



March 13, 2007

The Honorable Andrew C. von Eschenbach, MD  
Commissioner  
Food and Drug Administration  
Washington, DC

Dear Dr. von Eschenbach:

Consumers Union, the independent, non-profit publisher of *Consumer Reports*, notes the recent letter of the U.S. Food and Drug Administration to Takeda Pharmaceuticals North America (posted on the FDA website March 8 and sent to the company March 5) that

“requests that Takeda immediately cease the dissemination of violative promotional materials for Rozerem...”

The FDA letter describes how Takeda Pharmaceuticals ran so-called ‘reminder’ ads on television that very clearly attempt to promote the use of sleeping pills in children. The company did this without submitting the advertisement to the FDA, without noting the very serious side effects that this drug may have, including increased thoughts of suicide in already depressed patients, ‘cognitive and behavior changes,’ and according to the Product Labeling:

**PRECAUTIONS (relating to pediatric use)**

***Use in Adolescents and Children***

ROZEREM has been associated with an effect on reproductive hormones in adults....It is not known what effect chronic or even chronic intermittent use of ROZEREM may have on the reproductive axis in developing humans.

**Pediatric Use**

Safety and effectiveness of ROZEREM in pediatric patients have not been established. Further study is needed prior to determining that this product may be used safely in pre-pubescent and pubescent patients.

This advertisement geared to children going ‘back to school’ is outrageous, and we urge the FDA take stronger and more timely actions in cases such as this.

It appears from the FDA letter that the advertisement in question ran in early September. We suspect that since it refers to ‘back to school,’ that the ad has not been used for some months. Asking the company to stop running a ‘back to school’ ad in March is less than a slap on the wrist—it is embarrassing. The company should be subject to a requirement for corrective advertisements to warn parents that this product may be both ineffective and hazardous in children.

We hope that the FDA will support legislation in Congress during the PDUFA user fee debate and the debate on Kennedy-Enzi (S. 484) to add language that will strengthen the requirements for timely, mandatory pre-approval of ads, civil monetary penalties for violations (especially repeat violations), and the more frequent placement of corrective ads so as to prevent the type of abuse seen in this case.

Sincerely,  
William Vaughan  
Senior Policy Analyst  
Consumers Union, publisher of *Consumer Reports*