CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-805

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

PATENT INFORMATION UNDER 21 CFR 314.53(c)

US Patent:	5,789,395
Effective Filing Date	August 30, 1996
Effective Issue Date:	August 4, 1998
Expiration Date:	August 30, 2016
Type of Patent:	Method of Use
Patent Owner:	The Research Foundation of State University of New York

DECLARATION

In accordance with 21 CFR 314.53© the undersigned declares that Patent No. 5,789,395 covers the formulation, composition, and/or method of use of Oracea™. This product is the subject of this application for which approval is being sought.

Respectfully submitted,

Christopher Powala
Vice President, Drug Development
And Regulatory Affairs
CollaGenex Pharmaceuticals, Inc.
41 University Drive
Newtown, PA 18940

Irving N. Feit
Attorney for Patent Owner
Hoffmann & Baron
6900 Jericho Turnpike
Syoffet, NY 11791

PATENT INFORMATION

Patents Issued:

NDA 50-805 contains three (3) method of use patents for which the Sponsor certifies. These patents are:

Patent No. 5,789,395: Method of using tetracycline compounds for inhibition of endogenous nitric oxide production.

Patent No. 5,919,775: Method of inhibiting inducible nitric oxide synthase with tetracyclines.

Patent No. 6,015,804: Method of using tetracycline compounds to enhance interleukin-10 production.

A copy of the licensing agreement between CollaGenex Pharmaceuticals, Inc. and the Research Foundation of the State University of New York is attached. This document provides CollaGenex Pharmaceuticals with rights to the above referenced patents. This Agreement immediately follows this summary.

Patents Pending:

During the review period of NDA 50-805, the Sponsor anticipates that the following patents will be issued by the U.S. Patent and Trademark Office that will cover further the formulation and methods of use for Oracea™. The Sponsor will submit these patents as a minor amendment to this NDA within 30 days of the date of issuance as required by 21 CFR 314.53(d)(1). Those patents expected to issue during the NDA review period are:

Application Serial No. 10/117,709: Method of treating acne wherein the said acne is acne rosacea.

Application Serial No. 10/414,808: Method of simultaneously treating ocular rosacea and acne rosacea.

Application Serial No. 10/272,499: Use of tetracyclines and tetracycline derivatives to treat acne and telangiectasia.

Application Serial No. 10/474,240: Controlled delivery of tetracyclines and tetracycline derivatives.

Application Serial No. 10/819,620: Once daily formulations of doxycycline.

1.3.2 Patent Certification

The Sponsor certifies Patent Numbers 5,789,395; 5,919,775, and 6,015,804. Copies of the certifications follow.

PEDIATRIC PAGE

(Complete for all filed original applications and efficacy supplements)

NDA/BLA #: 50 - 805 **Supplement Type (e.g. SE5):** _____ **Supplement Number:**

HFD-540 **Trade and generic names/dosage form:** _____

Applicant: CollaGenex Pharmaceuticals, Inc. **Therapeutic Class:** 3S

Indication(s) previously approved:

Each approved indication must have pediatric studies: Completed, Deferred, and/or Waived.

Number of indications for this application(s): 1

Indication #1: **For the topical treatment of psoriasis vulgaris in adults aged 18 years and above**

Is there a full waiver for this indication (check one)?

X Yes: **Please proceed to Section A.**

No: **Please check all that apply:** ____**Partial Waiver** ___**Deferred** ___**Completed**
NOTE: More than one may apply
Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☑ **Too few children with disease to study**
- ☐ **There are safety concerns**
- ☐ **Other:** _____

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min_____	**kg**_____	**mo.** 0	**yr.** __	**Tanner Stage**_____
Max_____	**kg**_____	**mo.** 0	**yr.**_____	**Tanner Stage**_____

Reason(s) for partial waiver:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- **Too few children with disease to study**
- **There are safety concerns**
- ☐ **Adult studies ready for approval**
- ☐ **Formulation needed**
- ☐ **Other: Sponsor specified exact population to study.**

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.