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Amnion Successfully Completes Comprehensive 8-Day FDA Inspection Advancing Regulatory Standing and Strengthening Market Confidence

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HST Global, Inc. (OTC: HSTC), the parent company of Virginia-based Amnion LLC, a wholly owned subsidiary of HST Global, Inc., today announced that Amnion has successfully completed a comprehensive 8-day inspection conducted by the U.S. Food and Drug Administration (FDA). The inspection covered all aspects of Amnion's operations, including laboratory practices, standard operating procedures (SOPs), documentation controls, internal audit processes, and tissue handling and storage protocols.

The FDA inspection team conducted a detailed, rigorous, on-site review of Amnion's Sterling, Virginia laboratory, examining the company's tissue processing and banking operations against federal regulatory requirements governing human cellular and tissue-based products (HCT/Ps) under 21 CFR Part 1271. The conclusion of the inspection without formal regulatory action reflects Amnion's ongoing commitment to quality, patient safety, and continuous improvement. Four procedural observations were noted in an accompanying Form 483, to which Amnion is responding within the required 15 business-day timeframe.

The FDA inspection milestone comes on the heels of two landmark achievements for Amnion: a successful voluntary multi-day audit resulting in ISO 13485 certification - the internationally recognized standard for quality management systems in medical device and tissue banking organizations - and another successful weeklong AATB voluntary audit leading to full accreditation by the Association for Advancing Tissue and Biologics (AATB), the tissue banking industry's highest voluntary standard for quality and safety. Together, these three accomplishments mark a defining period of regulatory and quality achievement for the company.

Amnion currently distributes human tissue products to healthcare providers and surgical centers across multiple states and maintains licensing in every state in the United States that requires a tissue bank license, *i.e.*, California, Maryland, New York, Illinois, Delaware, Oregon, and Florida. Amnion markets products to providers in Canada as well under a Canadian CTO certificate.

> *"The successful completion of an FDA inspection, along with our ISO 13485 and AATB certifications, is a significant accomplishment that shows our commitment to delivering safe and high-quality products. I am truly proud of the team we have developed and our commitment to ensuring we are building a culture of quality at the foundation of our company."*
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> **- Paul Behrends, Laboratory Director and Quality Manager, Amnion LLC**

Opening the Door to Global Expansion

The successful completion of the FDA inspection, combined with Amnion's ISO 13485 certification and AATB accreditation, advances the company's application for a Certificate to Foreign Government (CFG) from the FDA. The CFG is an official FDA certification that enables U.S.-based tissue banks and medical product manufacturers to export their products to international markets. A CFG serves as formal documentation to foreign governments and regulatory authorities that Amnion's products are legally marketed in the United States and that Amnion's operations comply with applicable U.S. federal law and regulatory standards. Many countries require a CFG as a prerequisite for importation, making it a critical credential for any tissue bank seeking to compete in international markets.

Amnion has already begun preliminary discussions with potential distribution partners in multiple countries across several international markets. The company's ability to demonstrate compliance with FDA inspection requirements, ISO 13485 certification, and AATB accreditation simultaneously has significantly strengthened its position in those discussions, providing prospective international partners with the regulatory documentation and confidence they require before entering into distribution agreements.

> *"The combination of a successful FDA inspection, ISO 13485 certification, and AATB accreditation creates a compelling and credible regulatory profile for Amnion in international markets. We are actively engaged in preliminary discussions with potential distributors in multiple countries, and the ability to present this trifecta of regulatory achievements, hopefully later culminating in our pursuit of a CFG from the FDA, opens doors that were previously out of reach. We believe international distribution represents a significant and near-term growth opportunity for Amnion and for HST Global."*
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> **- Michael P. Fortkort, Chief Executive Officer, HST Global, Inc.**

Advancing AmGraft™ Toward Medicare Reimbursement: The Path to a Q-Code

The successful FDA inspection also significantly advances Amnion's application for a **Q-code** from the Centers for Medicare & Medicaid Services (CMS) for its flagship wound care graft product, **AmGraft™**. A Q-code is a temporary billing code assigned by CMS under the Healthcare Common Procedure Coding System (HCPCS) Level II that enables healthcare providers to seek Medicare and Medicaid reimbursement for tissue-based wound care products

used in outpatient and clinical settings. For any amniotic membrane or tissue-based wound care graft to be commercially viable at scale within the U.S. healthcare system, a Q-code is essential.

