

**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 10/19/2009 - 11/10/2009*
	FEI NUMBER 3003102962

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Mark M. Silverberg, Executive VP, Operations, Global Quality Assurance**

FIRM NAME Akorn, Inc.	STREET ADDRESS 1925 W. Field Court, Suite 300
CITY, STATE, ZIP CODE, COUNTRY Lake Forest, IL 60045	TYPE ESTABLISHMENT INSPECTED Human and Veterinarian Drug 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 I OBSERVED:**

**OBSERVATION 1**

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

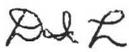
1. The written procedure, Complaint Receipt, RA120, effective date 12-22-08, does not include procedures that describe the specific reference for the receipt and documentation of MedWatch forms from regulatory agencies.
2. The written procedure, Processing and Investigation of Complaints, SOP RA110, effective date 10-19-09, is deficient in that it does not state when the final Quality Assurance review is required. The final Quality Assurance review was not completed within 90 calendar days for the following complaints.
  - a) Complaint File # 900170412, Reference # AKO-4951, received 1/26/09 for Paremyd, Lot 8B24A, the final QA review was on 5/27/09.
  - b) Complaint File # 900279210, Reference # AKO-4958, received 3/6/09 for Akten Gel 3.5%, Lot 8E86B, the final QA review was on 8/10/09.
  - c) Complaint File # 900206012, Reference # none, Received 3/5/09 for Akwa Tears Solution, Lot 111078, the final QA review was on 6/22/09.
3. The written procedure, Processing and Investigation of Complaints, SOP RA110, effective date 10-19-09, does not include instructions for handling investigations of complaints from contract customers that extend beyond 90 calendar days. The following complaint investigations were not completed within 90 days and are still open.
  - a) Complaint File # 900548210, Reference # A100-2009-05, Received 6/24/09 for AnaSed, Lot LA (b) (4) manufactured by Akorn for (b) (4)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Debra I. Love, Investigator <i>Debra I. Love</i>	DATE ISSUED 11/10/2009
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER
TO: Mark M. Silverberg, Executive VP, Operations, Global Quality Assurance		3003102962
FIRM NAME	STREET ADDRESS	
Akorn, Inc.	1925 W. Field Court, Suite 300	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Lake Forest, IL 60045	Human and Veterinarian Drug Manufacturer	

- b) Complaint File # 900648210, Reference # A100-2009-06, Received 6/24/09 for AnaSed, Lot LA (b) (4), manufactured by Akorn for (b) (4)
  - c) Complaint File # 900148610, Reference # T-2009-01, Received 7/17/09 for Tolazine Injection, Lot LA (b) (4), manufactured by Akorn for (b) (4)
  - d) Complaint File # 900248610, Reference # T-2009-02, Received 7/17/09 for Tolazine Injection, Lot LB (b) (4) manufactured by Akorn for (b) (4)
4. The Adverse Drug Experience Decision Tree, form # ra0006, was not reviewed by Quality Assurance for the following complaints.
- a) Complaint File # 800179210, Reference # AKO-4942, received 11/11/08 for (b) (4) Lot (b) (4) complaint closed 2/10/09.
  - b) Complaint File # 800279210, Reference # AKO-4943, received 12/3/08 for (b) (4) Lot (b) (4) complaint closed 3/3/09.
  - c) Complaint File # 900279210, Reference # AKO-4958, received 3/6/09 for (b) (4) Lot (b) (4) complaint closed 8/10/09.

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	Debra I. Love, Investigator 	11/10/2009

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**OBSERVATION 2**

Complaint records are deficient in that they do not include the findings of the follow-up.

Specifically, the following complaints regarding lack of effect and/or adverse events do not include documentation of attempts to obtain more follow-up information than initially provided by the complainant.

1. Complaint File # 800179210, Reference # AKO-4942, received 11/11/08 for (b) (4) Lot (b) (4) complaint closed 2/10/09. Only one attempt to obtain follow-up information.
2. Complaint File # 800279210, Reference # AKO-4943, received 12/3/08 for (b) (4) Lot (b) (4) complaint closed 3/3/09. Only one attempt to obtain follow-up information.
3. Complaint File # 900279210, Reference # AKO-4958, received 3/6/09 for (b) (4) Lot (b) (4) complaint closed 8/10/09. Only one attempt to obtain follow-up information.
4. Complaint File # 800270412, Reference # AKO-4958, received 5/12/08 for (b) (4) Lot (b) (4) complaint closed 6/24/08. Only one attempt to obtain follow-up information.

**\* DATES OF INSPECTION:**

10/19/2009(Mon), 10/22/2009(Thu), 10/23/2009(Fri), 10/26/2009(Mon), 10/28/2009(Wed), 10/29/2009(Thu), 10/30/2009(Fri), 11/04/2009(Wed), 11/10/2009(Tue)

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