ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Lupin Ltd.; Gavis Pharmaceuticals LLC; and Novel Laboratories, Inc.

File No. 151-0202

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Lupin Ltd. ("Lupin") and Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. (collectively "Gavis")

United States. All five companies offer the 100 mg strength, but only four companies offer the 50 mg and 75 mg strengths.

Mesalamine ER capsules are used to treat ulcerative colitis. Valeant Pharmaceuticals markets Apriso, the branded version of the product, which is available in a 375 mg formulation. No generic version of mesalamine ER capsules is currently available in the United States. Lupin and Gavis are developing generic mesalamine ER capsules products, and are two of a limited number of suppliers capable of entering the market in the near future.

II. Entry

Entry into the two relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisitions. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

The Proposed Acquisitions likely would cause significant anticompetitive harm to consumers by eliminating current competition between Lupin and Gavis in the market for generic doxycycline monohydrate capsules. Market participants characterize generic doxycycline monohydrate capsules as commodity products. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisitions would combine two of only four companies offering the 50 mg and 75 mg strengths of generic doxycycline monohydrate capsules, likely leading consumers to pay higher prices.

In addition, the Proposed Acquisitions likely would cause significant anticompetitive harm to consumers by eliminating future generic competition that would otherwise have occurred in the mesalamine ER capsule market if Lupin and Gavis remained independent. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisitions due to the elimination of an additional independent entrant in the market for generic mesalamine ER. Customers and competitors expect that the price of this pharmaceutical product will decrease with new entry by Lupin and Gavis. Thus, absent a remedy, the Proposed Acquisitions will likely cause U.S. consumers to pay significantly higher prices for generic mesalamine ER.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisitions in the markets at issue by requiring Gavis to divest all its rights and assets relating to doxycycline monohydrate capsules and mesalamine ER to G&W. Founded in 1919, G&W is a privately held, family-owned, generic pharmaceutical company. G&W develops, manufactures, sells, and distributes generic pharmaceuticals and over-the-counter products within the United States.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisitions. If the Commission determines that