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July 11, 2003

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 clarify the record with respect to two erroneous claims advanced by Ben Venue Laboratories ("Ben Venue") in its most recent submission to this docket (01P-0574/RC7). Specifically, Ben Venue (a) attempts to divorce itself from the actions of its own division, Bedford Laboratories ("Bedford"), and (b) suggests that a generic version of the withdrawn acetic acid Sandostatin® s.c. product should be approved because no generic version of the current, improved lactic acid product could be approved prior to 2015. Neither argument is valid.

1. Ben Venue Cannot Ignore Bedford's ANDAs For Lactic Acid Products

Ben Venue asserts, "We would like to clarify that Ben Venue did not submit an ANDA for the currently marketed product. Ben Venue submitted an ANDA for the discontinued formulation of Sandostatin." RC7 at 1. In view of the parent/subsidiary relationship between Ben Venue and Bedford, this statement is at best disingenuous. In two letters dated April 12, 2002, Bedford notified Novartis that it had filed two ANDAs (No. 76-313 and 76-330) for generic versions of the currently-available, improved s.c. product which utilizes lactic acid. See Exhibits 1 and 2 (enclosed). Although the subject of those letters is discussed below, they are relevant here because they indicate that Bedford is a division of Ben Venue. Additionally, Bedford's website – which is linked to Ben Venue's website – also refers to Bedford as a division of Ben Venue and states that Ben Venue is its "parent company." See www.bedfordlabs.com/about.html. Novartis' prior submissions always have highlighted the Ben Venue/Bedford relationship that Ben Venue chooses to disregard in its most recent letter. Plainly, Ben Venue's claim that it did not submit these ANDAs for the currently marketed product overlooks its corporate relationship with Bedford and for that reason is misleading.

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2. Ben Venue Has Misstated The Patent Situation For The Currently-Available Sandostatin s.c. Product

Ben Venue also contends, "However, what Novartis neglected to mention concerning generic products which are a duplicate of the current formulation is the fact that these generic products will not be eligible for final FDA approval until the expiration of the current patent which extends until 2015, regardless of the review status by the FDA." RC7 at 2. Obviously, patent issues would arise with exact duplicates of the subject matter claimed in Novartis' patent. However, the two letters from Ben Venue's Bedford division dated April 12, 2002 (cited above), claimed that Bedford would produce a lactic acid product but not infringe Novartis' patent that expires in 2015. Novartis has no information regarding the Ben Venue/Bedford product beyond what is set forth in those short letters. However, based upon the limited information in the letters, Novartis decided at the time it received them not to exercise its statutory right to initiate patent litigation prior to approval of the ANDAs. Accordingly, under the Hatch-Waxman Act, there is no patent-based reason why FDA cannot act on Bedford's ANDAs for lactic acid s.c. products. Despite its suggestion to the contrary, Ben Venue clearly was aware of this fact at the time that it made its most recent submission to this docket and thus understood the invalidity of its own insinuation that no lactic acid product could be approved prior to 2015.

Conclusion

Ben Venue continues to cast aspersions on the clinical trial safety evidence submitted to this record by Novartis, while also continuing to fail to submit a shred of clinical evidence of its own demonstrating that the outdated acetic acid-containing product (that has been off the market for over seven years) was not withdrawn for safety reasons.

Ben Venue cannot submit such evidence because none exists. It cannot be reasonably doubted, therefore, that Ben Venue is unable to sustain its regulatory burden in the context of this administrative proceeding and that its petition must be denied. Accordingly, as Ben Venue requests, the Agency should decide this matter and close this docket to further disingenuous submissions by Ben Venue.

Respectfully submitted,

Martha Propsner
Associate Director
Drug Regulatory Affairs

Enclosures

cc: Mr. Gary J. Buehler, Director, Office of Generic Drugs (HFD-600)
David Orloff, M.D., Director, Division of Metabolic and Endocrine Drug Products (HFD-510)
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