CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number NDA 50-781

ADMINISTRATIVE DOCUMENTS
CORRESPONDENCE

APPLICATION #: NDA 50-781 HFD-540

DRUG NAME: ARESTIN (minocycline hydrochloride) microspheres, 1 mg

K1.1

K1.1

N50781

N50781

APPLICANT: ORAPHARMA, INC

Rec 4/24/01 2:03PM

CHEMICAL TYPE & THERAPEUTICPOTENTIAL: 3S

Submission Date:	2/29/00
Receipt Date:	3/1/00
Goal Date:	2/17/01
Action:	Approval

CORE REVIEW TEAM MEMBERS

REGULATORY PROJECT MANAGER/ CSO : Kalyani Bhatt Phone # & Office Room #: (301) 827-2020, 9201 Corporate Blvd. Room N241
MEDICAL: Clarence Gilkes, D.D.S
CHEMISTRY: Mamta Gautam-Basak, Ph.D.
PHARM/TOX: Norman See, Ph.D.
BIOPHARMACEUTICS: Tapash Ghosh, Ph.D.
BIOMETRICS: Atair Rahman, Ph.D.
OTHER: Fred Marsik, Ph.D. (Microbiology), Brian Riley, Ph.D.(Clinical Microbiology)

Volume 1 of 1

Administrative volume #(s): 1

Advisory Committee Meeting #(s): NA

Clinical volume #(s): 1

CMC volume #(s): 1

Pharmacology/Toxicology volume #(s): 1

NDA/EFFICACY SUPPLEMENT ACTION PACKAGE CHECKLIS

NDA 50-781 _____ _____

Drug ARESTIN (minocycline hydrochloride) microspheres 1mg Applicant ORAPHARMA

RPM Kalyani Bhatt Phone 301-827-2020

☒ 505(b)(1)
☐505(b)(2) Reference listed drug

☐Fast Track ☐Rolling Review Review priority: ☒ S ☐P

Pivotal IND(s)

Application classifications:
Chem Class 3s
Other (e.g., orphan, OTC) _____

PDUFA Goal Dates:2-17-00
Primary 12-17-00
Secondary 2-17-01

Arrange package in the following order:

Indicate N/A (not applicable), X (completed), or add a comment.

GENERAL INFORMATION:

- User Fee Information: ☐ User Fee Paid
  ☒User Fee Waiver (attach waiver notification letter)
  ☐ User Fee Exemption

- Action Letter..... ☒ AP ☐ AE ☐NA

- Labeling & Labels
  FDA revised labeling and reviews..... Yes
  Original proposed labeling (package insert, patient package insert) ..... Yes
  Other labeling in class (most recent 3) or class labeling.....
  Has DDMAC reviewed the labeling ..... ☒Yes (include review) ☐ No
  Immediate container and carton labels ..... Yes
  Nomenclature review ..... Yes

- Application Integrity Policy (AIP) ☐ Applicant is on the AIP. This application ☐ is ☐ is not on the AIP.
  Exception for review (Center Director's memo)..... N/A
  OC Clearance for approval..... N/A

- Status of advertising (if AP action) ☐ Reviewed (for Subpart H – attach review) ☐ Materials requested in AP letter

- Post-marketing Commitments — N/A
  - Agency request for Phase 4 Commitments — NO
  - Copy of Applicant's commitments —

- Was Press Office notified of action (for approval action only)? ☐ Yes ☒ No
  - Copy of Press Release or Talk Paper — N/A

- Patent
  - Information [505(b)(1)] — Yes
  - Patent Certification [505(b)(2)] — Yes
  - Copy of notification to patent holder [21 CFR 314.50 (i)(4)] — Yes

- Exclusivity Summar — Yes

- Debarment Statement — Yes

- Financial Disclosure
  - No disclosable information — Yes
  - Disclosable information – indicate where review is located — Clinical Review

- Correspondence/Memoranda/Faxes — Yes

- Minutes of Meetings —
  - Date of EOP2 Meeting _____ — N/A
  - Date of pre NDA Meeting June 7, 1999 — Yes
  - Date of pre-AP Safety Conference _____ — N/A

- Advisory Committee Meeting — N/A
  - Date of Meeting — N/A
  - Questions considered by the committee — N/A
  - Minutes or 48-hour alert or pertinent section of transcript — N/A

- Federal Register Notices, DESI documents — N/A

CLINICAL INFORMATION: **Indicate N/A (not applicable), X (completed), or add a comment.**

