

December 12, 2022

Stephen P. Carey
Senior Vice President, Finance and Chief Financial Officer
ANI Pharmaceuticals, Inc.
210 Main Street West
dette , Minnesota 56623

Pharmaceuticals, Inc.
Fiscal Year Ended December 31, 2021
2022
August 8, 2022

Re: ANI
Form 10-K for
Filed March 15,
Form 8-K furnished
File No. 001-31812

Dear Stephen P. Carey:

We have reviewed your December 5, 2022 response to our comment letter and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our November 1, 2022 letter.

Form 8-K furnished November 9, 2022

Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation, page Table3

1. We note your non-GAAP adjustment for In-process research and development in the three months ended September 30, 2022. We believe the adjustment is inconsistent with Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretation. Please confirm to us you will no longer include the adjustment in any non-GAAP financial measure presented in accordance with Item 10(e) of Regulation S-K or Regulation G.

Stephen P. Carey
FirstName LastNameStephen
ANI Pharmaceuticals, Inc. P. Carey
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December NameANI
2022 Pharmaceuticals, Inc.
December
Page 2 12, 2022 Page 2
FirstName LastName
Correspondence dated December 5, 2022

Non-GAAP Financial Measures, page 6

2. You state in response to comment 1 that in connection with the November 2021 acquisition of Novitium Pharma LLC you acquired a fourth pharmaceutical manufacturing plant. During the integration of Novitium you determined that three manufacturing plants would support your manufacturing capacity needs and you thus decided

to close the
Canada plant and move the majority of production being undertaken in
Canada to the
remaining U.S. based manufacturing plants. As the operations appear to
be continuing,
although at a different manufacturing facility, it is unclear why it
is appropriate to include
a non-GAAP adjustment for the Canada operations. Please confirm you
will revise your
presentation in the future, or clarify to us further why you believe
revenues and expenses
relating to products previously manufactured at the Canada facility
will not continue at the
new manufacturing facility.

3. We acknowledge your response to comment 2. Although you are no longer
adjusting for
Cortrophin pre-launch charges and sales and marketing expenses, we
continue to believe
that the non-GAAP adjustments in prior periods are not appropriate
since these costs are
normal costs incurred in your business to achieve FDA approval,
regardless of whether or
not regulatory approval is ultimately obtained. Please confirm you
will revise to eliminate
these adjustments in future filings or tell us why these costs are
different from costs
incurred by other companies in your industry to obtain regulatory
approval.

You may contact Ibolya Ignat at 202-551-3636 or Mary Mast at
202-551-3613 with any
questions.

Sincerely,

Division of

Office of Life

Corporation Finance
Sciences