Over-the-counter drugs cannot be marketed unless the FDA has approved them as safe and effective for their intended use.\textsuperscript{271} The statute preempts state requirements that relate to the regulation of non-prescription drugs and are different from, in addition to, or otherwise not identical to a requirement under the federal statute.\textsuperscript{272} A savings clause states, however, that nothing in the federal statute should be construed to modify or affect any action or the liability of any person under state product liability law.\textsuperscript{272}

Because part of the FDA’s authority includes approving or specifying requirements for labels, claims that are based on the inadequacy of the label may be preempted, but not claims relating to marketing.\textsuperscript{274} In addition, a claim that the manufacturer should have petitioned the FDA to approve stronger warnings may not be preempted.\textsuperscript{275}

Footnotes

\textsuperscript{271} 21 U.S.C. § 355.

\textsuperscript{272} 21 U.S.C. § 379r(a).


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