Clinical Review of NDA 21-493
Prior Approval Supplement

NDA 21-493/S-011
SDN-180

Submission Date: December 8, 2016
Receipt Date: December 8, 2016
Review Date: January 23, 2017

Applicant:

Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Applicant's Representatives:

Hillary Keir
Senior Associate, Glaobal Regulatory Affairs
714-246-3384

Drug: ZYMAR (gatifloxacin ophthalmic solution) 0.3%

Pharmacologic Category: quinolone antimicrobial

Submitted:
The applicant has submitted proposed labeling in compliance with the Agency's draft guidance on "Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products Content and Format." The proposed labeling also includes revisions that correspond to the recent changes to the ZYMAXID labeling approved September 8, 2016.

Following is the current labeling from S-010 which was approved on May 21, 2015.
The applicant's additions are noted by underline and deletions by.
The reviewer's additions are noted by underline and deletions by.

8 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

Recommendations:

The supplement (S-011) is not recommended for approval. Labeling consistent with the revisions contained within this review should be submitted.

Rhea Lloyd, MD
Medical Officer

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

/s/

RHEA A LLOYD
01/23/2017

WILLIAM M BOYD
01/23/2017