

Drugmaker settles with FDA in fish-oil drug marketing case

March 8 2016

The maker of a prescription fish-oil drug says it has reached a legal settlement that will allow it to promote unapproved uses of its drug for lowering fat levels.

The closely watched case between Amarin and the Food and Drug Administration could strengthen drugmakers' ability to promote drugs for uses that have not been approved as safe and effective by regulators.

In August, Amarin won a surprise victory over the FDA when a U.S. District Court judge ruled the company had a First Amendment right to distribute journal articles about unapproved indications for Vascepa, which lowers a type of fat in the bloodstream.

Amarin said in a statement Tuesday that the FDA agreed to be bound by the earlier court decision.

An FDA spokeswoman could not immediately comment.

© 2016 The Associated Press. All rights reserved.

Citation: Drugmaker settles with FDA in fish-oil drug marketing case (2016, March 8) retrieved 4 July 2023 from

<https://medicalxpress.com/news/2016-03-drugmaker-fda-fish-oil-drug-case.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is

provided for information purposes only.