# Adult SSRI Use And Suicidality To Get FDA Advisory Con Review, J&J Says

May 26, 2005-

FDA will convene an advisory committee within the next few months to assess tl suicidality in adults using selective serotonin reuptake inhibitors, Johnson & Johr and Therapeutic Area Head-Internal Medicine Joanne Waldstreicher said May 26.

"There is going to be an FDA advisory committee within the next few months to and suicidality in adults," Waldstreicher said during the company's R&D day in N

J&J submitted an NDA for its SSRI dapoxetine in December ("The Pink Sheet" DA 2004). The company is seeking a premature ejaculation indication for the produ

An advisory committee meeting on SSRI use and adult suicidality would have im most of the major products in the antidepressant category, including Forest's ***Le Celexa*** and generics; GlaxoSmithKline's ***Paxil CR*** and Paxil generics; Lilly's ***Syn Prozac*** generics; Pfizer's ***Zoloft***; Organon's ***Remeron***; and generic versions of Squibb's ***Serzone***.

The meeting also would likely impact the two approved serotonin and norepinep inhibitors: Lilly's ***Cymbalta*** and Wyeth's ***Effexor***.

All antidepressants now carry a "black box" warning and other language concern pediatric suicidality ("The Pink Sheet" DAILY, March 4, 2005).

FDA requested the black box class warning following a recommendation by the a Psychopharmacologic Drugs & Pediatric Advisory Committees in September ("Th DAILY, Sept. 14, 2004).

Dapoxetine's label presumably would have to include the same black box warnin

Nevertheless, J&J is attempting to differentiate dapoxetine from the rest of the S

"There are lots of SSRIs on the market but dapoxetine is different," Waldstreiche a different pharmacokinetic profile. Dapoxetine has a fast onset of action, peaks more than an hour and is rapidly cleared. This makes the drug ideal for as-need rather than needing to take it on a daily basis."

"This is unlike the long-acting SSRIs, which are already on the market for other depression, where the drug hangs around for a long period of time and accumul said.

In dapoxetine clinical trials there were no adverse events related to suicide, Wal noted.

"In our *Phase III* pivotal U.S. trials in over 3,000 men we have seen no suicide-r adverse events," she said.

Dapoxetine is undergoing a standard review at FDA, with an estimated user fee Oct. 27.

The company expects an advisory committee review of the dapoxetine NDA sepa

SSRI class review on adult suicidality.

- *Andrew Shelton*