- Summary memoranda (e.g., Office Director's memo, Division Director's memo, Group Leader's memo) — N/A

- Clinical review(s) and memoranda — Yes

- Safety Update review(s) ..... Yes

- Pediatric Information
  ☒ Waiver/partial waiver (Indicate location of rationale for waiver) ☐ Deferred
  Pediatric Page..... Yes
  ☐ Pediatric Exclusivity requested? ☐ Denied ☐ Granted ☐ Not Applicable

- Statistical review(s) and memoranda ..... Yes

- Biopharmaceutical review(s) and memoranda..... Yes

- Abuse Liability review(s) ..... N/A
  Recommendation for scheduling ..... N/A

- Microbiology (efficacy) review(s) and memoranda ..... Yes

- DSI Audits ..... Yes
  ☒Clinical studies ☐ bioequivalence studies .....

CMC INFORMATION: **Indicate N/A (not applicable), X (completed), or add a comment.**

- CMC review(s) and memoranda ..... Yes

- Statistics review(s) and memoranda regarding dissolution and/or stability ..... N/A

- DMF review(s) ..... Yes

- Environmental Assessment review/FONSI/Categorical exemption ..... Yes

- Micro (validation of sterilization) review(s) and memoranda ..... Yes

- Facilities Inspection (include EES report)
  Date completed January 31, 2001 ..... ☒Acceptable ☐ Not Acceptable

- Methods Validation ..... ☒ Completed ☐ Not Completed

PRECLINICAL PHARM/TOX INFORMATION: **Indicate N/A (not applicable), X (completed), or add a comment.**

- Pharm/Tox review(s) and memoranda X

- Memo from DSI regarding GLP inspection (if any) X

Statistical review(s) of carcinogenicity studies ..... N/A

CAC/ECAC report ..... N/A

Food and Drug Administration
Rockville MD 20857

FEB -1 2000

Mr. Markus F. Herzig
Executive Director, Regulatory Affairs
OraPharma, Inc.
732 Louis Drive
Warminster, PA 18974

RE: OraPharma, Inc., Minocycline PTS (NDA ——)
Small Business Waiver Request 2000.005

Dear Mr. Herzig:

This letter responds to your November 8, 1999, letter to the Office of the Chief Mediator and Ombudsman, Food and Drug Administration (FDA), requesting a waiver of the prescription drug application fee for Minocycline PTS (NDA ——) under the small business waiver provision of section 736(d)(1)(E) of the Prescription Drug User Fee Act of 1992 (PDUFA) as amended by the Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Waiver Request 2000.005). In July 1999, responsibilities related to certain waivers were transferred from the Chief Mediator and Ombudsman to the Associate Director for Policy at the Center for Drug Evaluation and Research. For the reasons described below, FDA grants the request from OraPharma, Inc. (OraPharma) for a small business waiver.

According to your waiver request, OraPharma presently employs 20 individuals and has never submitted a new drug application (NDA) for human use. OraPharma expects to submit NDA —— for Minocycline PTS on or about February 16, 2000. You state that Minocycline PTS (minocycline periodontal therapeutic system) is a nonsterile, extended-release product containing the antibiotic incorporated into a bioresorbable polymer for administration into periodontal pockets. The intended indication will be as an adjunct to scaling and root planing procedure for reduction of pocket depth in patients with adult periodontitis.

Under PDUFA as amended, a waiver of the application fee shall be granted to a small business for the first human drug application that a small business or its affiliate[1] submits to the FDA for review. The small business waiver provision entitles a qualified small business to a waiver when the business meets two criteria: first, a business must employ fewer than 500 persons, including employees of its affiliates; and second, the marketing application must be the first human drug application, within the meaning of PDUFA, that a company or its affiliate submits to FDA.

[1] "The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly – (A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has the power to control, both of the business entities" (21 U.S.C. 379g(9)).

