

Oregon Attorney General Announces \$545,000 Settlement with Retailer

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The Oregon AG recently [announced](#) a \$545,000 settlement with the Vitamin Shoppe over allegations that the store violated Oregon state law by selling dietary supplements containing ingredients that FDA has deemed unsafe or unlawful. The new settlement agreement places significant burdens on the Vitamin Shoppe to monitor developments on ingredient status. The burdens are the same regardless of whether the Vitamin Shoppe sells a product under one of its own brands – or if it sells a product that was manufactured, labeled, and sold to it by a third party vendor.

Under the terms of the agreement, if the Vitamin Shoppe “receives or learns of” a “written notice” from FDA that an ingredient may be unsafe or unlawful, it must “take immediate action to suspend the sale of such products or products known to contain the ingredients.” If the Vitamin Shoppe becomes aware of any other “public announcement, warning, alert, publication, notice, or report” suggesting that the U.S. government, Australia, Canada, Britain, or the EU might consider a dietary ingredient unsafe or unlawful under the FDCA, then the Vitamin Shoppe must conduct a “reasonable due diligence review,” which may result in a decision not to sell any products containing the ingredient.

This settlement is notable for at least two reasons:

1. It identifies FDA warning letters sent to the Vitamin Shoppe or anyone else as “written notice” that FDA has deemed an ingredient unsafe or unlawful. Warning letters, however, state only allegations and are not considered “guidance” under FDA’s rule on “good guidance practices.” Well after a warning letter is issued, the lawfulness of a particular dietary ingredient can be the subject of much ongoing debate, and even the FDA’s official guidance document on ingredient status remains in flux after years of debate.
2. The settlement represents an aggressive stance by Oregon on a retailer’s liability for product formulation and labeling by third parties. As we’ve discussed [before](#), there isn’t a whole lot of precedent for regulators going after the retailer, rather than the product seller.

The Oregon Attorney General is currently in litigation against another retailer over similar allegations related to the legal status and safety of a dietary ingredient.

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