DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 040148/S-053

SUPPLEMENT APPROVAL

Actavis Laboratories FL, Inc.
4955 Orange Drive
Fort Lauderdale, FL 33314

Attention: Janet Vaughn
Director, Regulatory Affairs

Dear Ms. Vaughn:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated and received September 25, 2014, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hydrocodone Bitartrate and Acetaminophen Tablets USP, 2.5 mg/325 mg, 5 mg/325 mg, 7.5 mg/325 mg and 10 mg/325 mg, and NORCO® (Hydrocodone Bitartrate and Acetaminophen Tablets, USP), 7.5 mg/325 mg and 10 mg/325 mg.

This Changes Being Effected supplemental abbreviated new drug application provides for the revised labeling in accordance with the rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II.

We have completed the review of this supplemental application. It is approved effective on the date of this letter. However, please make the following revisions to the labeling and submit them in a Supplement- Changes Being Effected.

GENERAL COMMENTS

1. For 2.5/325 mg and 5/325 mg only: Revise the manufacturing statement on all labeling to reflect the manufacturer name change to Actavis Laboratories FL, Inc.
2. We note that you have not submitted the labeling for the trade name, Norco 2.5/325 mg strength. Please comment or submit the labeling if you intend to market this strength.

To facilitate review of your next submission please provide a side-by-side comparison of your proposed labeling with the last approved labeling of the RLD with all differences annotated and explained.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is

identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files. If you have any questions, call or email Julie Call, Labeling Project Manager, at (240) 402-8598 or julie.call@fda.hhs.gov.

Sincerely,

John F. Grace -S

Digitally signed by John F. Grace -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John F. Grace -S, 0.9.2342.19200300.100.1.1=1300074582
Date: 2014.12.19 09:27:54 -05'00'

for Koung Lee, RPh, MSHS
Acting Director
Division of Labeling Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: Content of Labeling