DA's decision to grant a small business waiver to OraPharma is based on two findings. First, letter dated January 5, 2000, the Small Business Administration (SBA) determined that, as of ovember 29, 1999, OraPharma had fewer than 500 employees and had no affiliates. Second, cording to FDA records, the marketing application for Minocycline — is the first human ug application, within the meaning of PDUFA, to be submitted to FDA by OraPharma.

onsequently, your request for a small business waiver of the application fee for Minocycline TS (NDA ——— is granted, provided that FDA receives the marketing application no later an November 29, 2000, one year after the effective date of the size determination made by the BA. Once OraPharma submits the marketing application, if FDA refuses to file the application OraPharma withdraws the application before it is filed by FDA and the company plans to submit its application, a reevaluation of the waiver will be required. If this occurs, OraPharma ould contact this office approximately 90 days before it expects to resubmit its marketing plication to determine whether OraPharma continues to qualify for a small business waiver.

ease include a copy of this letter in the marketing application for Minocycline PTS. If any lling questions arise concerning the marketing application, please contact Beverly Friedman or ichael Jones at 301-594-2041.

DA plans to disclose to the public information about its actions granting or denying waivers d reductions. This disclosure will be consistent with the laws and regulations governing the sclosure of confidential commercial or financial information.

you have any questions about this small business waiver, please contact Kathleen Locke at 01-594-2041.

Sincerely,

/s/

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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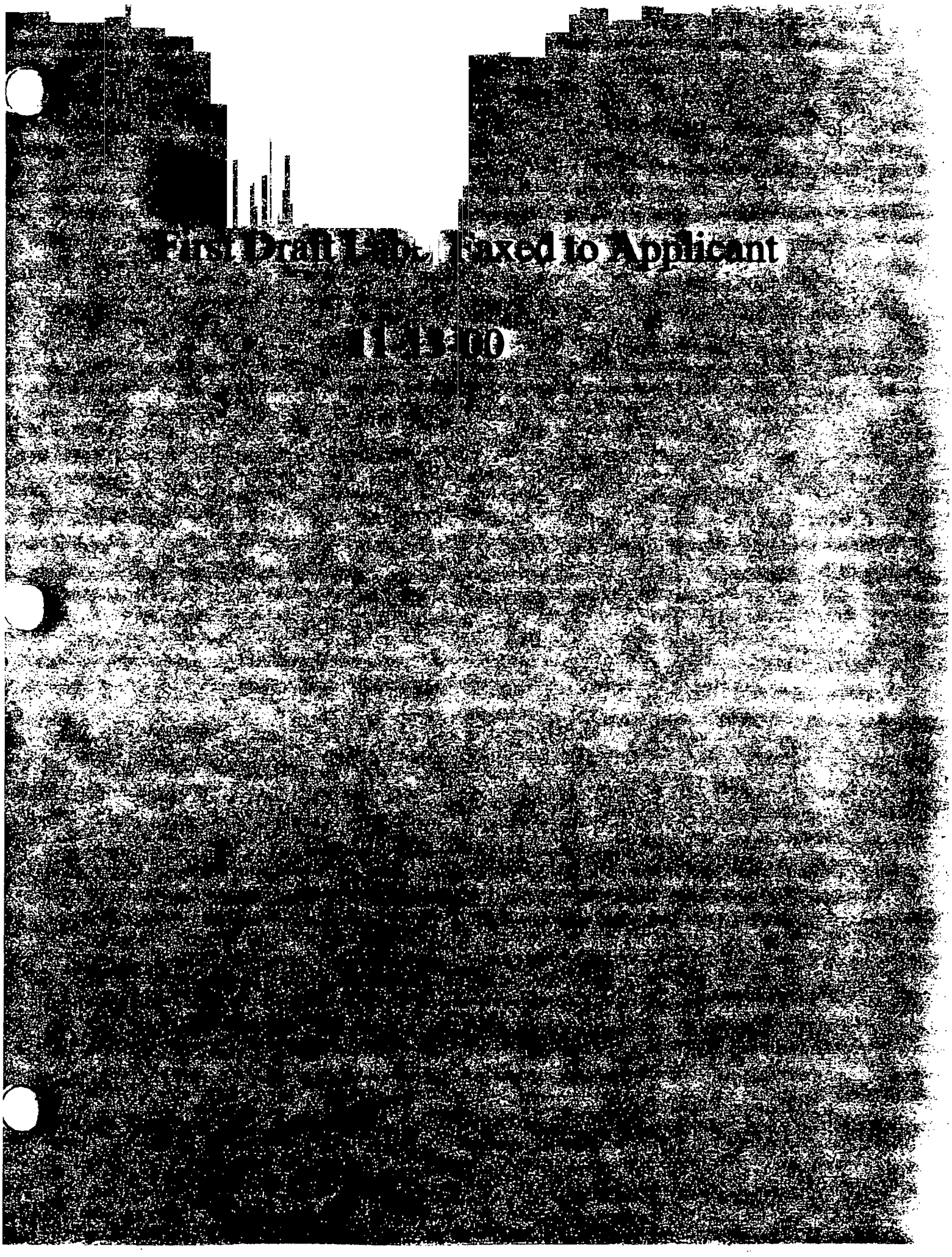
First Draft Faxed to Applicant

