Proposed Acquisition would substantially increase concentration in this market, provide the combined firm a market share of 46%, and reduce the number of suppliers of generic etomidate injection from four to three.

- Fluorouracil injection treats colon, rectal, breast, stomach, and pancreatic cancers. In this highly concentrated market, four firms have supplied fluorouracil injection in the recent past – Mylan, Fresenius, Teva Pharmaceutical Industries Ltd. ("Teva"), and Sandoz International GmbH. ("Sandoz"). A number of these suppliers, however, have experienced significant manufacturing issues. Agila is the only other company that currently holds an approved ANDA to sell generic fluorouracil in the United States. The Proposed Acquisition would reduce the number of firms capable of supplying generic fluorouracil injection from five to four.

- Labetalol hydrochloride injection treats severe hypertension. The market for labetalol hydrochloride injection is highly concentrated and only five firms are capable of supplying the drug today – Mylan, Agila, Hospira, Akorn, Inc., and Apotex Inc. Currently, Hospira and Akorn make most of the sales in this market, and Mylan, Agila, and Apotex are the only other firms with approved ANDAs and manufacturing facilities currently capable of producing this product. The Proposed Acquisition would reduce the number of firms capable of supplying generic labetalol hydrochloride injection from five to four.

- Mesna injection is a detoxifying agent used to prevent damage to the urinary tract caused by ifosfamide, a third-line chemotherapy drug used to treat germ cell testicular cancer. There are four current, significant suppliers of generic mesna injection – Mylan, Agila, Fresenius, and Baxter International Inc. The Proposed Acquisition would increase concentration in this market substantially, and reduce the number of current suppliers of generic mesna injection from four to three.

- Methotrexate sodium preservative-free injection treats several types of pediatric cancers, as well as certain autoimmune disorders such as rheumatoid arthritis and multiple sclerosis. Five firms currently supply the market for methotrexate sodium preservative-free injection – Mylan, Agila, Fresenius, Teva, and Hospira. The Proposed Acquisition would reduce the number of current suppliers of this drug from five to four.

In addition, the Proposed Acquisition will significantly reduce future competition in the markets for the following generic injectable products: (1) acetylcysteine injection; (2) fomepizole injection; (3) ganciclovir injection; and (4) meropenem injection. In each of these markets, either Mylan or Agila, or both, currently do not supply an existing generic product, but will likely do so in the near future, and entry by one or both of the parties will likely increase price competition in that market significantly absent the Proposed Acquisition. The structure of each of these markets is as follows:

- Acetylcysteine injection prevents or minimizes liver damage resulting from acetaminophen overdose. There are two generic acetylcysteine injection products currently on the market, and Mylan and Agila are two of only a limited number of firms

that have generic products in development. Therefore, the Proposed Acquisition would significantly reduce the number of likely future suppliers of generic acetylcysteine injection.

- Injectable fomepizole treats accidental poisoning caused by ethylene glycol or methanol ingestion. Three firms currently supply the highly concentrated market for generic fomepizole injection – Mylan, X-Gen Pharmaceuticals, Inc., and Sandoz. Agila is developing its own generic fomepizole injection product and likely would

Competitive Effects

Absent a remedy, the Proposed Acquisition would likely cause significant anticompetitive harm to consumers in the relevant generic injectable pharmaceutical markets, either by eliminating significant current or potential competition in concentrated existing markets, or by eliminating significant potential competition among a limited number of likely competitors in a future market. In each of these markets, Mylan and Agila are two of only a limited number of current or likely future suppliers of the drugs in the United States. The evidence shows that prices may continue to decrease even after a number of suppliers have

experience in generic markets, Intas, JHP, and Sagent are expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Intas, JHP, Sagent, or Gland are not acceptable acquirers, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Intas, JHP, Sagent, or Gland and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan, Agila, and Strides to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan and Agila must transfer their respective manufacturing technology and [illegible] pursuant to [illegible]