

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Drug Master File Staff
Beltsville MD 20705-1266
USA

Pharmaceutical Systems

SCHOTT Schweiz AG

St. Josefen-Str. 20
9001 St. Gallen
Switzerland

Phone +41 (0) 71 274 1600
Fax +41 (0) 71 274 1616
www.schott.com/pharmaceutical_systems

Date: December 14, 2015

DMF#: 9205

Holder: SCHOTT Schweiz AG

Subject: PRIMARY PACKAGING MATERIAL (VIALS, CARTRIDGES) MANUFACTURED IN ST. GALLEN
SWITZERLAND

Letter of Authorization for: Entire DMF 9205

SCHOTT Schweiz AG hereby authorizes the following company to incorporate by reference information regarding packaging material in DMF 9205 into any application filed by this company for their product. We also authorize the FDA to review all information in DMF 9205 when considering any application filed by this company.

Information to be referenced: Entire Type III DMF 9205,
Date of Submission: Reorganized January 22, 2014

Company: Sanofi-aventis US LCC and Sanofi-aventis US Inc
55 Corporate Drive

08807 Bridgewater, New Jersey
USA

Product: Insulin lispro solution for injection 100 IU/mL

The DMF holder states that DMF 9205 is current and will comply with the statements made within it.
We request that all information in this file be treated as confidential within the meaning of 21 CFR 314.420.

Sincerely,
SCHOTT Schweiz AG



Yvonne Putzi
Customer Service

Office of Submissions & Intellectual Property
ATTN: Drug Master File Administration Unit
Therapeutic Products Directorate
Health Canada
101 Tunney's Pasture Driveway,
Finance Building
Address Locator 0201A1
Ottawa, Ontario

Pharmaceutical Systems

SCHOTT Schweiz AG

St. Josefen-Str. 20
9001 St. Gallen
Switzerland

Phone +41 (0) 71 274 1600
Fax +41 (0) 71 274 1616
www.schott.com/pharmaceutical_systems

December 09, 2015

1995-086

Dear Sir or Madam:

RE: PRIMARY PACKAGING MATERIAL VIALS CARTRIDGES - DMF 1995-086

Please accept this letter as authorization for the company and their product listed below to make reference to our drug master file, PRIMARY PACKAGING MATERIAL VIALS CARTRIDGES 1995-086 for the following components in support of their drug submission(s) to be filed with Health Canada.

Components to be referenced: Entire Type II DMF 1995-086,
Date of Submission: Reorganized October 24, 2013

Company: Novartis Pharmaceuticals Corp.
One Health Plaza
07936 East Hanover, NJ
USA

Product: Signifor (pasireotide) powder for suspension for injection

This authorization is, however, subject to all applicable regulations regarding confidentiality of such information.

Yours sincerely,
SCHOTT Schweiz AG



Yvonne Putzi
Customer Service