VIA EDGAR

September 29, 2017

Ms. Dorrie Yale and Mr. Christopher Edwards
U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F. Street, N.E.
Washington, D.C. 20549

Re: ANI Pharmaceuticals, Inc.
10-K for Fiscal Year Ended December 31, 2016
Filed March 2, 2017
File No. 001-31812

Dear Ms. Yale and Mr. Edwards:

We are hereby submitting this letter in response to your September 15, 2017 comment letter (the "**Comment Letter**") from the staff ("**Staff**") of the Securities and Exchange Commission ("**Commission**") to ANI Pharmaceuticals, Inc. (the "**Company**").

Paragraphs No. 1 and 2 set forth below respond to the Staff's comments in the Comment Letter. Bold face type indicates the Staff's comment set forth in the Comment Letter.

Item 1. Business
Manufacturing, Suppliers, and Raw Materials, page 6

1. We refer to your statement that you generally only qualify a single source of API. In future filings, please expand your disclosure to discuss the availability of raw materials for your products. Refer to Item 101(c)(1)(iii) of Regulation S-K.

RESPONSE:

In response to the Staff's comment, we propose that we will include the following disclosure in future 10-K filings:

Manufacturing, Suppliers, and Raw Materials

We require a supply of quality raw materials, including active pharmaceutical ingredients ("API"), and components to manufacture and package our pharmaceutical products. In order to manufacture Opium Tincture, Oxycodone oral solution, and Oxycodone capsules, we must submit a request to the DEA for a quota to purchase the amount of opium and oxycodone needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers.

We source the raw materials for our products from both domestic and international suppliers, which we carefully select. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a Prior Approval Supplement ("PAS") by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare, but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we select suppliers with great care, based on various factors including quality, reliability of supply, and long-term financial stability. Certain of the APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, such as EEMT, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections.

Research and Development, page 9

2. In future filings, please expand your discussion of your material agreements to disclose for each agreement

- **aggregate amounts paid or received to date;**
- **aggregate potential milestone payments to be paid;**
- **the percentages involved in any profit-sharing arrangements within a ten-point range;**
- **the duration of the agreement; and**
- **the termination provisions.**

Please also file your Sofgen agreements, or alternatively, please tell us why that is not required.

In future filings, we will expand our discussion of material agreements to disclose the income statement impact of aggregate amounts paid or received to date, aggregate potential milestone payments to be paid, duration of agreements, and termination provisions. We will take into consideration the facts and circumstances of each agreement and disclose information related to profit-sharing arrangements in a manner that provides accurate information that we believe would be material to shareholders. We feel that a blind undertaking by the Company to disclose profit-sharing arrangements within a ten-point range in all circumstances would put the Company at a competitive disadvantage to its peers because many of the Company's public-company peers do not always disclose profit-sharing arrangements within a ten-point range, and there could be profit-sharing arrangements where a ten-point range is not adequate to protect the economic interests of the Company. In situations where the Company believes disclosure of its profit-sharing arrangements within a ten-point range would not put the Company at a competitive disadvantage, the Company would make such disclosure in its Exchange Act reports.

Although we describe our agreements with Sofgen Pharmaceuticals (the "Sofgen Agreements") in our Annual Report on Form 10-K for the year ended December 31, 2016 in order to give context to our shareholders about our research and development activities, we do not view the Sofgen Agreements as "material contracts" that are required to be filed, as defined in Item 601(b)(10) of Regulation S-K. Total net revenues for the distribution of product sold under the Sofgen Agreements were less than 1% of our total net revenues in 2016 and are therefore immaterial to our business. Total costs under both agreements were less than 1% of total operating expenses in 2016. Due to the immaterial nature of the Sofgen Agreements, we may remove the disclosure regarding the Sofgen Agreements in our Annual Report on 10-K for the year ended December 31, 2017.

Thank you for reviewing our response. Should you have any questions, please do not hesitate to contact Brian Lee at (212) 768-6926.

Sincerely,

/s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and CFO

cc: Arthur S. Przybyl, President and CEO
Paul A Gajer, Esq., Dentons US LLP
Brian Lee, Esq., Dentons US LLP

210 Main Street West, Baudette, MN 56623 ● Phone (218) 634-3500 ● Fax (218) 634-3540
Toll-Free (800) 434-1121