

AMAG PHARMACEUTICALS INC.

Form 8-K

July 22, 2016

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

**FORM 8-K**

**CURRENT REPORT PURSUANT  
TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): **July 19, 2016**

**AMAG PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-10865**  
(Commission File  
Number)

**04-2742593**  
(IRS Employer Identification  
No.)

**1100 Winter St.  
Waltham, Massachusetts**  
(Address of principal executive  
offices)

**02451**  
(Zip Code)

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(617) 498-3300

(Registrant's telephone number, including area code)

(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))
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**Item 8.01 Other Events.**

On July 19, 2016, AMAG Pharmaceuticals, Inc. (the *Company*) was notified by the U.S. Food and Drug Administration that the Prior Approval Supplement for Coldstream Laboratories, Inc. (which is owned by Piramal Enterprises Limited) was approved for the manufacture of the single-dose, 1 mL, preservative-free formulation of Makena® (hydroxyprogesterone caproate injection). This approval provides the Company with an alternative manufacturer for the single-dose formulation of Makena.

**SIGNATURES**

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.

**AMAG PHARMACEUTICALS, INC.**

By: /s/ Joseph D. Vittiglio, Esq.  
Joseph D. Vittiglio, Esq.  
Senior Vice President, General Counsel and Secretary

Date: July 21, 2016