DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-050/S-031

Akorn, Inc
2500 Millbrook Drive
Buffalo Grove, IL 60089

Attention: Sam Boddapati, PhD.
Vice President, Regulatory Affairs

Dear Dr. Boddapati:

Please refer to your supplemental new drug application dated December 6, 2006, received December 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sufenta (Sufentanil Citrate Injection, USP).

This "Changes Being Effected" supplemental new drug application provides for changes to your carton and container labeling to add the statements "Preservative Free" and "For I.V. and EPIDURAL USE."

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL).

We remind you of your agreement, in your email dated May 31, 2007, to implement the changes listed below at the next printing of your labeling, expected to take place in late 2008 when your current supply is depleted.

1. Replace the abbreviation "I.V." with the word "intravenous" on both the carton and container (ampule) labels.

2. Relocate the route of administration statement to the central portion of the label on the carton and container (ampule) labels. We note that you agreed to switch the location of your company name ("Taylor Pharmaceuticals") with the location of the route of administration on the 2 and 5 mL ampule labels.

   We also note that in order to implement the same change on the 1 mL ampule, you will remove the statement "May be habit forming" on the 1 mL ampule. The removal of this statement on this presentation of the product, in order to allow room for this change is acceptable to the Agency.

3. In all labeling, present the total drug content per total volume followed by the milligram per milliliter concentration rather than *vice versa*. For example:

   100 mcg/2 mL
   (50 mcg/mL)

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

/s/

Bob Rappaport

6/4/2007 05:55:11 PM