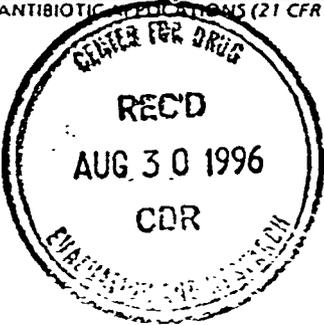


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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE <i>(Title 21, Code of Federal Regulations, 314)</i>		Form Approved: OMB No. 0910-0001 Expiration Date: March 31, 1990. See OMB Statement on Page 3.	
		FOR FDA USE ONLY	
		DATE RECEIVED 30 Aug 96	DATE FILED
		DIVISION ASSIGNED 540	NO/ANDA NO ASS 20642
NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).			
NAME OF APPLICANT CollaGenex Pharmaceuticals, Inc.		DATE OF SUBMISSION August 30, 1996	
ADDRESS (Number, Street, City, State and Zip Code) 301 South State Street Newtown, PA 18940		TELEPHONE NO (Include Area Code) (215) 579-7619	
		NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued) 20-642	
DRUG PRODUCT			
ESTABLISHED NAME (e.g., USPI/USAN) doxycycline hyclate capsules USP		PROPRIETARY NAME (if any) Periostat™	
CODE NAME (if any)	CHEMICAL NAME 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		
DOSAGE FORM capsule	ROUTE OF ADMINISTRATION oral	STRENGTH(S) 20mg	
PROPOSED INDICATIONS FOR USE Treatment of adult periodontitis			
LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION: AADA 62-374 AADA 62-839			
			
See Attachment 1 for Drug Master File References			
INFORMATION ON APPLICATION			
TYPE OF APPLICATION (Check one)			
<input checked="" type="checkbox"/> THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) <input type="checkbox"/> THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)			
IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION			
NAME OF DRUG		HOLDER OF APPROVED APPLICATION	
STATUS OF APPLICATION (Check one)			
<input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> AN AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> SUPPLEMENTAL APPLICATION <input checked="" type="checkbox"/> ORIGINAL APPLICATION <input type="checkbox"/> RESUBMISSION			
PROPOSED MARKETING STATUS (Check one)			
<input checked="" type="checkbox"/> APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx) <input type="checkbox"/> APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)			

CONTENTS OF APPLICATION

This application contains the following items: (Check all that apply)

<input checked="" type="checkbox"/>	1. Index	Vol 2.1
<input checked="" type="checkbox"/>	2. Summary (21 CFR 314.50 (c))	Vol 2.2
	3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))	Presubmitted on May 31, 1996
	4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)	
<input checked="" type="checkbox"/>	b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))	Vols 2.3-2.4
	c. Labeling (21 CFR 314.50 (e) (2) (ii))	
<input checked="" type="checkbox"/>	i. draft labeling (4 copies)	Vol 2.4
	ii. final printed labeling (12 copies)	
<input checked="" type="checkbox"/>	5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))	Vols 2.5-2.10
<input checked="" type="checkbox"/>	6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))	Vols 2.11-2.17
<input checked="" type="checkbox"/>	7. Microbiology section (21 CFR 314.50 (d) (4))	Vols 2.18-2.19
<input checked="" type="checkbox"/>	8. Clinical data section (21 CFR 314.50 (d) (5))	Vols 2.20-2.109
<input checked="" type="checkbox"/>	9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))	
<input checked="" type="checkbox"/>	10. Statistical section (21 CFR 314.50 (d) (6))	Vols 2.110, 2.21-2.109
<input checked="" type="checkbox"/>	11. Case report tabulations (21 CFR 314.50 (f) (1))	Vols 2.111-2.128
<input checked="" type="checkbox"/>	12. Case reports forms (21 CFR 314.50 (f) (1))	Vols 2.129
<input checked="" type="checkbox"/>	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))	Vol 2.1
<input checked="" type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))	Vol 2.1
<input checked="" type="checkbox"/>	15. OTHER (Specify)	

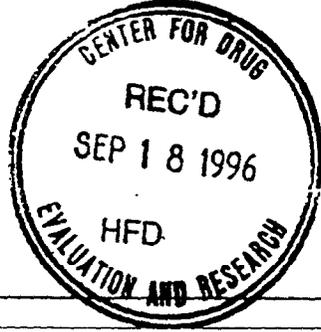
I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211.
2. Labeling regulations in 21 CFR 201.
3. In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.
4. Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.
5. Regulations on reports in 21 CFR 314.80 and 314.81.
6. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT Christopher V. Powala Director, Drug Development & Regulatory Affairs	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT <i>Christopher V. Powala</i>	DATE 8/30/96
ADDRESS (Street, City, State, Zip Code) CollaGenex Pharmaceuticals, Inc. 301 S. State Street, Newtown, PA 18940		TELEPHONE NO. (Include Area Code) (215) 579-7619

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec.1001.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE <i>(Title 21, Code of Federal Regulations, 314)</i>		Form Approved: OMB No. 0910-0001 Expiration Date: March 31, 1990. See OMB Statement on Page 3.	
		FOR FDA USE ONLY	
		DATE RECEIVED	DATE FILED
		DIVISION ASSIGNED	NOA/ANDA NO ASS
NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).			
NAME OF APPLICANT CollaGenex Pharmaceuticals, Inc.		DATE OF SUBMISSION 9/17/96	
ADDRESS (Number, Street, City, State and Zip Code) 301 South State Street Newtown, PA 18940		TELEPHONE NO (Include Area Code) (215) 579-7619	
		NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued) 50-744	
DRUG PRODUCT			
ESTABLISHED NAME (e.g., USPIUSAN) doxycycline hyclate capsules USP		PROPRIETARY NAME (if any) Periostat™	
CODE NAME (if any)	CHEMICAL NAME 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro- 3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1- naphthacene-carboxamide monohydrochloride		
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AADA 62-374 AADA 62-839			
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<input checked="" type="checkbox"/> THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) <input type="checkbox"/> THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)			
IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION			
NAME OF DRUG		HOLDER OF APPROVED APPLICATION	
STATUS OF APPLICATION (Check one)			
<input type="checkbox"/> PRESUBMISSION ORIGINAL APPLICATION		<input checked="" type="checkbox"/> AN AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> RESUBMISSION	
		<input type="checkbox"/> SUPPLEMENTAL APPLICATION	
PROPOSED MARKETING STATUS (Check one)			
<input checked="" type="checkbox"/> APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)		<input type="checkbox"/> APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)	

CONTENTS OF APPLICATION

This application contains the following items: (Check all that apply)

- 1. Index
- 2. Summary (21 CFR 314.50 (c))
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- 7. Microbiology section (21 CFR 314.50 (d) (4))
- 8. Clinical data section (21 CFR 314.50 (d) (5))
- 9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))
- 10. Statistical section (21 CFR 314.50 (d) (6))
- 11. Case report tabulations (21 CFR 314.50 (f) (1))
- 12. Case reports forms (21 CFR 314.50 (f) (1))
- 13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
- 14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (i) (2) (A))

15. OTHER (Specify) **Minor Amendment**

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

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NAME OF RESPONSIBLE OFFICIAL OR AGENT Christopher V. Powala <small>Director, Drug Development & Regulatory Affairs</small>	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	DATE 9/17/96
ADDRESS (Street, City, State, Zip Code) CollaGenex Pharmaceuticals, Inc. 301 S. State Street, Newtown, PA 18940	TELEPHONE NO. (Include Area Code) (215) 579-7619	

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