CUMBERLAND PHARMACEUTICALS INC
Form 8-K
January 28, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): January 28, 2019 (January 28, 2019)

CUMBERLAND PHARMACEUTICALS INC.
_____
(Exact name of registrant as specified in its charter)

Tennessee	001-33637	62-1765329
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2525 West End Avenue, Suite 950, Nashville, Tennessee 37203
(Address of principal executive offices) (Zip Code)

(615) 255-0068
Registrant's telephone number, including area code:

Not Applicable
_____

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company o
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. o

Item 8.01 Other Events

On January 25, 2019, Cumberland Pharmaceuticals Inc. (the "Company" or "we") received the notice of approval from the U.S. Food and Drug Administration ("FDA") for an application associated with our next generation Caldolor® (ibuprofen) injection product (the "Product"). This Product features a new, patented formulation in a more convenient to use package.

We submitted the approval application for the Product to the FDA in February 2018 and in April 2018 the FDA determined that the application was complete and notified us of their acceptance for review. There were then a number of communications with the FDA and their questions were addressed through multiple amendments that we submitted to the application. In August 2018, the Company received a complete response from the FDA outlining additional information needed for the application's approval. We provided the requested quality and nonclinical data to the FDA in September 2018.

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first injectable product approved by the FDA for fever. It was also the first non-steroidal anti-inflammatory drug (NSAID) approved for pain and fever in pediatric patients six months of age and older.

For full prescribing instructions, including important safety information visit www.caldolor.com. Information on the website is not, and will not be deemed, a part of this report or incorporated into any other filings the Company makes with the Securities and Exchange Commission.

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.

Cumberland Pharmaceuticals Inc.

Dated: January 28, 2019 By: /s/ Michael Bonner

Name: Michael Bonner
Title: Chief Financial Officer