DR. REDDY'S

Dr. Reddy's Laboratories, Inc.

107 College Road East
Princeton, NJ 08540

Tel: (609) 375-9900
Fax: (877) 445-3741

www.drreddys.com

VIA CERTIFIED MAIL –
RETURN RECEIPT REQUESTED

TO: **Chief Executive Officer**
Galderma Labs L.P.
14501 N. Freeway
Ft. Worth, TX 76177

FROM: **Dr. Reddy's Laboratories, Ltd.**
Dr. Reddy's Laboratories, Inc.

DATE: **June 22, 2015**

RE: **NOTICE OF PARAGRAPH IV CERTIFICATION RE DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S DOXYCYCLINE CAPSULES 40MG; U.S. PATENT NOS. 7,211,267; 7,232,572; AND 8,603,506**

Dear Sirs:

Pursuant to § 505(b)(3)(B) of the Federal Food, Drug and Cosmetic Act ("the Act") and § 314.52 of Title 21 of the Code of Federal Regulations ("C.F.R."), please be advised that Dr. Reddy's Laboratories, Ltd. ("DRL") has filed a patent certification pursuant to § 505(b)(2)(A)(IV) of the Act and § 314.50(i)(1)(i)(A)(4) of Title 21 of the C.F.R. in support of their New Drug Application ("the DRL NDA") Number 208286 with respect to doxycycline capsules, 40 mg ("the Proposed DRL Doxycycline Product"). We understand that Galderma

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Labs L.P. ("Galderma") is the assignee of U.S. Patent Nos. 7,211,267 ("the '267 Patent"); 7,232,572 ("the '572 Patent"); and 8,603,506 ("the '506 Patent") (collectively "the Ashley Patents"). We also understand that Galderma is the holder of approved Application No. N050805 under § 505(b) of the Act (New Drug Application or "NDA") in connection with doxycycline capsules, 40mg (ORACEA®).

DRL provides the following information:

(1) The U.S. Food and Drug Administration ("FDA") has received the DRL NDA submitted by DRL with respect to doxycycline capsules, 40 mg;

(2) The DRL NDA number is 208286;

(3) The established name of the proposed drug product, as defined in § 502(e)(3) of the Act, is doxycycline;

(4) The active ingredient of the Proposed DRL Doxycycline Product is C22H24N2O8, HCl, ½ C2H5OH, ½ H2O, also known as:

2-Naphthacenecarboxamide, 4-(dimethylamino)1, 4,4a,5, 5a, 6, ll,12a-octahydro-3,5,10,12,12a-pentahydroxy- 6-methy1-1,11-dioxo-, monohydrochloride, compound with ethanol (2: 1), monohydrate, [4*S*-(4α,4aα,5α,6α,12α)] (or)

4-(Dimethylamino)-1,4,4a,5,5a, 6, 11,12a-octahydro- 3,5,10, 12,12a-pentahydroxy-6-methyl-1,11-dioxo-2 naphthacene carboxamide monohydrochloride, compound with ethyl alcohol (2: 1), monohydrate (or)

Hydrochloride hemiethanol hemihydrate of (4S,4aR,5S, 5aR,6R,12aS)-4-(dimethylamino)- 3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11, 12a-octahydrotetracene-2-carboxamide

All of which are commonly known as doxycycline hyclate; the strength is 40 mg per capsule; the dosage form is a capsule and the route of administration is oral;

(5) The U.S. Patent Numbers and expiration dates, as known to DRL, of the patents alleged to be invalid, unenforceable or not infringed are:

U.S. Patent No. 7,211,267 entitled "Methods Of Treating Acne," issued on May 1, 2007, which is listed in the Orange Book as expiring on April 5, 2022;

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

U.S. Patent No. 7,232,572 entitled "Methods Of Treating Rosacea," issued on June 19, 2007, which is listed in the Orange Book as expiring on April 5, 2022; and

U.S. Patent No. 8,603,506 entitled "Methods Of Treating Acne," issued on December 10, 2013, which is listed in the Orange Book as expiring on April 5, 2022.

(6) The information detailed in this letter and the attached memorandum is supplied for the sole purpose of efficiently addressing all patent-related issues relating to the above-referenced statutes and regulations, and neither DRL nor its attorneys waive any attorney-client privilege or attorney work product immunity concerning the subject matter of this communication; and

(7) DRL reserves its right to supplement this letter and the attached memorandum detailing the factual and legal basis for DRL's assertion of invalidity, unenforceability and/or non-infringement of the Ashley Patents should subsequent investigations reveal additional grounds for asserting invalidity, unenforceability and/or non-infringement.

DRL is seeking approval from the FDA to market and sell the Proposed DRL Doxycycline Product, which will be indicated for treatment of patients with rosacea. DRL is certifying with the FDA pursuant to § 505(b)(2)(A)(iv) of the Act and 21 C.F.R. § 314.50(i)(1)(i)(A)(4) ("Paragraph IV Certification") that the Ashley Patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, offer to sell in the United States or importation into the United States of the Proposed DRL Doxycycline Product for which DRL has submitted its application.

Offer of Confidential Access: In addition to and not in lieu of the limitations contained in 21 U.S.C. § 355(c)(3)(D)(i)(III) (as amended December 8, 2003) DRL hereby offers conditional access to only those portions of the DRL NDA that, in DRL's judgment, are needed by Galderma to determine whether an action under Section 355 should be filed within 45 days of

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

the receipt of this letter. Access to the information is and shall be limited to only those attorneys acting as outside counsel for Galderma that are needed to evaluate the information for that purpose and such persons who are to have access shall be identified to DRL's counsel, William L. Mentlik of Lerner David, Littenberg, Krumholz & Mentlik, LLP, 600 South Avenue West, Suite 300, Westfield, NJ 07090, before access is granted. Such persons so identified shall agree in writing that the information can only be used for the purpose of determining whether to file suit within the 45-day period. Those persons receiving access to the DRL NDA materials shall not engage, formally or informally, directly or indirectly in: any work before any patent office, including the United States PTO, relating to doxycycline; or in any counseling, litigation or other work before or involving a regulatory agency, including the United States FDA, relating to doxycycline. The DRL NDA and any tangible form of information derived from a review of the DRL NDA shall be destroyed, with notice to DRL's counsel, within 45 days of receipt of this letter or upon the filing of an action against DRL, whichever is earlier.

Pursuant to 21 C.F.R. § 314.95(c)(7), DRL authorizes the following agent to accept service of process:

William L. Mentlik
Lerner David, Littenberg, Krumholz & Mentlik, LLP
600 South Avenue West
Westfield, New Jersey 07090

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Attached hereto is a memorandum setting forth DRL's detailed factual and legal basis supporting its Paragraph IV Certification.

Dr. Reddy's Laboratories, Inc. on behalf of Dr. Reddy's Laboratories, Ltd.

By: _____

Lee Banks, Esq.
Vice President, Intellectual Property
Dr. Reddy's Laboratories, Inc.
107 College Road East
Princeton, NJ 08540

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.