1.5 Specific Requirements for Different Types of Applications

1.5.2 Information for Generic, 'Hybrid' or Bio-similar Applications

This application is a generic application, according to Directive 2001/83/EC article 10(1) as amended by Directive 2004/27/EC.

The Notice to Applicants Volume 2A Chapter 1 issued in November 2005 states that the medicinal product to which the essential similarity is claimed must:

- Have been authorised within the Community, in accordance with Community provisions in force,
- Have been authorised within the Community for not less than 6/10 years,

In the aforementioned NTA the criteria for essential similarity have been outlined as follows:

- The same qualitative and quantitative composition in terms of active principles/substances,
- The same pharmaceutical form as the reference medicinal product,
- and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Both the term 'same qualitative and quantitative composition in terms of active principles/substances' and the term 'same pharmaceutical form' must be understood broadly and covers all products containing the same active substance and having the same properties with regards to safety and efficacy.

The medicinal product "Teriparatide 20 µg/80 µl, solution for injection in pre-filled pen" which has been developed at

is a "Generic" of the following reference product:

Name of medicinal product	Forsteo
Strengths	20 µg/80 µl
Pharmaceutical form	solution for injection
Manufactured by	
Marketing Authorization Holder	Eli Lilly Nederland BV, Papendorpseweg 83, 3528 BJ Utrecht The Netherlands
Marketing Authorization Number	EU/1/03/247/001-002

We have demonstrated in our application that our product meets the criteria for being a Generic product of the above reference product by:

- Detailed pharmaceutical characterization of our medicinal product in comparison to the reference product (Refer to Module 3.2.P.2. Pharmaceutical Development)

- Our medicinal product has the same qualitative and quantitative composition in terms of active substance as the reference product, and there is no difference in properties with regard to efficacy and safety.

- A bioequivalence study was not performed since Teriparatide 20 µg/80 µl is a solution for injection containing the same active substance as the currently approved product.

In conclusion, the product under consideration, Teriparatide 20 µg/80 µl, solution for injection in pre-filled pen complies with all criteria for essential similarity and can therefore be applied as a generic application according to article 10.(1) of Directive 2001/83/EC as amended.

Conclusion

Based on the above evidences, we have conclusively demonstrated that Teriparatide 20 µg/80 µl, solution for injection in pre-filled pen is essentially similar to Forsteo® 20 µg/80 µl, solution for injection in pre-filled pen.