DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-619/S-032

Akorn, Inc.
150 S. Wykles Road
Decatur, IL 62522

Attention: Amber Sheriff
Regulatory Affairs

Dear Ms. Sheriff:

Please refer to your supplemental new drug application dated September 5, 2002, received September 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sublimaze (fentanyl citrate) Injection.

We acknowledge receipt of your submission dated August 26, 2003, which constituted a complete response to our March 28, 2003, action letter.

This supplemental new drug application provides for a revised package insert. Reference to Inapsine (droperidol) is deleted from all the applicable sections of the labeling.

We have completed the review of this application, as amended, and it is approved effective on the date of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Kimberly Compton, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

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