## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

VELOXIS PHARMACEUTICALS, INC., Plaintiff,	) ) )	
v. UNITED STATES FOOD AND DRUG	) ) )	Civil Action No. 14-cv-2126
ADMINISTRATION, et al.,	)	
Defendants.	) ) )	

## DEFENDANTS' MOTION TO STAY PROCEEDINGS PENDING FINAL AGENCY ACTION

Defendants, United States Food and Drug Administration ("FDA"), Margaret Hamburg, M.D., Sylvia Mathews Burwell, and United States Department of health and Human Services (collectively, "Defendants"), hereby move the court, pursuant to the Court's inherent power, for a limited stay of proceedings until January 12, 2015, to allow FDA time to issue a final decision regarding the matter at hand.

Since FDA's October 30, 2014 letter granting tentative approval to Envarsus XR ("Envarsus"), a once-daily extended-release tacrolimus product indicated for use in kidney transplant patients, Envarsus' sponsor, Veloxis Pharmeceuticals, Inc. ("Veloxis"), has met with FDA, and submitted additional information for the agency's consideration on four occasions: November 14, December 2, December 8, and December 12, 2014. On December 12, 2014, FDA informed Veloxis that it intends to issue a final decision on the underlying merits in this matter no later than January 12, 2015. Because the agency is diligently considering the complex scientific and regulatory issues presented by Veloxis' submissions, Veloxis' lawsuit is unripe; judicial intervention at this time would be contrary to Article III of the U.S. Constitution and

well-settled law that "no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." *McKart v. United States*, 395 U.S. 185, 193 (1969); *see also Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967) ("injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution.").

This Court has "broad discretion" to determine whether to stay proceedings. *Clinton v. Jones*, 520 U.S. 681, 706 (1997) (citation omitted). "[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). This lawsuit is precisely the type of case that calls for the Court to invoke such discretion.

In the interest of judicial economy, and so as not to waste the limited agency resources that could be better spent reaching a final decision on the underlying issues, the Government respectfully requests that this Court issue a short stay of the present proceedings—until January 12, 2015, after which time the Government would be happy to discuss an expedited schedule for merits briefing and production of the Administrative Record, if necessary.

Counsel for the Government has met and conferred with Plaintiff's counsel on this motion per Local Rule 7(m), and Plaintiff has not agreed to join in this motion.

Dated December 17, 2014.

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

I certify that on December 17, 2014, I caused a true and correct copy of the above-entitled DEFENDANTS' MOTION TO STAY PROCEEDINGS PENDING FINAL AGENCY ACTION to be served via the Court's Electronic Case Filing system to counsel for the plaintiff as follows:

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<u>s/ HEIDE L. HERRMANN</u> HEIDE L. HERRMANN