DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207986/S-001

SUPPLEMENT APPROVAL

Otonomy, Inc.
Attention: Barbara M. Finn
VP Regulatory Affairs and Quality Assurance
6275 Nancy Ridge Drive, Suite 100
San Diego, CA 92121

Dear Ms. Finn:

Please refer to your Supplemental New Drug Application (sNDA) dated January 19, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Otiprio (6% ciprofloxacin otic suspension).

This "Changes Being Effected" supplemental new drug application provides for edits to the Table of Contents in the Package Insert.

APPROVAL & LABELING

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

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 Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 796-1202.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

SUMATHI NAMBIAR
01/27/2016