**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| RANBAXY LABORATORIES, LTD. and RANBAXY, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, et al.,<br><br>Defendants. | No. 1:14-cv-01923-BAH |

**DEFENDANTS' NOTICE OF ADMINISTRATIVE ACTION**

Defendants Sylvia Mathews Burwell, in her official capacity as Secretary of Health and Human Services, Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs, and United States Food and Drug Administration ("FDA") (collectively, "federal Defendants"), hereby withdraw their argument that Ranbaxy's claims in this matter regarding generic esomeprazole are unripe and lack final agency action.

Today, FDA determined that Ranbaxy had forfeited its eligibility for 180-day exclusivity for esomeprazole because it failed to obtain tentative approval of its ANDA within 30 months after the date on which the ANDA was submitted and that failure was not caused by a change in or a review of the requirements for approval, and notified Ranbaxy of this determination. Also today, FDA separately approved ANDA 78003 (submitted by Ivax Pharmaceuticals, Inc., a subsidiary of Teva Pharmaceuticals USA) for esomeprazole magnesium delayed-release capsules

USP, 20 mg and 40 mg. FDA also responded to and denied a citizen petition related to generic esomeprazole today. *See* Docket no. FDA-2012-P-0661.[1]

Federal Defendants now, in light of these developments, withdraw their argument that Ranbaxy's claims in this matter regarding generic esomeprazole are unripe and lack final agency action. Federal Defendants' arguments on the merits of this matter, as set forth in their opposition to Plaintiffs' motion for a temporary restraining order (Dkt. No. 23), their memorandum in opposition to plaintiffs' motion for a preliminary injunction and in support of motion for summary judgment (Dkt. Nos. 52, 55), and their reply in further support of motion for summary judgment (Dkt. Nos. 63, 65), apply to both Ranbaxy's valganciclovir and esomeprazole ANDAs, and demonstrate that the Court should deny Ranbaxy's motion for a preliminary injunction and grant summary judgment in the Federal Defendants' favor.

[1] The citizen petition, submitted on behalf of Sandoz, Inc., addressed how FDA should calculate the 30-month period in which an applicant must obtain tentative approval. In reaching its decision on the issues raised in the citizen petition, FDA considered comments submitted by Ranbaxy to the citizen petition docket. *See* Ranbaxy, Inc. – Comment, docket no. FDA-2012-P-0661-0004.

Dated: January 26, 2015

Respectfully submitted,

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