FDA committee recommends approval for Viagra rival

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A committee of specialists at the US Food and Drug Administration (FDA) has recommended that the administration proceed with the approval of Uprima (apomorphine), a new drug for impotence that doctors predict will compete strongly with the highly popular drug sildenafil (Viagra).

The administration usually follows its panel's advice and is expected to decide by July whether Uprima can be sold in the United States. The panel's support, however, came on condition that the manufacturer, TAP, based in Illinois, provides strong warnings to patients about possible serious side effects.

Placed under the tongue, Uprima encourages erections by stimulating the release of dopamine, which mediates the cerebral role in triggering erections. Although Uprima is new, its active ingredient, apomorphine, has been used for various disorders for many years.

In medical studies, almost 60% of men taking Uprima had an erection, whereas only 35% of men taking a placebo were able to achieve an erection successfully. A major area of concern was Uprima's safety profile, not its effectiveness. Nausea was seen in 32% of the men and dizziness and sweating in about 15%; 60% of the men had to drop out of the

studies owing to side effects. Most of these side effects, however, occurred in men taking at least 5 mg of the drug. If approved, Uprima will be sold in doses of 2 mg to 4 mg.

Uprima also seemed to interact with nitrates and alcohol, leading to concerns about the potential for more serious side effects, such as syncope, hypotension, and bradycardia.

"[Erectile dysfunction] is a major quality of life issue," said the committee's chairman, Ricardo Azziz. Although this drug may need to be used only in certain men, there is no question that it had a definite benefit, he said.