

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**022424Orig1s000**

***Trade Name:*** Flowtuss

***Generic Name:*** hydrocodone bitartrate and guaifenesin

***Sponsor:*** Mikart, Inc.

***Approval Date:*** May 14, 2015

***Indication:*** symptomatic relief of cough, to help loosen phlegm (mucus) and thin bronchial secretions to make cough more productive

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**APPROVAL LETTER**



NDA 22424

**NDA APPROVAL**

Mikart, Inc.  
1750 Chattahoochee Avenue, NW.  
Atlanta, GA 30318

Attention: Jason Waldroup  
Director, Regulatory Affairs

Dear Mr. Waldroup:

Please refer to your New Drug Application (NDA) dated November 29, 2010, received November 29, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flowtuss, (hydrocodone bitartrate and guaifenesin), oral solution, 2.5 mg/5 mL hydrocodone bitartrate and 200 mg/5 ml guaifenesin.

We acknowledge receipt of your amendments dated January 6, February 23, April 14, May 13 and 16, June 23, and October 7, 2011; February 2, 2012, November 18, and December 18, 2014; and January 13, February 9, and 19, March 20, April 20, and 28, May 11, and 14, 2015.

The November 18, 2014, submission constituted a complete response to our September 28, 2011, action letter.

This new drug application provides for the use of Flowtuss, (hydrocodone and guaifenesin) oral solution for symptomatic relief of cough, to help loosen phlegm (mucus) and thin bronchial secretions to make cough more productive.

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

**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). 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**

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels and carton and immediate container labels submitted on May 14, 2015, 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 22424.**” 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, contact Laura Musse, Regulatory Health Project Manager, at (240) 402-3720

Sincerely,

*{See appended electronic signature page}*

Lydia Gilbert-McClain, M.D.

Deputy Director

Division of Pulmonary, Allergy, and Rheumatology  
Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling

Carton and Container Labeling