NDA 208742/S-005

SUPPLEMENT APPROVAL

Ocular Therapeutix, Inc.
Attention: Nicole M. Oliynyk
24 Crosby Drive
Bedford, MA 01730

Dear Ms. Oliynyk:

Please refer to your supplemental new drug application (sNDA) dated and received October 17, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the linear bar code on the DEXTENZA sample carton, 1 count commercial carton, and 10 count commercial carton.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELING

We acknowledge your October 17, 2019, submission containing final printed carton and container labeling.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Derek Alberding, Regulatory Health Project Manager, at (240) 402-0963.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
(Acting) Director
Division of Ophthalmology
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

WILEY A CHAMBERS
03/02/2020 06:11:50 PM