DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 206406

TENTATIVE APPROVAL

Veloxis Pharmaceuticals, Inc.
Attention: Michelle A. McGuinness
VP Global Regulatory Affairs & Quality Assurance
499 Thornall Street
3rd Floor
Edison, NJ 08837

Dear Ms. McGuinness:

Please refer to your New Drug Application (NDA) dated December 28, 2013, received December 30, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) for Envarsus XR (tacrolimus extended-release tablets), 0.75 mg, 1 mg, and 4 mg.

We acknowledge receipt of your amendments dated:

January 10, 2014	April 16, 2014	July 18, 2014(2)	October 9, 2014 (3)
January 14, 2014	April 25, 2014 (2)	July 23, 2014	October 10, 2014
January 23, 2014	May 13, 2014	August 29, 2014	October 16, 2014 (2)
February 12, 2014	May 20, 2014	September 5, 2014	October 20, 2014
February 27, 2014	June 4, 2014	September 10, 2014	October 24, 2014
March 14, 2014	June 6, 2014	September 19, 2014	
March 21, 2014	July 7, 2014	September 25, 2014	
March 31, 2014	July 17, 2014 (2)	September 26, 2014	

This NDA provides for the use of Envarsus XR (tacrolimus extended-release tablets), 0.75 mg, 1 mg and 4 mg for prophylaxis of organ rejection in kidney transplant patients.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the enclosed agreed-upon labeling text. This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

As noted in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), the listed drug product Astagraf XL (NDA 204096), with which you share

conditions of approval for which new clinical studies were essential, is subject to a period of exclusivity protection under sections 505(c)(3)(E)(iii) and 505(j)(5)(F)(iii) of the Act. Therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until that product's exclusivity period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1) expiration of the exclusivity protection or 2) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL."** This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Tacrolimus, the active moiety in Envarsus XR, has orphan designation for the indication of prophylaxis of organ rejection in patients receiving allogeneic kidney transplant; therefore, PREA requirements do not apply to this application.

POSTMARKETING COMMITMENTS NOT SUBJECT TO REPORTING REQUIREMENT UNDER SECTION 506B

At the time of approval, we will request that you conduct studies listed in your submission dated October 10, 2014 as post-marketing commitments.

If you have any questions, call Ms. Lois Almoza, Regulatory Health Project Manager, at 301-796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Medication Guide
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RENATA ALBRECHT
10/30/2014