

To: STN 125062/674

From: Adriane Fisher, MPH, MBA

Subject: Final Draft Labeling

Recommendation: Acceptable

Background:

I did a comparison of the June 9, 2021 (Sequence 0559) draft labeling and the final draft June 15, 2021 (Sequence 0561) for OCTAPHARMA Pharmazeutika Produktionsges.m.b.H. 125062/674 and that there were no other changes.

> Adriane D. Digitally signed by Adriane D. Fisher -S Fisher -S

Date: 2021.06.22 12:33:30 -04'00'