Without a Q-code, hospitals, wound care centers, and outpatient facilities cannot bill Medicare or Medicaid for the use of a tissue graft product, effectively limiting its commercial reach to cash-pay and private insurance markets. With a Q-code, AmGraft™ will become billable across the full spectrum of Medicare Part B-covered procedures, dramatically expanding its market accessibility and making it a viable option for the millions of Medicare beneficiaries who suffer from chronic wounds, diabetic ulcers, and post-surgical tissue defects each year.

CMS evaluates Q-code applications based on a product's regulatory standing, manufacturing quality, and documentation of clinical and operational compliance. Amnion's demonstrated combination of ISO 13485 certification, AATB accreditation, and a successful FDA inspection provides precisely the regulatory foundation that CMS requires when assessing AmGraft™'s eligibility. Each milestone strengthens the application by establishing that Amnion's tissue banking operations meet or exceed the quality, traceability, and safety standards that CMS demands of products seeking reimbursement status.

> *"Obtaining a Q-code for AmGraft™ will be one of our most important near-term commercial objectives, and every regulatory milestone we have achieved — the ISO 13485 certification, the AATB accreditation, and now this FDA inspection — moves us meaningfully closer to that goal. A Q-code will unlock Medicare reimbursement and transform AmGraft™ from a strong product into a scalable commercial platform accessible to providers and patients across the entire healthcare system."*
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> **- Michael P. Fortkort, Chief Executive Officer, HST Global, Inc.**

Amnion's Growing Product Portfolio

The regulatory achievements underpinning the FDA inspection also advance Amnion's broader commercial strategy across its full portfolio of amniotic membrane allograft products, all of which are processed under Amnion's proprietary AmnioCleanse™ tissue purification technology. Sourced exclusively from pre-screened, elective Cesarean-section placentas and terminally sterilized using state-of-the-art electron beam (e-beam) technology, every Amnion product is validated for a five-year shelf life at room temperature and is minimally manipulated and intended for homologous use in accordance with FDA regulations.

AmGraft™ and AmGraft™ Plus: Single and Dual Layer Wound Care Grafts

AmGraft™ is Amnion's flagship amniotic membrane wound care graft, available in both single-layer and dual-layer (AmGraft™ Plus) configurations. When placed over a wound site, AmGraft™ serves as a protective biological barrier that conforms naturally to the wound surface. Available in sizes ranging from 1×1 cm to 7×7 cm in both single- and dual-layer configurations, AmGraft™ is engineered for ease of use and can be sutured or gently placed over the surgical site. Amnion is actively pursuing CMS Q-code designation for AmGraft™ to enable Medicare reimbursement and expand patient access nationwide.

AmGraft Core™ Dual Layer Amnion Chorion Graft

AmGraft Core™ is Amnion's advanced dual-layer amnion-chorion graft, incorporating both the amnion and chorion membrane layers for applications requiring a thicker biological barrier and

additional structural support. The chorion layer adds mechanical reinforcement to the amnion's biological properties, making AmGraft Core™ particularly well-suited for applications where greater graft thickness is required. Like all Amnion products, AmGraft Core™ is processed under the AmnioCleanse™ platform, terminally sterilized via e-beam, and validated for a five-year shelf life. Available in sizes from 1×1 cm to 7×7 cm.

AmDisc™ Amniotic Membrane Allograft for Ocular Use

AmDisc™ is Amnion's precision-designed circular amniotic membrane allograft for ophthalmic procedures. Custom-configured for ease of placement and optimal patient comfort during in-office ocular surface procedures, AmDisc™ hydrates instantly upon contact with the ocular surface, adheres naturally without suturing in most applications, and can be placed with either side in contact. At a single-layer thickness of approximately 35 microns, AmDisc™ is available in 8 mm, 10 mm, and 12 mm circle sizes to accommodate a range of ocular surface procedures. AmDisc™ is reimbursable under CPT Code 65778 (amniotic membrane placed on the ocular surface, self-retaining), providing immediate billing infrastructure for ophthalmology practices.

