bleeding from the vessel.) Use to achieve rapid cessation of bleeding at the vessel itself is a significant modification in the intended use of the Syvek NT Patch devices, requiring a new premarket notification submission as required by Title 21, Code of Federal Regulations, Part 807.81(a)(3)(ii).

Your prior correspondence indicates your belief that your promotional materials fall within your existing clearance as a hydrophilic wound dressing "for use in the local management of bleeding wounds such as vascular access site." It is true that your materials use the phrase "vascular access site." However, as already explained, your materials indicate that using the Syvek NT Patch will promote rapid, complication-free closure of the puncture in the blood vessel and thus cessation of bleeding from the blood vessel itself. By contrast, your existing clearance as a hydrophilic wound dressing is limited to use in managing external bleeding. Wound dressings are all devices with external application and effect. Your premarket notification submissions did not contain any information addressing the safety or effectiveness of your product in managing bleeding or promoting hemostasis internally, at the point of puncture in the vessel itself, nor are the predicate devices on which your substantial equivalence determination was based intended to have an effect on internal body structures.

Your promotion and introduction into interstate commerce of the Syvek NT Patch for these uncleared indications renders your devices adulterated under section 501(f)(1)(B) of the Act, for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency [21 CFR 807.81(b)].

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 applicable requirement of the Act and regulations for every FDA-regulated product that you market. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, or civil money penalties. Also, Federal agencies are informed about Warning Letters we issue, such as this one, so they may consider this information when awarding government contracts.

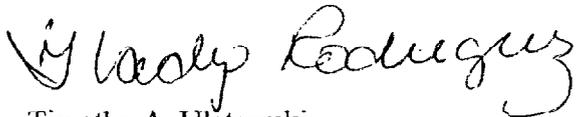
Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please direct your response to Mr. Steven E. Budabin, M.S., Consumer Safety Officer, Cardiovascular and Neurological Devices Branch (HFZ-341), at the letterhead address.

Finally, we acknowledge receipt of the labeling materials for [REDACTED] and [REDACTED]. Each complaint will be evaluated and the extent of any follow-up is dependent upon the nature of the problem, the possible impact on the public health, and the availability of our resources. In all situations, Federal rules prohibit us from discussing the status of any of our investigations until they are completed. Information on actions or correspondence resulting from a complaint may be obtained pursuant to a Freedom of Information Act (FOIA) request. Written requests of information may be sent to the following address:

Freedom of Information Office
5600 Fishers Lane
HFI-35, Room 12A16
Rockville, Maryland 20857

Sincerely yours,

for 
Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

[REDACTED]