Division of Dermatologic and Dental Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, HFD-540
Rockville, MD 20857

FACSIMILE TRANSMISSION RECORD

DATE: 12/5/00 Pages (including cover) 10

TO: Markus Herzig

COMPANY: Orapharma

ADDRESS:

FAX PHONE#: 215-443-9531 Our Fax # (301) 827-2075

Voice # (301) 827-2020

MESSAGE:

Enclosed Copy of Label 2nd draft from FDA.

NOTE: We are providing the attached information via telephone facsimile for your convenience. This material should be viewed as unofficial correspondence. Please feel free to contact me if you have any questions regarding the contents of this transmission.

FROM: Kalyani Bhatt

TITLE: Project Manager

TELEPHONE: 301 827-2020

WITHHOLD 27 PAGE (S)

[redacted] Second Review via E-mail

[redacted]-28-00

WITHHOLD 2 PAGE (S)

PDRA Review of Tradename

-10-00

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications

TO: Kalyani Bhatt, Project Manager, Div. of Dematological and Dental Drug Products, CDER, HFD-540

Through: Mark Askine, Branch Chief, Div. of Drug Marketing, Advertising, and Communications, CDER, HFD-42

From: Warren Rumble, CSO, DDMAC, HFD-42

DATE: September 21, 2000

SUBJECT: Labeling review of NDA 50-781 Minocycline PTS 1 mg. Labeling amendment dated August 16, 2000

Draft product labeling

DDMAC reviewed the proposed product labeling that accompanied the physician sample carton and has the following comments.

1. [redacted]

   Moving the information will make this label consistent with the approved product labeling for [redacted]. We note that the word "group" in the first sentence of this information should be "groups." [redacted]

2. [redacted]

3. [redacted]

Physician Sample Carton

We note that the carton includes the indication and instructions for use of the product. [redacted] We also note that the sponsor plans to include a "www.xxx.com" and a 1-800 number. We reserve the right to take an action on this sample box should the www address be false or misleading in any particular.

If you have any questions, please call me at 827-3907 or e-mail me at rumblew@cder.fda.gov.

Thank you.

Warren Rumble

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

(Division/Office):			FROM:	
Cheryl Roberts, DDMAC, HFD-42			Kalyani Bhatt, PM, DDDP, HFD-540	
DATE: 8-24-00	IND NO.	NDA NO. 50-781	TYPE OF DOCUMENT: Label, Carton.	DATE OF DOCUMENT
NAME OF DRUG: Minocycline PTS Inj.	PRIORITY CONSIDERATION		CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE: 9/30/00

NAME OF FIRM:

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE–NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER (SPECIFY BELOW):

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES PROTOCOL REVIEW OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISION RICK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:

Please review Label + Carton packaging + PPI.
We would like to have the action package ready by
Nov. 15, 2000.

NATURE OF REQUE	72049	METHOD OF DELIVERY (Check one) ☐ MAIL ☐ HAND
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER

[redacted] Applicant's Fax [redacted]
[redacted] Supporting [redacted] Trade Name "ARESTIN"

4-10-00

OraPharma, Inc.
732 Louis Drive
Warminster, PA 18974
215-956-2200
Facsimile: 215-443-9531

ORAPHARMA INC.

FAX COVER SHEET

To:	Ms. Kalyani Bhatt, Project Manager	**From:**	Markus Herzig
Company:	Division of Dermatologic / Dental Drug Products	**Date:**	04/10/00
Fax No.:	301-827-2075	**No. of pages w/cover:**	1
RE:	Tradename for minocycline PTS (IND [redacted]		

[X] *Urgent* [ ] *Reply ASAP* [ ] *Please comment* [ ] *Please review* [ ] *For your information*

Kalyani:

Ms. F. Beam from the FDA asked me to also provide you with the report I am faxing to her regarding our request to us "Arestin" as the tradename.

