



October 31, 2018

Re: Breckenridge's Polyethylene Glycol 3350 –  
NDCs 51991-457-58 (255gm) and 51991-457-57 (527gm)

Dear Valued Customer,

As a purchaser of Breckenridge's Polyethylene Glycol 3350 under NDCs 51991-457-58 and 51991-457-57 (**PEG3350**), we wanted to provide you with updated information about the status of the Abbreviated New Drug Application (**ANDA**) under which we have supplied you with PEG3350.

As we previously advised, FDA published a notice ordering that all approvals of all ANDAs for prescription PEG3350 would be withdrawn on May 2, 2018, which was later extended by FDA to November 2, 2018. Following issuance of that order, we appealed FDA's decision to withdraw the ANDA to the United States Court of Appeals for the District of Columbia Circuit (**Court**).

Most recently, on October 30, 2018, the Court issued a decision in favor of FDA. Therefore, as determined by FDA, all ANDAs for prescription PEG3350 will be withdrawn on November 2, 2018.

Best regards,

*Alex*

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Associate Vice President, Sales & Marketing

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