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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**Form 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): June 25, 2019

**Akorn, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Louisiana**  
(State or Other Jurisdiction of Incorporation)

**001-32360**  
(Commission File Number)

**72-0717400**  
(I.R.S. Employer Identification Number)

**1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045**  
(Address of Principal Executive Offices) (Zip Code)

**(847) 279-6100**  
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock, No Par Value</b>	<b>AKRX</b>	<b>The NASDAQ Global Select Market</b>

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### **Item 7.01. Regulation FD Disclosure.**

On June 25, 2019, Akorn, Inc. (“Akorn” or the “Company”) issued a press release announcing that it received a warning letter from the U.S. Food and Drug Administration (FDA) related to an inspection of its Somerset, New Jersey manufacturing facility in July and August of 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including exhibit 99.1 attached hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

### **Cautionary Note Regarding Forward-Looking Statements**

This report and press release may include forward-looking statements about, among other things, the Company’s expectations regarding quality systems, action plans, operations, initiatives, continued production of product, and other statements regarding Akorn’s goals and strategy that are subject to substantial risks and uncertainties which could cause actual results to differ materially from those expressed or implied by such statements. These risk factors include, but are not limited to: (i) the effect of the Delaware court’s recent decision against the Company on the Company’s ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, or its operating results and business generally, (ii) the risk that ongoing or future litigation related to the court’s decision may result in significant costs of defense, indemnification and/or liability, (iii) the outcome of the investigation conducted by the Company with the assistance of outside consultants, into alleged breaches of FDA data integrity requirements relating to product development at the Company and any actions taken by the Company, third parties or the FDA as a result of such investigations, (iv) the difficulty of predicting the timing or outcome of product development efforts, including FDA and other regulatory agency approvals and actions, if any, (v) the timing and success of product launches, (vi) difficulties or delays in manufacturing, (vii) the Company’s increased indebtedness and compliance with certain covenants and other obligations under the Standstill Agreement, which create material uncertainties and risks to its growth and business outlook, (viii) the Company’s obligation under the Standstill Agreement to enter into a Comprehensive Amendment that is satisfactory in form and substance to the Lenders, (ix) the Company’s obligation under the Standstill Agreement to pay certain fees and expenses and increased interest margin, (x) such other risks and uncertainties outlined in the risk factors detailed in Part I, Item 1A, “Risk Factors,” of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (as filed with the Securities and Exchange Commission (“SEC”) on March 1, 2019), detailed in Part II, Item 1A, “Risk Factors,” of the Company’s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2019 (filed with the SEC on May 7, 2019) and other risk factors identified from time to time in the Company’s subsequent reports on Form 8-K and in other Company filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on the Company’s forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. The Company undertakes no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes or developments.

### **Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b><u>Exhibit No.</u></b>	<b><u>Description of Exhibit</u></b>
<a href="#">99.1</a>	<a href="#">Press release dated June 25, 2019, entitled “Akorn Receives FDA Warning Letter.”</a>

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Akom, Inc.

Date: June 25, 2019

By: /s/ Duane A. Portwood

Duane A. Portwood  
Chief Financial Officer

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**Investors/Media:**  
(847) 279-6162  
Investor.relations@akorn.com

## **Akorn Receives FDA Warning Letter**

LAKE FOREST, Ill., June 25, 2019 – Akorn, Inc. (Nasdaq: AKRX), a leading specialty generic pharmaceutical company, announced that it received a warning letter from the U.S. Food and Drug Administration (FDA) related to the inspection of its Somerset, New Jersey manufacturing facility in July and August of 2018.

Akorn is committed to the highest standards of quality and compliance, and will continue to work collaboratively with the FDA to resolve all issues addressed in the warning letter. The Company will respond to the FDA letter within the required 15 working days from receipt of the letter.

Douglas Boothe, Akorn's President and Chief Executive Officer, stated, "Akorn is committed to resolving the warning letter in a comprehensive and effective manner. Earlier this year, Akorn launched a companywide action plan to improve the timing and effectiveness of our operations, quality systems and compliance enhancement initiatives, with an emphasis on transparency and quality. We believe the execution of this action plan, which has already begun to yield tangible results, will strengthen and further standardize our quality systems across the entire Akorn network."

The Company has full confidence in the quality of the products manufactured at the Somerset facility and expects to continue production at the plant.

### **Cautionary Note Regarding Forward-Looking Statements**

This press release may include forward-looking statements about, among other things, the Company's expectations regarding quality systems, action plans, operations, initiatives, continued production of product, and other statements regarding Akorn's goals and strategy that are subject to substantial risks and uncertainties which could cause actual results to differ materially from those expressed or implied by such statements. These risk factors include, but are not limited to: (i) the effect of the Delaware court's recent decision against the Company on the Company's ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, or its operating results and business generally, (ii) the risk that ongoing or future litigation related to the court's decision may result in significant costs of defense, indemnification and/or liability, (iii) the outcome of the investigation conducted by the Company with the assistance of outside consultants, into alleged breaches of FDA data integrity requirements relating to product development at the Company and any actions taken by the Company, third parties or the FDA as a result of such investigations, (iv) the difficulty of predicting the timing or outcome of product development efforts, including FDA and other regulatory agency approvals and actions, if any, (v) the timing and success of product launches, (vi) difficulties or delays in manufacturing, (vii) the Company's increased indebtedness and compliance with certain covenants and other obligations under the Standstill Agreement, which create material uncertainties and risks to its growth and business outlook, (viii) the Company's obligation under the Standstill Agreement to enter into a Comprehensive Amendment that is satisfactory in form and substance to the Lenders, (ix) the Company's obligation under the Standstill Agreement to pay certain fees and expenses and increased interest margin, (x) such other risks and uncertainties outlined in the risk factors detailed in Part I, Item 1A, "Risk Factors," of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (as filed with the Securities and Exchange Commission ("SEC") on March 1, 2019), detailed in Part II, Item 1A, "Risk Factors," of the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2019 (filed with the SEC on May 7, 2019) and other risk factors identified from time to time in the Company's subsequent reports on Form 8-K and in other Company filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on the Company's forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this press release. The Company undertakes no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes or developments.

### **About Akorn**

Akorn, Inc. is a specialty generic pharmaceutical company engaged in the development, manufacture and marketing of multisource and branded pharmaceuticals. Akorn has manufacturing facilities located in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; Hettlingen, Switzerland and Paonta Sahib, India that manufacture ophthalmic, injectable and specialty sterile and non-sterile pharmaceuticals. Additional information is available on Akorn's website at [www.akorn.com](http://www.akorn.com).

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