

September 30, 2008

J Jimmy Mitchell, R.Ph., M.P.H., M.S.
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03
Rockville, Maryland 20857

**Open Letter to HRSA Office of Pharmacy Affairs
Regarding the Yasmin® Limited Distribution System**

Dear Mr. Mitchell:

Bayer HealthCare Pharmaceuticals Inc. ("Bayer") distributes Yasmin®, an oral contraceptive product used by millions of women in the United States.

Beginning with the fourth quarter of 2008, we anticipate that we will be unable to meet demand for Yasmin®. Based on our past experience, we anticipate increased ordering activity resulting from operation of the 340B program's "penny price" policy which will make the 340B ceiling price for Yasmin® \$0.01 per cycle as a result of the new CMS regulation requiring brand manufacturers to include the best price of an authorized generic in the Best Price of the branded product. Therefore, in an effort to ensure that all of our customers have an equal opportunity to meet their future needs for Yasmin®, we are instituting a limited distribution system for Yasmin® beginning in the fourth quarter of 2008. This system will apply to all orders for Yasmin® received on or after October 1, 2008 and will limit the amount of Yasmin® any customer (340B, commercial or other) may purchase to that customer's historical average quarterly ordering volume on a percentage basis applied to the then current quarter's available supply. We anticipate that the system will remain in place for the foreseeable future.

As we discussed with you earlier this week, this system will impact all customers, including 340B covered entities, in a fair and consistent fashion. Based on our review of the guidance received from the Office of Pharmacy Affairs ("OPA"), the system complies with the relevant 340B program guidance. Additionally, this system is substantially similar to the system we put in place for Yasmin® in the second quarter of 2007 when faced with similar circumstances. Please feel free to share this information with 340B covered entities and other interested parties as you think appropriate.

Limited Distribution System

Under Bayer's limited distribution system, Bayer will limit the number of Yasmin® cycles each US customer may purchase beginning with the fourth quarter of 2008 to an amount equal to that customer's average quarterly purchase volume between October 1, 2007 and September 30, 2008 (i.e., based on the most recent 12 months) on a percentage basis applied to the then current quarter's available supply. A percentage-based allocation will provide Bayer with more flexibility to adjust customers' maximum order quantities in response to changes in product availability, as they may occur, while maintaining equity among all customers. We will fill all orders for all customers on a first-in, first-out ("FIFO") basis until a customer reaches its determined limit for the quarter. Once a customer reaches its limit for a particular quarter, the customer will be able to place additional orders for Yasmin® at the beginning of the following quarter (subject to that quarter's limit). Importantly, neither a customer's 340B participation status nor the price it pays for Yasmin® will affect its quarterly allotment of Yasmin®. Bayer will not require minimum purchase amounts per transaction.

Bayer has calculated the average quarterly purchase volume of Yasmin® for each customer who has purchased Yasmin® during the period from October 1, 2007 through September 30, 2008. We believe this twelve-month period is an appropriate time frame upon which to base maximum customer order quantities given recent changes in the competitive landscape for this product and the resulting changes in customer purchasing patterns, following the introduction of a generic product. For customers with no historical purchases of Yasmin®, Bayer will establish a maximum purchase level based on the overall average quarterly purchase volume of customers in that purchaser's class of trade. We will apply this average equally to all such customers.

Under our system, all customers will be permitted to order Yasmin® through their normal distribution pathway (either direct from Bayer or through a wholesaler). Bayer will advise wholesalers of their purchase limits and will ask each wholesaler to limit sales of Yasmin® to all of their customers within those limits. Bayer will notify existing direct customers of the distribution system immediately.

Conclusion

Bayer is committed to making our products available through the 340B program at appropriately discounted prices. However, based on our past experience with 340B orders when Yasmin® was last subject to the penny price policy, and given current supply forecasts, Bayer anticipates being faced with a distribution problem which threatens to affect the ability of millions of women to obtain Yasmin® from their customary health care provider. Without equitable and non-discriminatory restrictions on Yasmin® purchasing beginning with the fourth quarter of 2008, 340B covered entities, as well as the Medicaid program, the Department of Veteran Affairs and Federal Supply Schedule entities, could be precluded from being able to purchase Yasmin®. We are implementing this limited distribution system in order to best ensure that all patients of all providers have equal access to Yasmin® during the time period in which the 340B penny price policy is in effect.

Bayer appreciates your office's cooperation during this period.

Very truly yours,

BAYER HEALTHCARE PHARMACEUTICALS INC.

/John A. Calvo/
Senior Counsel