

November 24, 2020

COM-2020-088

RECALL NOTIFICATION



FDA PUBLICATION DATE:

November 23, 2020

**DRUG NAME: CORE Essential
Nutrients and Immune Boost
Sublingual Vitamin D3**

**COMPANY: Fusion Health and
Vitality LLC**

**REASON: Due to detection of
hordenine HCL, an
unapproved new drug under
FDA labeling laws**

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on November 23, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for all 2020 lots of Core Essential Nutrients and Immune Boost Sublingual Vitamin D3 manufactured by Fusion Health and Vitality LLC.

The voluntary recall is due to the detection of hordenine HCl, an unapproved new drug under FDA labeling laws. When taken by mouth, hordenine HCl could be unsafe to the patients since it may increase heart rate and blood pressure.

Pharmacy required actions(s):

- Identify if the product is in inventory and immediately stop dispensing it. The product should be returned to Fusion Health and Vitality for destruction.
- Advise patients to stop using the product and return it to Fusion Health and Vitality for destruction.

Contact information:

- Contact Fusion Health and Vitality by calling 1-888-964-5327 for questions about the recalled product and the return process.

Remember, you can report adverse events or side effects at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) by any of the following ways:

- Complete and submit the [MedWatch Online Voluntary Reporting Form](#) online.
- [Download](#) FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at:

- [FDA Recall for Core Essential Nutrients and Immune Boost Sublingual Vitamin D3](#)

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

PharmPix Clinical Department

Reference(s):

U.S. Food and Drug Administration. (2020). Fusion Health and Vitality Issues Voluntary Nationwide Recall of Core Essential Nutrients and Immune Boost Sublingual Vitamin D3 due to Unapproved Use of a Food Additive and Unapproved Marketing Statements. Retrieved on November 24, 2020 from <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fusion-health-and-vitality-issues-voluntary-nationwide-recall-core-essential-nutrients-and-immune>