



MAY 24 2000

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850**WARNING LETTER****VIA FEDERAL EXPRESS****VIA FACSIMILE**

Endre A. Balazs, M.D.  
Chief Executive Officer  
Biomatrix, Incorporated  
65 Railroad Avenue  
Ridgefield, New Jersey 07657

Re: Hylasine, K993362

Dear Dr. Balazs:

The Food and Drug Administration (FDA) has reviewed a March 29, 2000 press release as well as your web site at <http://www.biomatrix.com> for Hylasine Gel. This product is manufactured by Biomatrix, Incorporated (Biomatrix) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

In your original 510(k) submission, Biomatrix claimed that Hylasine was intended for use in sinus cavities to reduce the formation of synechiae/adhesions, reduce middle meatal stenosis (occlusion), to allow for unimpeded tissue healing, and to still operative bleeding occurring during and/or after endoscopic sinus surgery. After reviewing your submission, FDA's Office of Device Evaluation (ODE) determined that there were insufficient data to support these claims and limited your clearance for Hylasine to the following: *Intended for use in nasal/sinus cavities as a space occupying gel stent, to separate the mucosal surface and to help control minimal bleeding following surgery or nasal trauma.*

Your press release of March 29 makes similar claims for Hylasine that have not been cleared i.e., coats surgically altered tissue, stills intra-operative bleeding, and reduces post-surgical scarring and adhesions.

These claims represent a major modification in the intended use of the device as described under 21 CFR 807.81(a)(3)(ii) and require the submission of a new 510(k).

Continued promotion of Hylasine for coating surgically altered tissue, stilling intra-operative bleeding, reducing post-surgical synechiae/adhesions, or reducing middle meatal stenosis (occlusion), causes your device to be 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 Hylasine Gel is also misbranded within the meaning of section 502(o) of the Act, in that a notice or

Page 2 – Endre A. Balazs, M.D.

other information respecting the modifications in the intended use of the device were 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.

Please submit the data that would support claims of minimizing patient discomfort and shortening post-operative rehabilitation.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Hylasine device. 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.

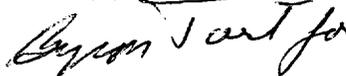
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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 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 Jersey District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New Jersey District Office (HFR-MA300), Waterview Corporate Center, 10 Waterview Boulevard, 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054.

Sincerely yours,



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