

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/07/2010 - 09/17/2010*
	FEI NUMBER 1419498

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kimberly J Wasserkrug, Executive Director, Quality Control and Assurance

FIRM NAME Akorn, Inc.	STREET ADDRESS 150 S Wyckles Rd
CITY, STATE, ZIP CODE, COUNTRY Decatur, IL 62522-1038	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Drug product production and control records, are not reviewed by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,
According to the firm's SOP QA 149 Forms, Logs, and Logbooks-Preparation, Revision and Control states that daily use logs or forms will be reviewed "(b) (4)" and maintenance logs are reviewed "(b) (4)".

- The Manual Inspection Booth Light Intensity Log forms were not regularly reviewed after the form is completed. After reviewing approximately 20 records located in this log book, 8 were not reviewed.
- Packaging (b) (4) Equipment Set Up, Use and Cleaning Log was missing quality review from 06/03/10 through 7/23/10.
- Equipment Cleaning and Set-Up log for LABLR (b) (4) (b) (4) LABELER was not reviewed from 08/07/08 through 04/29/09, then from 6/18/09 through 08/18/09, and then from 12/08/09 through 09/07/10.
- Maintenance Log for LABLR (b) (4) LABELER was not reviewed from 02/10/10 through 08/09/10.
- Maintenance Log for CODER (b) (4) was not reviewed from 02/09/10 through 08/23/10.
- Maintenance Log for LABLR (b) (4) was not reviewed from 02/09/10 through 08/31/10.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Phung Thien Nguyen, Investigator <i>P. Thien Nguyen</i> Carl A. Huffman III, Investigator <i>Carl A Huffman III</i>	DATE ISSUED 09/17/2010
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- Maintenance Log for (b) (4) was not reviewed from 02/08/10 through 08/31/10.

* DATES OF INSPECTION:

09/07/2010(Tue), 09/08/2010(Wed), 09/09/2010(Thu), 09/17/2010(Fri)

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OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Phung Thien Nguyen, Investigator
Carl A. Huffman III, Investigator

Phung Thien Nguyen
Carl A. Huffman III

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