1. QUANTITATIVE INFORMATION INCLUDED AND FAERS STATEMENT INCLUDED

A search of the FDA Adverse Event Reporting System (FAERS) database identified 20 cases of acidosis, which is too much acid in the blood, in patients taking DRUG B to treat constipation from March 2013 to June 6, 2014 (see Data Summary). FAERS includes only reports submitted to FDA so there are likely additional cases about which we are unaware. All patients required emergency room visits or hospitalization to treat the acidosis. Since June 2014, we have continued to receive additional FAERS reports for acidosis in patients taking DRUG B to treat constipation.

2. QUANTITATIVE INFORMATION INCLUDED, NO FAERS STATEMENT INCLUDED

A search of the FDA Adverse Event Reporting System (FAERS) database identified 20 cases of acidosis, which is too much acid in the blood, in patients taking DRUG B to treat constipation from March 2013 to June 6, 2014 (see Data Summary). All patients required emergency room visits or hospitalization to treat the acidosis. Since June 2014, we have continued to receive additional FAERS reports for acidosis in patients taking DRUG B to treat constipation.

3. QUANTITATIVE INFORMATION NOT INCLUDED, NO FAERS STATEMENT INCLUDED

The FDA Adverse Event Reporting System (FAERS) includes cases of acidosis, which is too much acid in the blood, in patients taking DRUG B to treat constipation from March 2013 to June 6, 2014 (see Data Summary). All patients required emergency room visits or hospitalization to treat the acidosis. Since June 2014, we have continued to receive additional FAERS reports for acidosis in patients taking DRUG B to treat constipation.