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November 19, 2002

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 concerns expressed by Sandostatin® patients regarding this ongoing proceeding. The petition on which these patients have commented presents a fairly straightforward safety issue for the Agency to resolve. The opinions and anecdotal evidence submitted by the patients do not alter the conclusions relevant to that decision: the original Sandostatin s.c. product was withdrawn because it caused more injection site pain and thus was less safe than the current improved product.

Based upon the patients' comments, it appears there might be some misinformation or misperception that this petition and Novartis' submissions are directed at any s.c. product. In fact, this petition and Novartis' subsequent comments have only addressed the original acetic acid product. This petition will only determine whether an application can be filed for such a product and will not affect the availability of duplicate versions of the improved and currently marketed lactic acid s.c. product being administered to these patients. Indeed, Ben Venue itself (using another name, Bedford Laboratories) has filed a separate application seeking approval of a generic version of the currently marketed s.c. product. However, just as Novartis is not marketing both products, neither should Ben Venue or any other firm. Others can follow Ben Venue's more enlightened decision and pursue a duplicate version of the improved lactic acid product. Assuming such products satisfy the prerequisites for approval, there will be one or more generics of the currently marketed product available to all patients when FDA completes its review of those applications.

With respect to the clinical safety issues raised by the pending petition, the patients' comments confirm Novartis' position that the original product resulted in pain at the injection site and support our position that pain with the original product (administered in accordance with its approved labeling) was worse than with the current product. Indeed, Dr. Kjell Öberg's medical opinion, included in the letter of one patient, corroborates Novartis' position: "[I]t is quite clear that the earlier preparations were causing these problems. The salt, Octreotide acetate had to be solved [sic] in acid solution and that was causing the local irritation. . . . Some patients were failing to use the old version because of irritation but these cases were really limited." (C2 at page 3).

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Based upon the anecdotal reports in the patients' comments, it appears that the currently marketed lactic product may not have completely eliminated all pain for all patients. However, these limited patient reports do not provide a reasonable basis for going back to an admittedly more painful acetic acid product. This is particularly true in light of the fact that the acetic acid product was never tested or used in conjunction with the Sandostatin LAR® depot product. Thus, as the Agency knows, the only clinical and postmarketing surveillance data available on the products' interaction is based on the currently marketed lactic acid product.

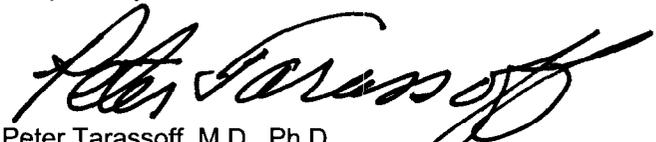
The patients' comments also present an interesting perspective on the injection site pain experienced with the withdrawn acetic acid product. Specifically, the comments suggest that injection site pain may be of little or no concern when the product is administered by infusion pump. Thankfully, these patients like all other users of Sandostatin are currently receiving the improved lactic acid product. Thus, as their comments indicate, they are not experiencing the same injection site pain documented with the old product – regardless of the manner in which the patient's physician is prescribing and administering the product.

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Although this petition presents a straightforward safety issue that should not involve consideration of economic issues, Novartis nonetheless has demonstrated a longstanding commitment to addressing the financial impact of lifesaving prescription drug products such as Sandostatin®, whose innovation depends upon research and development companies such as Novartis. Consistent with that commitment, Novartis maintains one of the most comprehensive and beneficial patient assistance programs in the industry for products like Sandostatin, as well as Gleevec®, Zometa® and Femara®.

These patients' comments have reaffirmed the longstanding and continuing role for Sandostatin in treating a debilitating and incurable condition. Novartis trusts that FDA's decision here will appropriately address patient safety and ensure that these and other patients are not exposed to the obsolete acetic acid product that has been off the market for over seven years.

Respectfully submitted,



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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, Associate Director, Drug Regulatory Affairs