类固醇激素系列生产技术

1，Steroidal APIs Classes

- Corticosteroids 皮质类固醇类
- Progestins 孕激素类
- Androgens 雄激素类
- Estrogens 雌激素类
- Anabolics，合成代谢类

2，Bulk for APIs: Producers

A. <u>Historical Western Producers</u>: (Upjohn, Aventis, Syntex, Schering, Roussell-Uclaf, Hoechst, Merck, etc.) – Fully backward integrated – Use of Betasitosterol (BS) as the starting material (see page 3: Route B), which material is cheap and widely available, also in the form of waste materials coming from other technological processes (soy, paper pulp, etc.) – Big chemical and fermentation plants are needed – Fermentation is a technology which cannot be renounced for the production of Steroids starting from BS – In the last thirty years these producers have developed enzymatic processes too, which processes drastically reduce the volumes required by classical fermentation processes

B. <u>Historical Chinese Producers:</u> [Tianjin Pharmaceutical Corp., Hua Lian (Shanghai), etc.] - Fully backward integrated – Use of Diosgenin as the starting material, which material is obtained from Dioscorea roots, by means of a destructive process – Nowadays Chinese Producers, due to a shortage of Diosgenin, with a consequent increased price of 16-DPA (see page 3: Route A) are trying to develop processes starting from BS but no important results have been achieved yet- Big chemical and fermentation plants are needed - Also in this case Fermentation is a technology which cannot be renounced for the production of Steroids – Chinese producers rather than APIs, which would require the well know sophisticated quality apparatus (GMP, FDA approval, etc), sell advanced intermediates, employed in turn by producers belonging to the following group

C. <u>Rest of the World Steroids Producers:</u> – Chemical Synthesis only - Multipurpose plants with relatively small volumes are needed – These Producers start from very advanced intermediates, purchased on Chinese Market only – Such a production is highly affected by fluctuation of USD currency and/or by possible shortages which may arise

3，Steroid series APIs