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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

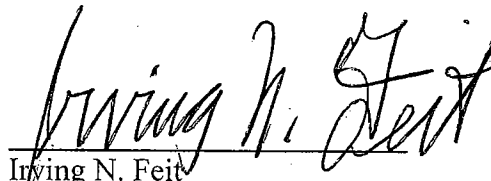
DECLARATION

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,



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Vice President, Drug Development
And Regulatory Affairs
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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)?

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.

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