



# Consumer Alert

April 10, 2007

## ***Topic: FDA Advises Discontinuation of Sales and Marketing of Zelnorm® (tegaserod)***

Recently, the U.S. Food and Drug Administration (FDA) asked Novartis to discontinue sales and marketing of Zelnorm® (tegaserod), a medication commonly used for the treatment of irritable bowel syndrome (IBS) and chronic idiopathic constipation. This request was made after a recent analysis of clinical trial data identified a statistically significant increase in the number of cardiovascular ischemic events in patients taking Zelnorm®, including heart attack, stroke and unstable angina. As a result, FDA has concluded that the overall risk versus benefit profile for the drug is unfavorable for continued marketing. According to FDA:

- ✓ Patients being treated with Zelnorm® should contact their physician to discuss alternative treatments for their condition.
- ✓ Patients who are taking Zelnorm® should seek emergency medical care right away if they experience severe chest pain, shortness of breath, dizziness, sudden onset of weakness or difficulty walking or talking or other symptoms of a heart attack or stroke.

More information about this Public Health Advisory can be found on FDA's website at: <http://www.fda.gov/cder/drug/advisory/tegaserod.htm>

If you have any questions regarding the information in this announcement, please contact your GBS Customer Service Representative at (410) 832-1333 or (800) 337-4973.