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FDA Advising of Risk of Birth Defects with Paxil *Agency Requiring Updated Product Labeling*

The Food and Drug Administration today is alerting health care professionals and patients about early results of new studies for Paxil (paroxetine) suggesting that the drug increases the risk for birth defects, particularly heart defects, when women take it during the first three months of pregnancy. Paxil is approved for the treatment of depression and several other psychiatric disorders. FDA is currently gathering additional data and waiting for the final results of the recent studies in order to better understand the higher risk for birth defects that has been seen with Paxil.

FDA is advising health care professionals to discuss the potential risk of birth defects with patients taking Paxil who plan to become pregnant or are in their first three months of pregnancy. Health care professionals should consider discontinuing Paxil (and switching to another antidepressant if indicated) in these patients. In some patients, the benefits of continuing Paxil may be greater than the potential risk to the fetus. FDA is advising health care professionals not to prescribe Paxil in women who are in the first three months of pregnancy or are planning pregnancy, unless other treatment options are not appropriate.

FDA is advising patients that this drug should usually not be taken during pregnancy, but for some women who have already been taking Paxil, the benefits of continuing may be greater than the potential risk to the fetus. Women taking Paxil who are pregnant or plan to become pregnant should talk to their physicians about the potential risks of taking the drug during pregnancy. Women taking Paxil should not stop taking it without first talking with their physician.

The early results of two studies showed that women who took Paxil during the first

three months of pregnancy were about one and a half to two times as likely to have a baby with a heart defect as women who received other antidepressants or women in the general population. Most of the heart defects reported in these studies were atrial and ventricular septal defects (holes in the walls of the chambers of the heart). In general, these types of defects range in severity from those that are minor and may resolve without treatment to those that cause serious symptoms and may need to be repaired surgically.

In one of the studies, the risk of heart defects in babies whose mothers had taken Paxil early in pregnancy was about 2 percent, compared to a 1 percent risk in the whole population. In the other study, the risk of heart defects in babies whose mothers had taken Paxil in the first three months of pregnancy was 1.5 percent, compared to 1 percent in babies whose mothers had taken other antidepressants in the first three months of pregnancy.

FDA has asked the manufacturer, Glaxo Smith Kline (GSK), to change the pregnancy category from C to D, a stronger warning. Category D means that studies in pregnant women (controlled or observational) have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risks to the fetus.

Based on results of the preliminary data, GSK updated the drug's labeling in September 2005 to add data from one study. As additional data have become available, the label has now been changed to reflect the latest data from the two studies and to change the pregnancy category.

Additional information concerning today's announcement is available on FDA's Web site at:

Public Health Advisory:

<http://www.fda.gov/cder/drug/advisory/paroxetine200512.htm> and

CDER Information Sheets:

<http://www.fda.gov/cder/drug/infopage/paroxetine/default.htm>.

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