Thank you,

Markus F. Herzig

MARKSMEN

818 S. Central
Glendale, CA 91204
Voice: 800.958.8838
Fax: 888.598.4558
International
Voice: +818.637.8058
Fax: +818.637.8059
www.marksmen.com
License PI 29504

April 4, 2000

VIA FACSIMILE
212.387.0167

PRIVILEGED AND CONFIDENTIAL
3 pages sent

MANJARI DATTA, ESQ.
Trademark & Patent Counselors of America, PC
915 Broadway
19th Floor
New York, NY 10010

Re: Vortech Pharmaceuticals

Trademark:	ARESTIN/ARRESTIN
File Number:	1031/047
Client Matter:	893.0500

Dear Manjari:

Our office received your request on March 28, 2000 instructing us to investigate the captioned company to determine if it is currently marketing goods or services using the name ARESTIN or ARRESTIN.

NO CURRENT USE CLAIMED BY CAPTIONED COMPANY. USE CEASED "OVER TEN YEARS AGO" AS A HUMAN-USE ANTI-SPASMODIC PHARMACEUTICAL.

Vortech Pharmaceuticals, 6851 Chase Road, Dearborn, MI 48126

Telephone directory assistance for Dearborn, MI and the surrounding area has one listing for Vortech Pharmaceuticals, 313.584.4088.

According to national and international business directories we consulted, Vortech Pharmaceutical Ltd., PO Box 189, Dearborn, MI 48121, 313.584.4088, wholesales and prepares pharmaceuticals. The company employs 11 individuals. There is no financial information provided. John MacNeil is the president, 6851 Chase Road, Dearborn, MI 48126.

A search of Lexis-Nexis® news databases yielded no relevant references to ARESTIN or ARRESTIN and Vortech Pharmaceuticals. There is one reference to Vortech Pharmaceuticals. A March 13, 1999 *Central News Agency* article states, "The ROC [Republic of China] has recently contracted Vortech Pharmaceuticals, USA to provide shipments of sodium pentobarbital, an injectable agent recognized by the American Veterinary Medical association for humane and painless euthanasia."

Domain Name registries show that www.vortechphar.com, www.telcee.com, and www.fatalplus.com were registered to Vortech Pharmaceuticals, at the captioned address, on April 7, 1999. The administrative contact is Peter MacNeil, 313.584.4048, jmacneil@att.net.

We searched the Internet and accessed the company Web site at www.vortechpharma.com, which consists of a generic home page for Register.com stating that the site is under construction. There is no company contact information provided on the site, nor are there any references to ARESTIN.

According to the records of the Michigan Secretary of State's office, Vortech Pharmaceuticals, Ltd. was incorporated in the State of Michigan on June 14, 1982 and is active and in good standing. The agent of record is John A. MacNeil, at the captioned address. There is no business address provided. There was a change of agent and/or office on August 30, 1982. There are no additional amendments provided.

We called 313.584.4048, the phone number for Vortech Pharmaceuticals provided by telephone directory assistance, business directories and domain name registries, where we spoke with Bert MacNeil, who answered the phone, "Vortech." Bert said Vortech has not carried ARESTIN "for the last ten years, I know." She said she does not know exactly when the product was discontinued, but said "we are a distributor, not a manufacturer. The company that made ARESTIN might still be making it for all I know." Bert said she did not know who manufactures, or manufactured ARESTIN. She suggested we call back another time to speak with someone in the office who would be more knowledgeable about the product.

We called 313.584.4048 a second time, and spoke with John MacNeil, who identified himself as president of Vortech. John said ARESTIN is a human-use pharmaceutical that Vortech no longer manufactures. He would not provide the date of discontinuation. John said ARESTIN was used for slowing down spasms in the gut," and noted that it was a catchy name. He described Vortech as a manufacturer of "almost entirely veterinary" products, noting that they manufacture two human-use lotions in addition to their veterinary products. John said Vortech is "a very small company," and confirmed it is located at the captioned address.

At this time, we have concluded our investigation of ARESTIN/ARRESTIN. If you have further need of our services on this or any other matter, please call us.

Best Regards,

Bill Shanks
Research Director

BS/kvh

CONSULTATION RESPONSE
Office of Post-Marketing Drug Risk Assessment
(OPDRA; HFD-400)

DATE RECEIVED: 12/13/99	DUE DATE: 3/13/00	OPDRA CONSULT #: 00-0009

TO : Jonathan Wilkin, M.D.
Director, Division of Dermatologic and Dental Drug Products
HFD-540

THROUGH: Kalyani Bhatt, Project Manager, DDDDP
HFD-540

PRODUCT NAME: **Arrestin PTS®** (minocycline) — **IND #:** —	**MANUFACTURER:** OraPharma, Inc.
Safety Evaluator: Peter Tam, R.Ph.	

