



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Mike Ferguson
House of Representatives
Washington, D.C. 20515-3007

JAN 15 2008

Dear Mr. Ferguson:

Thank you for your letter of October 25, 2007, in which you expressed concern regarding the Food and Drug Administration's (FDA or the Agency) revised antidepressant Medication Guide.

Your letter appears to have two major concerns. First, you note that the revised Medication Guide is directed to all patients taking antidepressants, rather than focusing on pediatric patients. Second, you state that the new Medication Guide is briefer and less informative than the original version.

As you note in your letter, the new Medication Guide is broader in focus because of new information derived from FDA's meta-analyses of suicidality data from adult antidepressant studies. In particular, it points out that the suicidality risk is present in young adults as well as children and teenagers. We presented this new information to our Psychopharmacologic Drugs Advisory Committee (PDAC) on December 13, 2006, and the Committee recommended that we expand antidepressant labeling and the Medication Guide to include this new information. The Committee members also expressed concern that the then-current labeling and Medication Guide might be having a negative effect, in the sense that they might be discouraging appropriate prescribing of antidepressant medications, which can be life-saving in the serious illnesses for which they are used. Thus, the Committee members asked that we balance the language in the labeling and Medication Guide to reflect the fact that depression itself is the most important cause of suicide. We have tried to take this advice into account, which is one reason that the new Medication Guide has a broader focus when addressing the issue of suicidality, still emphasizing the need for close monitoring of all patients but not suggesting that the drugs be avoided.

In the process of revising the Medication Guide, we sought advice from both external experts (PDAC) and individuals within the Agency with expertise in communication-of-risk information to patients. We received feedback indicating that the then-current Medication Guide was viewed as being too long and diffuse to be optimally useful to patients, that it was often redundant, and that it contained unnecessary detail. Based on this feedback, the Agency worked to restructure the Medication Guide to include only essential information and to present this information in a form that is consistent with effective communication-of-risk

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information to patients. The feedback we have had on the revised Medication Guide from prescriber and patient groups has generally been quite positive.

You cite examples of where you feel the current Medication Guide falls short in communicating important information. There is always a tension between presenting very extensive information and focusing on the most critical points. We have tried to be sure that the Medication Guide covers what we believe are the most important aspects of risk information regarding which patients or parents of patients need to be made aware. For example, the current Medication Guide still includes, near the beginning, the standard language, "What is the most important information" and then fully addresses the important issues of what risk is involved, the critical need for risk observation for certain behaviors, and the balance of risks and benefits. As noted above, the current Medication Guide also alerts patients and their families to the reality that depression itself is not a benign condition, is the most important cause of suicidal thoughts and actions, and should be taken very seriously.

We are continually receiving information about the risks of all medications, including antidepressants. As new information becomes available or we learn that risk communication tools we are employing are not having the effect intended, we will make changes in them.

Thank you again for contacting us concerning this matter. Please let us know if you have further questions.

Sincerely,



for Stephen R. Mason
Acting Assistant Commissioner
for Legislation