DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205433

TENTATIVE APPROVAL

Pulmoflow Inc.
c/o Lachman Consultant Services, Inc.
Attention: Donald H. Chmielewski
Senior Associate
1600 Stewart Avenue
Westbury, NY 11590

Dear Mr. Chmielewski:

Please refer to your New Drug Application (NDA) dated October 2, 2013, received October 23, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for KITABIS PAK (tobramycin inhalation solution USP) (300 mg/5 mL ampule) and PARI LC Plus Reusable Nebulizer.

We acknowledge receipt of your amendments dated November 5, and 13, and December 16, 2013; February 24, and 27, March 5, 21 and 25, May 9, 12, and 29, June 11, and 19, July 10, 11, 14, 17, 18, 20, and 21, and August 7, 11, 15, 19 (2), and 21, 2014.

This NDA provides for the use of KITABIS PAK (co-packaging of tobramycin inhalation solution (300 mg/5 mL ampule) and PARI LC PLUS Reusable Nebulizer) for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *Pseudomonas aeruginosa.*

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 agreed-upon enclosed labeling (text for the package insert, text for the patient package insert, instructions for use, carton and immediate container labels**)**. 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.

The listed drug upon which your application relies is subject to a period of patent and/or exclusivity protection and 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 the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1) expiration of the patent 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).

If you have any questions, call Frances V. LeSane, Chief, Regulatory Project Management Staff, at (301) 796-0747.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling
Patient Information
Instructions for Use
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/

KATHERINE A LAESSIG
08/22/2014