1. QUANTITATIVE INFORMATION INCLUDED AND FAERS STATEMENT INCLUDED

FDA reviewed the FDA Adverse Event Reporting System (FAERS) database from 1969 through 2012 and the medical literature from 1957 through August 2013 for cases describing serious adverse events associated with the use of DRUG B used to treat diabetes. FAERS includes only reports submitted to FDA so there are likely additional cases about which we are unaware. We identified 54 cases describing serious adverse events in 25 adults and in 29 children. Ten cases were reported to the FAERS database and 44 were published in the medical literature. The age of the consumers ranged widely from 8 days to 97 years, but most cases involved older adults and children younger than 5 years. Nearly two-thirds of the adults and nearly half of the children in whom adverse events were reported had one or more of the following:

- Dehydration, kidney disease, inflammation of the bowel, or delayed bowel emptying
- Use of medicines that may affect kidney function, including diuretics or water pills; angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) used to treat high blood pressure; and nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, and naproxen.

2. QUANTITATIVE INFORMATION INCLUDED, NO FAERS STATEMENT INCLUDED

FDA reviewed the FDA Adverse Event Reporting System (FAERS) database from 1969 through 2012 and the medical literature from 1957 through August 2013 for cases describing serious adverse events associated with the use of DRUG B used to treat diabetes. We identified 54 cases describing serious adverse events in 25 adults and in 29 children. Ten cases were reported to the FAERS database and 44 were published in the medical literature. The age of the consumers ranged widely from 8 days to 97 years, but most cases involved older adults and children younger than 5 years. Nearly two-thirds of the adults and nearly half of the children in whom adverse events were reported had one or more of the following:

- Dehydration, kidney disease, inflammation of the bowel, or delayed bowel emptying
- Use of medicines that may affect kidney function, including diuretics or water pills; angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) used to treat high blood pressure; and nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, and naproxen

3. QUANTITATIVE INFORMATION NOT INCLUDED, NO FAERS STATEMENT INCLUDED

FDA reviewed the FDA Adverse Event Reporting System (FAERS) database from 1969 through 2012 and the medical literature from 1957 through August 2013 for cases describing serious adverse events associated with the use of DRUG B used to treat diabetes. Some cases describing serious adverse events in adults and children were reported to the FAERS database and some were published in the medical literature. The age of the consumers ranged widely from 8 days to 97 years, but most cases involved older adults and children younger than 5 years. Some people in whom adverse events were reported had one or more of the following:

- Dehydration, kidney disease, inflammation of the bowel, or delayed bowel emptying
- Use of medicines that may affect kidney function, including diuretics or water pills; angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) used to treat high blood pressure; and nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, and naproxen