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April 20, 2017

PAOLO GOBBI FRATTINI S.r.l. Unipersonale Strada Provinciale per Vervio, 8 Tovo di S. Agata (SO) I-23030 Italy

Re: Drug Master File (DMF) 27342, Plastic Bags for Pharmaceutical Solutions and Their Components

Good Day:

We attach the Certificate of Drug Master File (DMF) issued by Registrar Corp verifying that PAOLO GOBBI FRATTINI S.r.l. Unipersonale is a Drug Master File holder with the U.S. Food and Drug Administration.

Filing of a Drug Master File does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of filing of Drug Master File is misleading. The U.S. Food and Drug Administration does not issue or recognize certificates of Drug Master Files.

Please contact us if you have any additional questions or need additional help with FDA compliance.

Sincerely,

David Lennarz Vice President

Registrar Corp is a private registration agent not affiliated with the U.S. Food and Drug Administration.



Certificate of Drug Master File (DMF)

Service Period June 1, 2017 – May 31, 2018

This certifies that:

PAOLO GOBBI FRATTINI S.r.l. Unipersonale Str. provinciale per Vervio, 8 23030 Tovo di S.Agata (SO) Italy

is a Drug Master File holder with the U.S. Food and Drug Administration pursuant to part 314 of Title 21, US Code of Federal Regulations, such filing having been verified as currently effective on the date hereof by Registrar Corp.

Drug Master File Number: 27342
Status: Active
Type: III

Subject: Plastic Bags for Pharmaceutical Solutions and Their

Components

Registrar Corp will confirm that such filing remains effective upon request and presentation of this certificate until May 31, 2018, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Filing of a Drug Master File does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of filing of Drug Master File is misleading. The U.S. Food and Drug Administration does not issue a certificate of Drug Master Files. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

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aved: April/20,2017