

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**205433Orig1s000**

*Trade Name:* Kitabis Pak and Pari LC Plus Reusable Nebulizer

*Generic Name:* Tobramycin inhalation solution USP

*Sponsor:* Pulmoflow Inc.

*Approval Date:* December 2, 2014

*Indication:* For the management of cystic fibrosis in adults and pediatric patients 6 years of age or older with *Pseudomonas aeruginosa*.

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## 205433Orig1s000

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RESEARCH**

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**APPROVAL LETTER**



NDA 205433

**NDA 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, and October 2, and November 20, 2014.

The October 1, 2014, submission constituted a complete response to our August 22, 2014, action letter.

This new drug application 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 note that your November 20, 2014, submission includes final printed labeling (FPL) for your package insert, patient information package insert, and instructions for use. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, patient information, and PARI LC PLUS Reusable Nebulizer). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

## **CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your July 18, 2014, submission containing final printed carton and container labels.

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on July 18, 2014, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 205433.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## **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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For

more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **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 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  
PARI PLUS LC Reusable Nebulizer

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KATHERINE A LAESSIG  
12/02/2014