

Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)  
143-147 bd Anatole France  
FR-93285 Saint Denis Cedex  
France

Copy to Regulatory Affairs **Welding GmbH & Co. KG**

29<sup>th</sup> January 2019

**Ref:** Letter of Access to ASMF for Teriparatide (**eCTD-PTH**).

Number of Active Substance Master File: **unknown**

Name of Active Substance: **Teriparatide**

Active Substance Master File holder: \_\_\_\_\_ [Address: \_\_\_\_\_]

To whom it may concern:

The aforementioned Active Substance Master File holder hereby authorises the **Agence Nationale de Sécurité du Médicament et des Produits de Santé** to refer to and review the above mentioned Active Substance Master File in support of the following Marketing Authorisation Application(s) or Marketing Authorisation Variation(s) submitted by **Welding GmbH & Co. KG**:

- Products:
  - **Teriparatide 20 µg/ 80µl Solution for injection in pre-filled pen (DE/H/6160/001/DC)**
- Marketing Authorisation Holder: **Welding GmbH & Co. KG**, [Esplanade 39, 20354 Hamburg, Germany]

The aforementioned Active Substance Master File holder commits to ensure batch to batch consistency and to inform **Welding GmbH & Co. KG**, and Competent Authority of any change in the Active Substance Master File likely to alter in any way the quality and/or safety of products.

The aforementioned Active Substance Master File holder hereby is informed of and accepts that the EEA National Competent Authorities, the EMA including all CHMP and CVMP Members and their experts, and the Certification of Substances Division of the European Directorate for the Quality of Medicines & Healthcare may share the assessment reports of the above mentioned Active Substance Master File amongst themselves.

Please be so kind as to acknowledge receipt.

Sincerely yours.

Sílvia Arrastua  
Regulatory Affairs