VIA EDGAR

October 31, 2018

Ms. Vanessa Robertson and Ms. Mary Mast
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, 2017
Filed February 27, 2018
File No. 001-31812

Dear Ms. Robertson and Ms. Mast:

We are hereby submitting this letter in response to your October 18, 2018 comment letter (the "**Comment Letter**") from the staff ("**Staff**") of the Securities and Exchange Commission ("**Commission**") to ANI Pharmaceuticals, Inc. (the "**Company**").

Paragraph No. 1 set forth below responds to the Staff's comment in the Comment Letter. Bold face type indicates the Staff's comment set forth in the Comment Letter.

5. Intangible Assets
Definite-lived Intangible Assets
Acquisition of New Drug Applications and Product Rights, page 89

1. We acknowledge your response to comment 1 in our letter dated September 7, 2018. With respect to the Product Rights Acquired from AstraZeneca, your response does not consider risks, other than marketing and promotional risks. At a minimum, please address the following potential risks:

- **The drugs are intended to treat significantly different conditions which bear the risk of potentially different long-term side effects. Branded drugs are subject to litigation which may not occur for years after being marketed;**
- **Each drug has a significantly different potential customer base with different regulatory risks;**
- **Each drug has different risks with respect to being on drug formulary lists; and**
- **Although the products have been marketed for more than 17 years, the competition differs for each of the different drugs, despite the lack of promotional activity for the drugs.**

In light of the risks, other than marketing and promotional risk, please tell us why you believe the product rights acquired from AstraZeneca do not have significantly different risk characteristics and thus meet the "practical screen" test in ASC 805-10-55-5A through 55-5C. If the acquisitions do not meet the "practical screen test" please address each of the criteria in ASC 805-10-55-5E in determining whether or not a substantive process was acquired, that together with the input acquired, significantly contribute to the ability to create outputs.

RESPONSE:

We acknowledge the Staff's comment and the FASB requirements with respect to the analysis of risks for the four products acquired from AstraZeneca in December 2017.

By way of further background, ANI is historically, and principally, a manufacturer, marketer and distributor of generic drugs. At this time, we have no brand marketing team, no brand managed market access team, no physician facing brand sales force, no therapeutic focus, or any of the internal infrastructure that one would typically associate with a branded pharmaceutical company, nor do we have any plans to acquire any such infrastructure to place behind the four products acquired from AstraZeneca.

In recent years, we have purchased a handful of what in the industry are known as “tail brands.” Tail brands are branded pharmaceutical products that have been genericized for many years, experienced significant generic volume erosion, and are generally no longer actively promoted by the innovator company in any material way. In fact, each of these brands has four or more generic competitors. Despite the presence of significant generic competition, brand products generally have residual volume market share for numerous years post introduction of generic competitors. Over time, this volume market share generally falls to the single digits to less than single digit share, however it tends not to go to zero until a product is removed from the market. There are two primary sources of the residual market share for tail brands: the first is a comprised of either patients or doctors who do not trust or otherwise “believe in” the use of generic products. The second is patients who have an allergy to a particular inactive ingredient of the generic products, but for whom the active ingredient of the brand medication is effective in treating their condition. Collectively, we will refer to these two groups as the “Tail Brand Customer Base.”

At a certain point in time, innovator companies tend to view tail brands as a distraction to their core strategy to research, develop and market novel therapies, and periodically “prune” such assets by selling them to other market participants. This allows the innovator company to monetize its asset and reallocate manufacturing and administrative capacity while not taking the more dramatic step of discontinuing a product and walking away from patients (and potentially incurring negative publicity). For a market participant such as ANI, these transactions provide an opportunity to continue to serve the existing patient base, further utilize our manufacturing, packaging, and distribution capabilities, and in turn, generate future cash flows.

We provide this further background as we believe that it is important to the analysis to understand the “lens” that ANI views the transaction through. Tables A and B are attached to further document the above discussion.

The drugs are intended to treat significantly different conditions which bear the risk of potentially different long-term side effects. Branded drugs are subject to litigation which may not occur for years after being marketed.

We acknowledge that, with the exception of Atacand and Atacand HCT, which treat the same condition (please refer to Table A), the products acquired from AstraZeneca treat different conditions with the potential for different long-term side effects. We also acknowledge that branded drugs are subject to litigation that may occur years after being marketed. However, the risk of new side-effects and other pharmacovigilance issues being found decreases with every year a product is on the market. As illustrated in Table A, these products have been marketed in the U.S. between 17 and 22 years, and the corresponding generic versions of these products have been in the market for 5 to 10 years. At this point in the product lifecycle, the products have been the subject of substantial clinical research and multiple years of adverse event reporting. As a result, the pharmacovigilance profiles of the drugs are widely known and as such, we believe the risk of future product liability related litigation is extremely low for each of these products.

