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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket 01P-0574/CP1

To whom it may concern:

On behalf of Novartis Pharmaceuticals Corporation ("Novartis"), I am writing to follow-up on the most recent submission to this docket by a Sandostatin® patient (01P-0574/C3).

As demonstrated by the clinical evidence and regulatory submissions Novartis filed in this docket to ensure the accuracy and completeness of the administrative record, the original acetic acid product was replaced because it caused more injection site pain and thus was less safe than the current, improved Sandostatin s.c. product. The first-hand evidence submitted by Novartis is based on the data from a clinical trial.

Ben Venue has not submitted the results of any comparable clinical trial that controverts in any respect the existing clinical evidence in this record. It was Ben Venue that sought clearance to market an outdated acetic acid-containing product that has been off the market for over seven years. Under the Agency's regulations, because Ben Venue wishes to file an ANDA for a product that was removed from the market, it is Ben Venue that bears the burden of demonstrating that the acetic acid product was not withdrawn for safety reasons. Ben Venue has failed to carry its burden.

Neither Ben Venue's failings in this proceeding nor Novartis' submissions to this docket will affect patients' access to duplicate versions of the improved lactic acid s.c. product – such as the one proposed in the ANDA Ben Venue filed under the name of its sister company, Bedford Laboratories. Assuming generic versions of the current s.c. product are able to satisfy the prerequisites for approval, patients will have access to one or more generic versions of the lactic acid product when FDA completes its review of the ANDAs proposing such products.

Respectfully submitted,

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Senior Director, Medical Services Oncology

01P-0574

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cc: Mr. Gary J. Buehler, Director, Office of Generic Drugs (HFD-600)
David Orloff, M.D., Dir., Div. of Metabolic and Endocrine Drug Prods. (HFD-510)
Martha Propsner, Assoc. Dir., Drug Regulatory Affairs, Novartis Pharms. Corp.