DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 040885

Nexgen Pharma, Inc.
Attention: Robert van Osdel
Vice President, Scientific Affairs
17802 Gillete Avenue
Irvine, CA 92614-6502

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 20, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Butalbital, Acetaminophen and Caffeine Capsules USP, 50 mg/300 mg/40 mg.

Reference is made to your amendments dated December 4, 2007; February 20, June 3, 2008; and March 9, September 11, and September 17, 2009. Reference is also made to the ANDA Suitability Petition (2004P-0561/CP1) submitted under Section 505(j)(2)(c) of the Act and approved by this office on March 31, 2005. This petition permitted the agency to file this ANDA for a drug product that differs in strength from the reference listed drug product (RLD). Specifically, 300 mg of the acetaminophen component is present in your drug product vs. 325 mg in the Mikart's RLD as noted below.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined that your Butalbital, Acetaminophen and Caffeine Capsules USP, 50 mg/300 mg/40 mg, can be expected to have the same therapeutic effect as that of the reference listed drug, (RLD), Butalbital, Acetaminophen and Caffeine Capsules USP, 50 mg/325 mg/40 mg of Mikart, Inc., upon which the agency relied

as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in

content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 040885".***

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-40885	ORIG-1	ANABOLIC LABORATORIES INC	BUTALBITAL;ACETAMINOPHEN ;CAFFEINE

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

/s/

ROBERT L WEST
11/16/2009
Deputy Director, for Gary Buehler