

### **3. FDA Won't Approve Statin-Fenofibrate Combo**

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The FDA said it won't approve a new combo capsule for dyslipidemia until it learns more about the safety and efficacy of the compound, a decision that may be linked to the FDA's review of the ACCORD trial findings.

The FDA informed AstraZeneca and Abbott Laboratories of its decision in a complete response letter, which details the reasons that the FDA will not approve a new drug application.

The combo capsule, Certriad, combines the potent statin rosuvastatin (Crestor) made by AstraZeneca with Abbott's fenofibric acid (TriLipix).

Rhea Lewis, senior manager for cardiovascular affairs at AstraZeneca, told MedPage Today that the companies "will be meeting soon with the FDA to find what information we may be able to provide to the FDA and to better understand what this letter means."

In response to a question about future plans for the drug, Lewis said only that the companies planned to meet with the FDA.

Earlier this month the FDA announced that it was conducting a review of the ACCORD trial results, with a focus on the safety and efficacy of fenofibric acid. That announcement was immediately following release of results from the ACCORD trial, which found no reduction in cardiovascular events when a fenofibrate was given in addition to statin therapy.

Asked if the FDA's complete response letter mentioned that review or if the review itself triggered the FDA's decision to withhold approval, Lewis declined to comment.

The FDA began issuing complete response letters in April 2009 as part of its plan to provide more transparency about its decisions.

On its Web site, the FDA said a complete response letter "provides a more consistent and neutral mechanism to convey that our initial review of an application is complete and we cannot approve the application in its present form.

"It provides a more consistent approach to informing applicants of changes that must be made before an application can be approved, with no implication regarding the ultimate approvability of the application."