The French National Agency for
Medicines and Health Products Safety
143-147 bd Anatole France
FR-93285 Saint Denis Cedex
France

Apr. 27, 2017

LETTER OF ACCESS

Version Number of Active Substance Master File: Applicant's Part V6.0 & Restricted Part V5.0
Name of Active Substance: Latanoprost

Manufacturing site:

Active Substance Master File Holder:

The aforementioned Active Substance Master File holder hereby authorizes the *French National Agency for Medicines and Health Products Safety/France* to refer to and review the above mentioned Active Substance Master File in support of the following Marketing Authorization Application submitted by *Laboratoire CHAUVIN*:

Name of product: Vizilatan 0,05 mg/ml, collyre en solution
Number of DCP: DK/H/2754/001/DC

Name of Applicant or Marketing Authorization holder: **Laboratoire CHAUVIN**
416 rue Samuel Morse CS 99535
MONTPELLIER Cedex 2, 34961
France

The aforementioned Active Substance Master File holder commits to ensure batch to batch consistency and to inform the *French National Agency for Medicines and Health Products Safety/France* and *Laboratoire CHAUVIN* of any change in the Active Substance Master File.

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.

Sincerely,