WARNING LETTER

XO Biologix, LLC

MARCS-CMS 697717 — DECEMBER 12, 2024

Delivery Method:
VIA UPS and Electronic Mail
Reference #:
CBER 25-697717
Product:
Biologics

Recipient:
David P. Janice
Chief Executive Officer and Owner
XO Biologix, LLC
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Austin, TX 78746
United States

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Issuing Office:
Center for Biologics Evaluation and Research (CBER)
United States

WARNING LETTER

CBER 25-697717

December 12, 2024

Dear Mr. Janice:

The United States Food and Drug Administration (FDA) inspected your facility located at the above address between January 3, 2024, and January 5, 2024. During the inspection, FDA documented that your company markets and distributes a product derived from amniotic fluid, MaviX™, pursuant to a contract with **(b)(4)** (hereinafter, "MaviX™" or "your product").

This letter is to advise you that your product is an unapproved new drug in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Your introduction or delivery for introduction of your product into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. § 331(d). Your product is also an

unlicensed biological product in violation of section 351(a)(1) of the Public Health Service Act (PHS Act), 42 U.S.C. § 262(a)(1)(A).

This Warning Letter also notifies you that your products are adulterated due to significant violations of current good manufacturing practice (CGMP) requirements identified at **(b)(4)**, including violations of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. § 351(a)(2)(B), and 21 CFR parts 210 and 211 (See Warning Letter number CBER 25-679023). Your firm is responsible for ensuring that all phases of the production of your product comply with CGMP requirements regardless of who manufactures, processes, packs, or holds it. Because the methods, facilities, or controls for manufacturing, processing, packing, or holding drugs do not conform to CGMP, your product is adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. § 351(a)(2)(B). Furthermore, MaviX™ is also misbranded under sections 502(a) of the FD&C Act, 21 U.S.C. § 352(a).

Your introduction or delivery for introduction of MaviX™, an adulterated and misbranded drug, into interstate commerce is a prohibited act under section 301(a) of the FD&C Act, 21 U.S.C. § 331(a).

Unapproved New Drug and Unlicensed Biological Product Violations

Based on information and records gathered prior to, during, and after the inspection and other information available to FDA, including your website (https://xobiologix.co/), your product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or conditions in humans and/or is intended to affect the structure or function of the body. For example, MaviX™ promotional material obtained during your inspection states the following: “Patient Benefits: Helps reduce pain, inflammation, and regenerate tissue”. Further, your website indicates that “MaviX™ is a heterogeneous, complex mixture of cell and tissue building blocks, which play a key role in repair and regeneration” and describes MaviX™ as “Anti-Inflammatory” and “Anti-Fibrotic.” Your product is therefore a drug as defined in section 201(g)(1) of the FD&C Act, 21 U.S.C. § 321(g)(1). Additionally, your product is a biological product as defined in section 351(i) of the PHS Act, 42 U.S.C. § 262(i).[1]

Subject to certain exceptions not applicable here, to lawfully introduce or deliver for introduction into interstate commerce a drug that is a biological product, a valid biologics license application (BLA) must be in effect under section 351(a)(1) of the PHS Act, 42 U.S.C. § 262(a)(1). Such licenses are issued only after showing that the products are safe, pure, and potent. Your product is not the subject of an approved BLA.

Current Good Manufacturing Practice Violations

Refer to Warning Letter number CBER 25-679023 for discussion of CGMP violations.

Misbranding Violation

Your product is also misbranded under section 502(a) of the FD&C Act, 21 U.S.C. § 352(a), because your labeling is false or misleading. Specifically, the instructions for use (IFU) for your product indicates that “the tissue is processed and may be cut into predetermined size patches using sterile cutting tools.” This description implies that your product is provided as sheets when it is actually a liquid solution. Further, your certificate of analysis for your product states that the expiry period is five (5) years, while your IFU states that your product has a “3-year shelf life.” Neither of these statements about the stability of your product are supported with stability data. These false or misleading representations about your product on your labeling cause this product to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. § 352(a).

Conclusion

Neither this letter nor the observations noted on the Form FDA-483, List of Inspectional Observations that was issued to **(b)(4)**, are intended to be an all-inclusive list of deficiencies that may exist. It is your responsibility to ensure full compliance with the FD&C Act, PHS Act, and all applicable regulations.

This letter notifies you of our findings and provides you an opportunity to address them. Failure to adequately address these matters may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

We request that you respond in writing within fifteen (15) working days from your receipt of this letter, outlining the specific steps you have taken or plan to take to address any violations and prevent their recurrence. Include any documentation necessary to show that the matters have been addressed. If you cannot address these matters within fifteen (15) working days, please explain the reason for your delay and the timeframe for completion. If you do not believe your products are in violation of the FD&C Act, PHS Act, or applicable regulations, include your reasoning and any supporting information for our consideration.

Send your electronic response to CBERDCMRecommendations@fda.hhs.gov. If you have questions regarding this letter, contact the Division of Case Management, CBER at (240) 402-9156.

Sincerely,
/S/

Melissa J. Mendoza
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Cc:
(b)(4)

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1 FDA does not consider MaviX™, an amniotic fluid-based product, to be a human cell, tissue, or cellular or tissue-based product (HCT/P). HCT/Ps, as defined in 21 CFR 1271.3(d), do not include secreted or extracted human products. Accordingly, secreted bodily fluids, such as amniotic fluid, are generally not considered HCT/Ps subject to regulation under 21 CFR part 1271.

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