OPDRA RECOMMENDATION:
OPDRA does not recommend the use of the proprietary name Arrestin PTS®.

Jerry Phillips 3/9/2000

Jerry Phillips, R.Ph.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment
Phone: (301) 827-3242
Fax: (301) 480-8173

/S/ 3/10/00

Peter Honig, MD
Director
Office of Post-Marketing Drug Risk Assessment
Center for Drug Evaluation and Research
Food and Drug Administration

Office of Post-Marketing Drug Risk Assessment
HFD-400; Rm 15B03
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

Date of Review: 3/1/00

IND#: [redacted]

Name of Drug: Arrestin PTS®
(minocycline)

NDA Holder: OraPharma, Inc.

I. INTRODUCTION

This consult was written in response to a request from the Division of Dermatologic and Dental Drug Products (HFD-540) on December 13, 1999, to review the proposed proprietary drug name, Arrestin PTS® in regard to potential name confusion with existing proprietary/generic drug names.

PRODUCT INFORMATION

There is no labeling or information submitted on the product strength and dosing regimen.

The proposed indication for the use of this product is for the treatment of periodontal disease.

II. RISK ASSESSMENT

In order to determine the potential for medication errors and to find out the degree of confusion of the proposed proprietary name, Arrestin PTS® with other drug names, the medication error staff of OPDRA searched Micromedex online, PDR (1999 Edition), American Drug Index (43rd Edition), Drug Facts and Comparison (updated monthly), the Electronic Orange Book, and US Patent and Trademark Office online database. In addition, OPDRA also searched several FDA databases for potential sound-alike and look-alike names to approved/unapproved drug products through DPR (Drug Products Reference), Medline, Decision Support System (DSS), Establishment Evaluation System, and

LNC database.

A. EXPERT PANEL DISCUSSION:

The expert panel consists of members of the OPDRA medication error safety evaluator staff and a representative from the Division of Drug Marketing, Advertising and Communication.

The panel discussion was conducted on 2/7/00. There is a previously approved product named identically Arrestin®. It is available as a 2 ml ampule injection and its established name is called trimethobenzamide manufactured by Vortech Pharmaceutical. In addition, there is another proprietary name, Fareston® 60 mg tablet, an antiestrogen agent, that also sounds similar to Arrestin PTS®

The panel did not recommend any prescription studies and further recommended rejecting this proposed proprietary name.

B. SAFETY EVALUATION:

The searches conducted within FDA did reveal an existing identical proprietary name for a different active ingredient called Arrestin® which was manufactured by North Pharmaceuticals, Inc. many years ago. The application was purchased by Vortech Pharmaceuticals, Inc. and Vortech had since ceased marketing Arrestin®. However, Arrestin® is still listed in Facts and Comparisons (1999 edition) as well as in USP Drug Information (1999 edition). The 2000 edition of USP Drug Information has deleted the reference to Arrestin®. The managing editors of Facts and Comparisons was contacted by OPDRA and the reference to Arrestin®will be deleted within the next 3 months.

A potential safety risk exists, since pharmacists frequently consult these reference books for drug information. For instance, if a physician orders Arrestin®, and the dispensing pharmacist is not familiar with such an order, he/she might consult Facts and Comparisons and find that Arrestin® is listed under anti-emetics in Facts and Comparisons with a generic name of trimethobenzamide. A generic equivalent of Arrestin® might subsequently be dispensed while the physician actually wants Arrestin PTS®, (minocycline) instead. The safety risk is high for an error to occur when there is an identical name still listed in one widely used pharmaceutical reference book.

Finally, we have serious concerns about the sound alike confusion between Arrestin PTS and Fareston, an anti-estrogen drug which comes as a 60 mg

tablet. They both have the exact character lengths (Arrestin has 8 and Fareston has 8). Both end in "n". Hence, the potential safety risk due to sound-alike similarity of these two names is very high on verbal orders.

III. RECOMMENDATIONS

OPDRA does not recommend the use of the proprietary name Arrestin PTS®.

Should you have any questions concerning this review, please contact Peter Tam at 301-827-3241.

3/9/00

Peter Tam, RPh.
Safety Evaluator
Office of Post-Marketing Drug Risk Assessment

Concur

3/9/00

Jerry Phillips, RPh.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment