**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**

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| _____, Individually and on behalf of all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>AKORN, INC., RAJAT RAI, and DUANE A. PORTWOOD,<br><br>Defendants. | Case No:<br><br>**CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**<br><br>JURY TRIAL DEMANDED |

Plaintiff _____ ("Plaintiff"), by Plaintiff's undersigned attorneys, individually and on behalf of all other persons similarly situated, alleges the following based upon personal knowledge as to Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Akorn, Inc. ("Akorn" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of a class consisting of all persons and entities, other than Defendants and their affiliates, who purchased or otherwise acquired publicly traded securities of Akorn from August 1, 2018 through January 8, 2019,

inclusive (the "Class Period"), seeking to recover compensable damages caused by Defendants' violations of federal securities laws (the "Class").

## JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. § 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 8 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

4. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b), as the Company conducts business and is headquartered in this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

## PARTIES

6. Plaintiff, as set forth in the attached Certification, acquired Akorn securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

7. Defendant Akorn develops, manufactures, and markets specialized generic and branded pharmaceuticals, over-the-counter drug products, and animal health products in the United States and internationally. Akorn is a Louisiana corporation with its headquarters located at 1925

W. Field Court, Suite 300, Lake Forrest, Illinois 60045. Akorn securities trade on the NASDAQ under the ticker symbol "AKRX."

8. Defendant Rajat Rai ("Rai") has been the Company's Chief Executive Officer ("CEO") since May 21, 2010. He was also Akorn's Interim CEO from March 2, 2009 to May 21, 2010.

9. Defendant Duane A. Portwood ("Portwood") has been the Company's Chief Financial Officer ("CFO") and Executive Vice President since October 30, 2015.

10. Defendants Rai, and Portwood are sometimes referred to herein as the "Individual Defendants."

11. Each of the Individual Defendants:

a. directly participated in the management of the Company;

b. was directly involved in the day-to-day operations of the Company at the highest levels;

c. was privy to confidential proprietary information concerning the Company and its business and operations;

d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

e. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

f. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

g. approved or ratified these statements in violation of the federal securities laws.

12. Akorn is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

13. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Akorn under *respondeat superior* and agency principles.

14. Defendant Akorn and the Individual Defendants are referred to herein, collectively, as the "Defendants."

## SUBSTANTIVE ALLEGATIONS

### Background

15. On May 16, 2018, the Food and Drug Administration ("FDA") issued Akorn a Form 483, a document used to communicate concerns discovered during inspection.

### Materially False and Misleading Statements Issued During the Class Period

16. On August 1, 2018, the Company filed a Form 10-Q for the quarter ended June 30, 2018 (the "2Q 2018 10-Q") with the SEC, which provided the Company's second quarter 2018 financial results and position. The 2Q 2018 10-Q stated that the Company's disclosure controls and procedures were effective as of June 30, 2018. The 2Q 2018 10-Q was signed by Defendant Portwood.

17. The 2Q 2018 10-Q contained signed certifications pursuant to the Sarbanes-Oxely Act of 2002 ("SOX") by Defendants Rai and Portwood attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud

18. On November 6, 2018, the Company filed a Form 10-Q for the quarter ended September 30, 2018 (the "3Q 2018 10-Q") with the SEC, which provided the Company's third quarter 2018 financial results and position. The 3Q 2018 10-Q stated that the Company's disclosure controls and procedures were effective as of September 30, 2018. The 3Q 2018 10-Q was signed by Defendant Portwood.

19. The 3Q 2018 10-Q contained signed SOX certifications by Defendants Rai and Portwood attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

20. That same day, in lieu of an earnings conference call, Akorn issued the following press release in connection with their third quarter earnings, noting that the Company received a Form 483 at the conclusion of an FDA inspection in May 2018:

> **Akorn Provides Third Quarter 2018 Results**
>
> LAKE FOREST, Ill., Nov. 06, 2018 (GLOBE NEWSWIRE) -- Akorn, Inc. (Nasdaq: AKRX), a leading specialty generic pharmaceutical company, today announced its financial results for the third quarter of 2018.
>
> **Business Highlights**
>
> - Revenues declined predominantly due to the effect of competition on key products such as Ephedrine Sulfate Injection, Lidocaine Ointment, Methylene Blue Injection and Nembutal
> - In the third quarter of 2018, the decrease in revenues due to pricing was approximately 3% compared to the same period in 2017, the lowest drop in the trailing six quarters
> - Overall portfolio well-balanced and diversified with no product contributing greater than 10% of total revenues
> - Received six new ANDA approvals and launched three new ANDAs in the first 10 months of 2018
> - Completed construction of new laboratory facilities at Decatur and Somerset manufacturing sites
> - Completed installation and qualification of serialization equipment on all required packaging lines ahead of FDA's November 2018 enforcement deadline for the Drug Supply Chain Security Act

- Continued to make progress on FDA action items and milestones as a result of recent inspections of our facilities in Decatur and Somerset, as well as data integrity assessments and remediation globally

**Summary Financial Results for the Quarter Ended September 30, 2018**

Akorn reported net revenue of $165.6 million for the three month period ended September 30, 2018, representing a decrease of $36.8 million, or 18.2%, as compared to net revenue of $202.4 million for the three month period ended September 30, 2017. The decrease in net revenue in the period was primarily due to $39.6 million decline in organic revenue that was partially offset by $3.4 million net revenue increase in new products and product relaunches. The $39.6 million decline in organic revenue was due to approximately $33.4 million, or 16.5% and $6.2 million, or 3.1%, in volume and price declines, respectively. The organic revenue decline was principally due to the effect of competition on Ephedrine Sulfate Injection, Lidocaine Ointment, Methylene Blue Injection and Nembutal.

Consolidated gross profit for the quarter ended September 30, 2018 was $57.3 million, or 34.6% of net revenue, compared to $97.8 million, or 48.3% of net revenue, in the corresponding prior year quarter. The decline in the gross profit percentage was principally due to increased operating costs associated with FDA compliance related improvement activities, unfavorable variances due to decreased production resulting from a planned maintenance shutdown at our Decatur manufacturing facility, as well as unfavorable product mix shifts.

GAAP net loss for the third quarter 2018 was $70.1 million, or $(0.56) per diluted share, compared to GAAP net loss of $2.9 million, or $(0.02) per diluted share, for the same quarter of 2017. Including a net adjustment of $63 million to net loss for non-GAAP items, adjusted diluted earnings per share for the third quarter 2018 were $(0.06), compared to $0.16 in the same quarter 2017, after a net adjustment of $23 million to net income for non-GAAP items.

Earnings before interest, taxes, depreciation and amortization (EBITDA) was $(56.2) million for the third quarter 2018 compared to $29.2 million for the third quarter 2017. Adjusted EBITDA, which is another non-GAAP measure used by management to evaluate the continuing operations of the Akorn business, was $10.0 million for the third quarter 2018, compared to $54.3 million for the third quarter 2017. See "Non-GAAP Financial Measures" below.

**Frequently Asked Questions**

While we are not hosting a 3Q earnings call, we understand that investors have many questions about our business. Below are answers to the more frequently asked questions.

**What is serialization or the Drug Supply Chain Security Act ("DSCSA")? Why was the serialization project notable for Akorn?**

Among other requirements, the DSCSA requires manufacturers to add a unique serial number to the unit of sale for each prescription pharmaceutical product. In order to comply with this new requirement, Akorn and its contract manufacturing partners needed to install and qualify new equipment on each and every packaging line. Akorn has incurred capital costs of approximately $50 million to date, and expects to spend up to $10 million more in late 2018 and 2019 to complete the customer requirements for data aggregation in its warehouses.

**Akorn's capital expenditures in recent years have been much higher than historical spending. What level of spending should we expect going forward?**

The higher spending was due to large discrete projects such as serialization, new quality control laboratories and facility modernization activities in Decatur and India. Going forward, we expect capital spending to be below the 2018 run rate.

**Can you provide an update on your ANDA pipeline?**

As of October 31, 2018, Akorn had 62 ANDAs pending at the FDA, representing approximately $6.8 billion in annual branded and generic market value according to IQVIA.

* * *

**What is the latest on the recent FDA inspections of Akorn's Decatur and Somerset facilities?**

***Our Decatur facility received a Form 483 at the conclusion of an FDA inspection in May 2018, to which we submitted a robust response in early June. We have made substantial progress (approximately 80% of our action items are complete) and we are on track to complete the majority of the remaining action items by the end of 2018.***

Our Somerset facility received a Form 483 following an FDA inspection ending in August 2018, to which we submitted a robust response in late September. We are on schedule with our action items and have made good progress already with approximately 45% of our action items completed.

**What costs has Akorn incurred in connection with the assessments and remediation activities related to data integrity?**

Year to date in 2018, we have incurred expenses of $23.7 million ($22.4 million charged to SG&A, $1.3 million to cost of goods) on the data integrity assessment and remediation efforts.

**What are Akorn's expectations for the appeal of the Delaware Court of Chancery ruling?**

We believe in the merit of our appeal, but the ultimate decision is up to the Supreme Court of the State of Delaware, which will hear oral arguments on December 5, 2018. We cannot predict the timing of the decision, however, we were pleased that the Court granted our Motion to Expedite.

**What happens if Akorn loses the appeal? When will you give guidance?**

It is premature to communicate any forward-looking guidance; we appreciate your patience as we work through the appeal process. If we do not prevail, we will continue our focus on creating long-term shareholder value and advancing our mission to improve patients' lives through the quality, availability and affordability of our products.

**What's the value proposition for shareholders now?**

Akorn has a long history of creating shareholder value through the manufacture and marketing of generic and branded prescription pharmaceuticals, as well as animal and consumer health products. We specialize in difficult-to-manufacture sterile and non-sterile dosage forms including ophthalmics, injectables, oral liquids, otics, topicals, inhalants and nasal sprays. While the ongoing litigation has created distractions and included many misleading and false allegations about Akorn, our commitment to running the business, complying with regulatory requirements and pursuing avenues for growth has not changed.

(Emphasis added.)

21. The statements referenced in ¶¶16-20 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Akorn's management misled investors about the severity of its manufacturing violations; (2) the Company's response to the Form 483 was inadequate; and (3) as a result, the Company's public statements were materially false and misleading at all relevant times.

## The Truth Emerges

22. On January 9, 2019, before the market opened, Akorn announced that it had received a warning letter "dated January 4, from the U.S. Food and Drug Administration (FDA) related to an inspection of its Decatur, Illinois manufacturing facility in April and May of 2018."

23. The letter from the FDA detailed a laundry list of "significant violations" of current good manufacturing practice regulations, stating, in pertinent part:

> Dear Mr. Rai:
>
> The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Akorn, Inc. at 1222 West Grand Avenue, Decatur, IL, from April 9 to May 16, 2018.
>
> This warning letter summarizes ***significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals***. See 21 CFR, parts 210 and 211.
>
> ***Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 50l(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 35l(a)(2)(B).***
>
> ***We reviewed your June 7, 2018, response in detail and acknowledge receipt of your subsequent correspondence.***
>
> During our inspection, our investigators observed specific violations including, but not limited to, the following.
>
> **1. Your firm failed to follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).**
>
> *Poor Aseptic Behavior*
>
> Operators displayed poor aseptic practices during aseptic set-up and filling operations. For example:
>
> a. Operators placed their head and upper torso inside the filling cabinet during interventions and performed interventions over open vials without clearing them.

b. Operators excessively handled sterile stopper bags before introduction into the stopper chute in the ISO 5 filling cabinet. Specifically, operators removed the outer secondary layer (sterility barrier) and manually handled the sterile single-layer bag. These stopper bags were then re-placed on the non-sterile shelving units located in the ISO 7 area for extended periods of time. During this time, operators unnecessarily touched and manipulated the bags. These bags are subsequently introduced into the stopper chute located in the ISO 5 filling cabinet. Notably, your procedures specifically prohibit manipulation of the stoppers once the outer bag has been removed.

In addition, operators shook stopper bags inside the ISO 5 area and the bag also contacted the interior of the stopper chute (critical product contact surface) during the loading process. Your procedures specifically prohibit agitating and shaking during loading.

Personnel also failed to disinfect stopper bags prior to their introduction into the ISO 5 area, again, as required per your procedure.

c. Operators placed sterile wipes on a ledge below the filling line and later used the same wipes to clean the interior of the ISO 5 filling area cabinet doors and part of the filling area machine where open sterile vials were exposed.

d. Interventions require a large door to be opened. When opened, the door is exposed to the ISO 7 area, and when being closed, there is a significant risk of the lower quality room air sweeping into the ISO 5 filling cabinet. Empty sterile vials are located extremely close to the door. In addition, although operators wiped the open door after interventions were complete, the wiping was vigorous, only disinfected part of the door, and was performed while closing the door. The line design and operator practices both contribute to an unacceptable risk of contamination of the open sterile vials.

In addition, certain interventions performed on the ISO 5 filling line were not documented in your intervention log records, as per your procedures.

*Non-Integral Cleanroom Materials*

Our investigators observed non-integral packages containing sterile gloves. Packages were also observed to contain foreign matter, such as fibers. These gloves, purported to be sterile, are worn by aseptic manufacturing operators who perform critical interventions and can present a contamination hazard to your products. Examples of such interventions include making aseptic connections, clearing

jammed and fallen vials, adjusting sterile production equipment, and changing environmental monitoring plates.

In another instance, our inspection found holes in the secondary packaging layer of your sterile wipes. Your firm assumed the outer layer provided a sterile barrier for the primary, interior package. Only by contacting the supplier during our inspection did you learn that the outer layer is not a sterile barrier. Firm management acknowledged the primary layer is never disinfected before use in the cleanroom. Further, your supplier qualification protocol remains insufficient, and your supplier qualification program does not require you to ensure the suitability of this supplier.

*Inadequate Cleanroom Design and Smoke Study Deficiencies*

Your stopper hopper leans diagonally over the top of the filling line during stopper loading operations, thereby blocking first air over open, exposed sterile vials.

In addition to this inadequate design, your smoke studies performed for your ISO 5 areas also lacked simulation of multiple critical interventions that occur during aseptic manufacturing operations.

Thorough smoke studies are essential to evaluate the effects of such interventions on unidirectional airflow and to ensure design modifications are made wherever necessary.

The ISO 5 area is critical because sterile product is exposed and therefore vulnerable to contamination. Your aseptic filling process should be designed, and operations executed, to prevent contamination hazards to your sterile product. The flawed design of the filling line and execution of the aseptic operations promote influx of contamination into the critical filling areas.

***Your firm's response is inadequate. We acknowledge you engaged a third party to assist in efforts to re-train personnel and provide additional oversight of aseptic practices, and that you are revising procedures. You also stated that you are installing restricted air barrier systems (RABS), as previously committed in 2016. You state that you plan to perform supplemental smoke studies for interventions not captured in the current studies and additional smoke studies once you install the new RABS.***

However, you did not provide a sufficient evaluation of all batches produced under inadequate conditions. You also did not commit to extensive redesign of your aseptic process operation.

In response to this letter, provide:

- A comprehensive, independent identification of all contamination hazards with respect to your aseptic processes, equipment, and

facilities. Include an independent risk assessment that covers, among other things, all human interactions with the ISO 5 area, equipment placement and ergonomics, air quality in the ISO 5 area and surrounding room, facility layout, personnel flow, and material flow.

- A detailed corrective action and preventative action (CAPA) plan, with timelines, to address the findings of the contamination hazards risk assessment. Describe how you will significantly improve aseptic processing operation design and control and personnel qualification.

- Your plan to ensure appropriate aseptic practices and cleanroom behavior during production. Include specific steps to ensure routine and effective supervisory oversight for all production batches. Describe the frequency of quality assurance oversight (e.g., audit) during aseptic processing and other operations. Also, provide your protocol and an update on your third party's independent assessment of your aseptic practices. As part of your assessment, summarize your review of past processing videos.

- A thorough risk assessment that evaluates how poor aseptic technique and cleanroom behavior, such as those observed during the inspection, may have affected quality and sterility of your drugs.

- A description of the extent of the missing batch record entries for interventions performed. Detail how you will remediate your system for recording interventions while also not adding further contamination risks to your products.

- A review of your supplier qualification, monitoring, and maintenance program to ensure you adequately address the quality of the materials brought into the cleanroom. Include a review of all materials, including but not limited to, disposable materials (e.g., sterile gloves and wipes) to ensure integrity and prevent contamination in the aseptic processing operation.

- A copy (e.g., a video file) of your new smoke study recordings and a detailed description or schematic of the RABS extension used to provide local protection of the stopper hopper area. Provide an independent assessment of the smoke studies.

**2. Your firm failed to perform operations within specifically defined areas of adequate size and to have separate or defined areas or such**

**other control systems necessary to prevent contamination or mix-ups in aseptic processing areas (21 CFR 211.42(c)(10)).**

*Environmental and Personnel Monitoring*

***Your environmental monitoring program is deficient.*** Your procedures allowed personnel performing aseptic interventions in the ISO 5 cabinet to have one colony-forming unit (CFU) on their gloves on a repeated basis without triggering an appropriate response. Your action limit for this location was two CFUs, and you had no alert limit. You lacked scientific justification for your limit and the associated procedure.

In addition, personnel were observed sanitizing their hands with isopropyl alcohol prior to personnel monitoring. Sanitizing gloved hands just before sampling is unacceptable because it can prevent microbial recovery and it undermines the reliability of personnel monitoring data.

***Your response is inadequate. While you commit to evaluate your environmental monitoring program, your target completion date is December 31, 2019. You commit to tighten the glove limit for personnel monitoring, but only after "critical" interventions in the ISO 5 areas. Growth observed on glove samples taken from personnel performing any activities within the ISO 5 area should trigger an alert or action condition that, at a minimum, should lead to trending and may indicate the need for further investigation. Notably, your SOP identifies numerous interventions, defined as major and minor, which require extensive activities within the ISO 5 zone. Any personnel who perform activities within the ISO 5 area should meet your tightened glove limit.***

In response to this letter, provide:

- A comprehensive, independent, retrospective review of your personnel and environmental monitoring program. Include a risk assessment of personnel and environmental monitoring data since April 2015. Indicate the changes you will make to your program to ensure it provides meaningful information by robustly detecting and responding to microbial data from your classified areas. Provide an updated timeline for implementation of your program and procedural changes.

- The most recent revision of your "Environmental Site Selection and Justification" document.

*Cleaning Operations*

Your cleaning program is deficient. While operator entries in sanitization records state that all required sanitization steps were completed in cleanrooms, many steps were actually skipped, and various pieces of equipment were not sanitized.

Your operators did not ensure the mop makes proper contact with the floor. Mops were not wetted frequently to ensure adequate coverage. For example, an operator cleaned the walls surrounding Line AH for several minutes without rewetting the mop.

***In your response, you stated that you have performed targeted training on sanitization procedures. Further, you note that your disinfectant efficacy program demonstrates the ability of your agents to reduce bioburden. Your response is inadequate. You are not consistently following your validated procedures.***

***Although you acknowledge that all disinfection activities had not been completed, you have not determined the scope of these poor practices observed at your facility, including identifying employees involved and how long this has been occurring. You did not extend your investigation to determine if complete disinfection activities and proper documentation practices were followed.***

In response to this letter, provide:

- The investigations and CAPAs initiated in response to the cleaning and disinfection observations by our investigators. Provide updated cleaning and disinfection forms.

- A comprehensive evaluation of the design, control, maintenance, and oversight of your cleaning and disinfection program.

- An overall management strategy that describes how your executive management will oversee improvements in design and execution of manufacturing operations and ensure ongoing scrutiny to enable sustainable quality assurance.

**3. Your firm failed to follow a written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).**

You cannot ensure the stability of your product, acetylcysteine injection 200 mg/mL, because you have not performed L-Cystine and L-Cysteine impurity testing on stability samples since 2016. At the time of the inspection, you also did not have a validated test method.

Your 2016 annual report for acetylcysteine injection 200 mg/mL to the agency notes that the L Cystine and L-Cysteine impurity tests are pending for stability samples. However, the tests are not included in the 2017 annual report. Your 2017 internal stability report states "NO TEST" for both impurity tests.

We acknowledge that you filed a field alert report during the inspection and initiated a recall of all lots of acetylcysteine injection 200 mg/mL on June 22, 2018, because the specification could not be confirmed over the shelf-life. We also acknowledge you filed a supplement to revise the test method.

***In your response, you state no other stability testing issues were noted with FDA-approved test methods. Your response is inadequate. You did not include such an evaluation for your other marketed products (irrespective of whether you hold a drug application).***

In response to this letter, provide a comprehensive assessment and CAPA to ensure the adequacy of your stability program. Your CAPA should include, but should not be limited to, a remediated standard operating procedure (SOP) describing your stability program; stability-indicating methods; stability studies to support each drug product in its container-closure system before distribution is permitted; an ongoing program in which representative batches of each product are added each year to the program to determine if the shelf-life claim remains valid; and specific attributes to be tested at each station. The stability program should ensure the suitability and validation of your analytical methods, and requirements to assess impact of insufficient methods on marketed products.

* * *

**Quality Systems**

Your firm's quality systems are inadequate. For guidance on establishing and following CGMP compliant quality systems, see FDA's guidance for industry:

- *Q8(R2) Pharmaceutical Development*, at https://www.fda.gov/downloads/drugs/guidances/ucm073507.pdf;
- *Q9 Quality Risk Management*, at https://www.fda.gov/downloads/Drugs/guidances/ucm073511.pdf; and
- *Q1O Pharmaceutical Quality System*, at https://www.fda.gov/downloads/drugs/guidances/ucm073517.pdf.

* * *

**Data Integrity Remediation**

As detailed above, FDA has concerns regarding the accuracy of intervention, sanitization, and other records produced at this facility. Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. See FDA's guidance

document, *Data Integrity and Compliance With Drug CGMP*, for guidance on establishing and following CGMP compliant data integrity practices at https://www.fda.gov/downloads/drugs/guidances/ucm495891.pdf.

We acknowledge that you are using a consultant to audit your operation and assist in meeting FDA requirements. In response to this letter, provide the following:

A. A comprehensive investigation into the extent of the inaccuracies in data, records, and reporting, including results of the data review for drugs distributed to the United States. Include a detailed description of the scope and root causes of your data integrity lapses.

B. A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analyses of the risks to patients caused by the release of drugs affected by a lapse of data integrity and analyses of the risks posed by ongoing operations.

C. A management strategy for your firm that includes the details of your global CAPA plan.

**Conclusion**

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations in all your facilities.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, and the Center for Veterinary Medicine (CVM) at AskCVM@fda.hhs.gov, or by telephone to 1-888-INFO-FDA (1-888-463-6332) so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Correct the violations cited in this letter promptly. ***Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved violations in this warning letter may also prevent other Federal agencies from awarding contracts.***

> ***Until these violations are corrected, we may withhold approval of pending drug applications listing your facility. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.***
>
> After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

(Emphasis added.)

24. On this news, the Company's shares fell $0.46 per share or over 11.6% to close at $3.48 per share on January 9, 2019, damaging investors.

25. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities Plaintiff and other Class members have suffered significant losses and damages.

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

26. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Akorn securities publically traded on NASDAQ during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

27. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Akorn securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or

thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Akorn or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

28. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

29. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

30. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Akorn;

c. whether the Individual Defendants caused Akorn to issue false and misleading financial statements during the Class Period;

d. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

e. whether the prices of Akorn securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

f. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

31. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

32. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. Akorn securities are traded in an efficient market;

d. the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

e. the Company traded on the NASDAQ and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

g. Plaintiff and members of the Class purchased, acquired and/or sold Akorn securities between the time the Defendants failed to disclose or misrepresented material facts

and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

33. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

34. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

## COUNT I

### Violations of Section 10(b) of The Exchange Act and Rule 10b-5 Against All Defendants

35. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

36. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

37. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Akorn securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Akorn securities

at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

38. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Akorn securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Akorn's finances and business prospects.

39. By virtue of their positions at Akorn, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

40. Defendants were personally motivated to make false statements and omit material information necessary to make the statements not misleading in order to personally benefit from the sale of Akorn securities from their personal portfolios.

41. Akorn showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or

directors of Akorn, the Individual Defendants had knowledge of the details of Akorn's internal affairs.

42. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Akorn. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Akorn's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Akorn securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Akorn's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Akorn securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

43. During the Class Period, Akorn securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Akorn securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Akorn securities was substantially lower than the prices paid by Plaintiff and the other members

of the Class. The market price of Akorn securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

44. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

45. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

## COUNT II

### Violations of Section 20(a) of The Exchange Act Against The Individual Defendants

46. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

47. During the Class Period, the Individual Defendants participated in the operation and management of Akorn, and conducted and participated, directly and indirectly, in the conduct of Akorn's business affairs. Because of their senior positions, they knew the adverse non-public information about Akorn's current financial position and future business prospects.

48. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Akorn's business practices, and to correct promptly any public statements issued by Akorn which had become materially false or misleading.

49. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and

public filings which Akorn disseminated in the marketplace during the Class Period concerning the Company's business, operational and accounting policies. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Akorn to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Akorn within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Akorn securities.

50. Each of the Individual Defendants, therefore, acted as a controlling person of Akorn. By reason of their senior management positions and/or being directors of Akorn, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Akorn to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Akorn and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

51. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Akorn.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as her reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: February _, 2019

Respectfully submitted,

**THE ROSEN LAW FIRM, P.A.**

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