Each drug has a significantly different potential customer base with different regulatory risks.

We respectfully note that, while the customer base of each drug is different when viewed through a therapeutic category lens as they are comprised of patients with different conditions to treat, the customer base of each drug is the same when viewed through the lens of competition as described in the discussion of the Tail Brand Customer Base, above. As noted above, the regulatory risks for these old, established brands are similarly low, as events raised from pharmacovigilance efforts are at a steady state once the product has been on the market for several years. In addition, as the products have been approved by FDA for many years, the chance of new regulatory issues arising is minimal. As a result, we determined that the risks related to the customer base and risks related to regulatory issues would be similar for each product.

Each drug has different risks with respect to being on drug formulary lists.

We respectfully note that, given the age of these products, the lack of any internal brand marketing team, brand managed market resources, and the consistent (albeit continuously declining) Tail Brand Customer Base, we do not put forth any efforts to have these products included on managed market formulary lists, nor do we offer rebates to any commercial insurers for the products. Sales of these products are not driven by active managed market sale efforts, rather, sales of these products are based on the residual volume of the marketing performed earlier in the brands lives and the factors described that cause patients to be prescribed the brand product despite the presence of lower cost generic alternatives. As a result, inclusion on drug formulary lists was not a consideration for purchase of these products and is not considered to be a significant risk for any of these products.

Although the products have been marketed for more than 17 years, the competition differs for each of the different drugs, despite the lack of promotional activity for the drugs.

We respectfully note that, because the sales of these products primarily stem from residual volume, and the factors described in defining Tail Brand Customer Base, competition for these products was not a key factor in our decision to acquire the products. In fact, the main competitors for market share for each of these branded products are the generic alternatives to the branded product. The brands rely on brand recognition and brand preferences to generate their market share. In addition, due to the nature of the Tail Brand Customer Base, prescription volume tends to be lost due to one or a combination of the following factors: a) the patient or doctor overcomes his or her aversion to a generic alternative, b) the incremental cost of the brand as compared to the generic alternative becomes prohibitive for the patient, c) the patient is cured of the underlying condition, and d) the patient is switched to a new class of therapy. All of these factors are the same across the four brands and therefore were evaluated as a homogenous group of similar assets.

Overall, we believe that, given the age of these drugs, the significant knowledge of the regulatory state of these drugs after hundreds of thousands (if not more) of life-to-date prescriptions for these drugs, the nature of the Tail Brand Customer Base and the lack of promotional effort by ANI to change the inevitable continual decline of these drugs in the marketplace, the risk profile for all four of these products across a wide range of categories, including marketing, distribution, promotion, regulatory, and legal is extremely similar and low. As stated in the background, these products are acquired to be small, gradually declining, sources of cash to the Company. As a result, we determined that the risks related to these four products were similar and therefore we classified the product rights assets as a group of similar assets that satisfies the "practical screen test."

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

TABLE A: Volume Market Share at Purchase

Brand	Molecule	Therapeutic Category	US FDA Approval	~Years in Mkt at ANI Purchase	First Generic Competition	~ Years Generic Competition	Monthly tablet volume (molecule) - Dec 2017	Brand tablet volume - Dec 2017	Brand market share - Dec 2017
Atacand®	Candesartan	Anti-hypertension	Jun 1998	19.5	May 2013	4.6	3,282,660	168,930	5.1%
Atacand HCT®	Candesartan Hydrochlorothiazide	Anti-hypertension	Sep 2000	17.2	Dec 2012	5.0	953,800	112,770	11.8%
Arimidex®	Anastrazole	Anticancer (breast)	Dec 1995	22.0	Jun 2010	7.5	15,130,030	46,950	0.3%
Casodex®	Bicalutamide	Anticancer (prostate)	Oct 1995	22.2	Jul 2008	9.4	2,010,920	4,050	0.2%

Source: IQVIA (based upon 2017 IQVIA data)

TABLE B: Volume Market Share by Year

Brand	2013	2014	2015	2016	2017	YTD 2018
Atacand®	55.9%	19.3%	11.2%	8.8%	5.7%	4.2%
Atacand HCT®	18.7%	16.3%	15.5%	12.8%	11.2%	9.3%
Arimidex®	1.9%	1.3%	0.8%	0.5%	0.4%	0.3%
Casodex®	0.8%	0.7%	0.4%	0.3%	0.2%	0.2%

Source: IQVIA (based upon 2013 through August 2018 YTD IQVIA data)