



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 40-811

Beckloff Associates, Inc.  
U.S. Agent for Pulsion Medical Systems AG  
Attention: Michael Whalon, Ph.D.  
Executive Director, Pharmaceutical Sciences  
Commerce Plaza II, Suite 300  
7400 West 110<sup>th</sup> Street  
Overland Park, KS 66210

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 26, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Indocyanine Green for Injection USP, 25 mg per vial.

Reference is also made to your amendments dated May 24, July 13, August 13, September 26, October 8, October 23, November 8 and November 19, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Indocyanine Green for Injection USP, 25 mg per vial to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, IC Green for Injection, 25 mg per vial of Akorn Inc.

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.

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  
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.

Sincerely yours,

*{See appended electronic signature page}*

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

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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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Gary Buehler

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