Together, these products position Amnion as a full-spectrum amniotic tissue company serving ophthalmology, wound care, dermatology, and dental surgery markets. The successful FDA inspection, ISO 13485 certification, and AATB accreditation collectively validate the manufacturing and quality systems that support the entire product line, strengthening Amnion's commercial credibility with hospitals, surgical centers, and specialty practices nationwide and internationally.

What the FDA Inspection Outcome Means for Amnion

Validated Quality Systems

The successful conclusion of the inspection confirms that Amnion's laboratory practices, SOPs, documentation controls, and quality management systems meet federal regulatory standards, providing confidence to healthcare partners, distributors, and patients. This reinforces the quality infrastructure already recognized through Amnion's ISO 13485 certification and AATB accreditation, and strengthens the regulatory foundation supporting the AmGraft™ Q-code application.

Strengthened Market Position

Completion of a rigorous multi-day FDA inspection, combined with ISO 13485 certification and AATB accreditation, positions Amnion among a select group of tissue banking organizations that have demonstrated compliance across all three major quality and regulatory frameworks. Healthcare institutions, surgical centers, and international distributors increasingly require this level of demonstrated compliance as a condition of partnership.

Expanded Distribution Confidence

Amnion's network of distribution partners across the United States and Canada can operate with confidence that Amnion's operations are validated against the highest federal and international standards. The combined achievement of ISO 13485, AATB accreditation, and a successful FDA inspection, along with the path it clears toward CFG issuance and AmGraft™ Q-code approval, supports continued expansion into new markets, domestically and internationally.

Regulatory Confidence and Risk Mitigation

These three achievements — ISO 13485 certification, AATB accreditation, and a successful FDA inspection — validate Amnion's proven compliance infrastructure and operational procedures, reducing regulatory risk and supporting the long-term scalability of Amnion's tissue banking operations across both domestic and international markets.

A Commitment to Excellence

> *"Throughout my two years building our team, Amnion has continually strived to ensure we deliver safe and high-quality products. We are fully confident in every product we release because of the robust quality management system we have created and implemented."*
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> **- Eileen Toussaint, Laboratory Manager, Amnion LLC**

With these milestones, Amnion strengthens its foundation for growth, reinforces its leadership in quality and compliance, and continues delivering biologic solutions across the United States and around the world.

About Amnion LLC

Amnion LLC is dedicated to advancing biologic and tissue-based therapies that promote healing, surgical innovation, and improved quality of life. Based in Sterling, Virginia, Amnion holds ISO 13485 certification, AATB accreditation, and has successfully completed a comprehensive FDA inspection, reflecting its commitment to the strictest compliance and quality standards in tissue banking. Amnion's growing product portfolio includes AmGraft™, AmGraft™ Plus, AmGraft Core™, and AmDisc™, processed under its proprietary AmnioCleanse™ tissue purification technology and terminally sterilized via e-beam irradiation with a five-year shelf life. Amnion distributes human tissue products to healthcare providers across the United States, maintains licensing in all required states including California, Maryland, New York, Illinois, Delaware, Oregon, and Florida, markets products in Canada under a Canadian CTO certificate, and is actively pursuing international distribution expansion. For more information, please visit www.amnion.net

About HST Global, Inc.

HST Global, Inc. is a Virginia Beach, Virginia-based technology holding company specializing in healthcare, software, and transportation. HST Global is also the parent company of Qwyit, LLC, a cybersecurity innovation firm with a portfolio spanning more than 25 years of patented breakthroughs, including the Fast Unbreakable Cipher, Real-Time Trust protocols, Provably Secure Authentication & Encryption (PSAE) engine, and Universal Unbreakable Encryption technologies. Together, HST Global and Qwyit continue to advance the global state of digital security across hardware, firmware, software, financial, communication, and government sectors. For more information, please visit www.HSTGlobal.com

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Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such

statements reflect current expectations regarding future events, including anticipated commercial performance, regulatory outcomes, Q-code designation, and distribution expansion. Actual results may differ materially due to risks and uncertainties, including regulatory delays, CMS coding decisions, market acceptance, manufacturing capacity, and other factors described in the company's public filings. The company undertakes no obligation to update or revise any forward-looking statements except as required by law.

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