

Phone: (612) 873-2288
(800) 328-5890
Fax: (612) 873-2289



WENDT LABORATORIES, INC.

~~200 West Beaver • B.P. Box 14832~~
Belle Plaine, Minnesota 56011

A Family of Pharmaceutical Manufacturers
Since 1927

**Dockets Management Branch (HTA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852**

April 25, 2000

Dear Sir or Madam,

This letter is in reference to Food and Drug Administration's Docket No. 00N-1198 according to Wendt Laboratories's records, the annual reports for Nitroflurazone ointment, 0.2oz (86-766) Bethanechol Chloride Tablets, 10 & 25mg, (84-185 & 84-186) Nitroflurazone Ointment, Meclizine Hydrochloride Tablets, 25mg (85-041), Isoniazid Tablets (85-040), Folic Acid Tablets (85-039), Menocarbamol Tablets (85-042) were submitted to the FDA and received on 08/06/99. Enclosed are copies of the acknowledgments as requested in the docket. Wendt Laboratories respectfully requests an opportunity for a hearing.

Sincerely,

**Wendt Laboratories
William E. Wendt, Pres.**

**WEW:pw
ENC 4**

00N-1198

HER 1

NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug Application.

INSTRUCTIONS

Complete a transmittal form for each application for which an annual report is being submitted. Retain the carbon copy labeled "applicant." Submit the remaining copies of the transmittal form along with two copies of the annual report to FDA.

If any part of the annual report applies to more than one application, list in item 7 all other applications to which such parts apply.

1. NDA OR ANDA NUMBER

N	8	5	0	4	0
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2. Report No. (FDA Complete)

Y-	0	1	1
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APPLICANT NOTE
Reference NDA and Y numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.

4. APPLICANT
Wendt Laboratories, Inc.

3. CFR SECTION NUMBER (Antibiotic only)

5. DRUG NAME
Isoniazid Tablets USP, 100mg.

6. TYPE OF REPORT (Check one)
 ANNUAL OTHER

7. OTHER NDA/ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)

8. PERIOD COVERED BY REPORT

FROM		TO	
YEAR	MONTH	YEAR	MONTH
1993	July	1999	July

REPORT INFORMATION REQUIRED (See § 314.81 for description)
9. (Enter type of information attached under "Identification." If you have nothing to report, enter None.)
(INFORMATION IN "9b" and "9c" IS ALWAYS REQUIRED.)

TYPE OF INFORMATION	IDENTIFICATION (Volume No.(s)/Tab(s)/Page(s) of Report)
a. SUMMARY OF SIGNIFICANT NEW INFORMATION	None
b. DISTRIBUTION DATA	Has not been manufactured or distributed
c. LABELING (Whether or not previously submitted)	Has not been manufactured or distributed
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES	None
e. NONCLINICAL LABORATORY STUDIES	None
f. CLINICAL DATA	None
g. STATUS REPORT POST-MARKETING STUDIES	None
h. STATUS OF OPEN REGULATORY BUSINESS (Optional)	None

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
Jennifer Eckhardt, Administrative Assistant

FDA USE ONLY

10. REPORT FILED IN NDA NUMBER

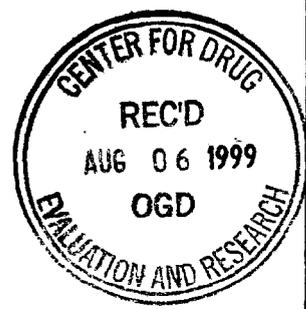
N	8	5	0	4	0
---	---	---	---	---	---

SIGNATURE
Jennifer Eckhardt

11. DATE OF RECEIPT

APPLICANTS RETURN ADDRESS (Type within the window envelope tic marks)

PO Box 128
Belle Plaine, MN 56011



NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug Application.

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1. NDA OR ANDA NUMBER
N 8 5 0 4 1

2. Report No. (FDA Complete)
Y- 0 1 2

APPLICANT NOTE
Reference NDA and Y numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.

4. APPLICANT
Wendt Laboratories, Inc

3. CFR SECTION NUMBER (Antibiotic only)

5. DRUG NAME
Meclizine Hydrochloride Tablets, 25 mg.

6. TYPE OF REPORT (Check one)
 ANNUAL OTHER

7. OTHER NDA/ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)

8. PERIOD COVERED BY REPORT
FROM TO
YEAR MONTH YEAR MONTH
1993 July 1999 July

REPORT INFORMATION REQUIRED (See § 314.81 for description)
9. (Enter type of information attached under "Identification." If you have nothing to report, enter None.)
(INFORMATION IN "9b" and "9c" IS ALWAYS REQUIRED.)

TYPE OF INFORMATION	IDENTIFICATION (Volume No.(s)/Tab(s)/Page(s) of Report)
a. SUMMARY OF SIGNIFICANT NEW INFORMATION	None
b. DISTRIBUTION DATA	Currently marketed as an OTC product; per 21 CFR, parts 330, and 336
c. LABELING (Whether or not previously submitted)	Labeled per 21 CFR, Part 336 requirements
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES	None
e. NONCLINICAL LABORATORY STUDIES	None
f. CLINICAL DATA	None
g. STATUS REPORT POST-MARKETING STUDIES	None
h. STATUS OF OPEN REGULATORY BUSINESS (Optional)	None

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
Jennifer Eckhardt, Administrative Assistant

FDA USE ONLY
10. REPORT FILED IN NDA NUMBER
N 8 5 0 4 1

SIGNATURE
Jennifer Eckhardt

11. DATE OF RECEIPT

APPLICANTS RETURN ADDRESS (Type within the window envelope tic marks)

PO Box 128
Belle Plaine, MN 56011



TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS FOR HUMAN USE (21 CFR 314.81)		DATE SUBMITTED	Form Approved: OMB No. 0910-0001 Expiration Date: December 31, 1992 See OMB Statement on Reverse of Part I.					
NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug Application.			1. NDA OR ANDA NUMBER					
INSTRUCTIONS			N	8	6	7	6	6
Complete a transmittal form for each application for which an annual report is being submitted. Retain the carbon copy labeled "applicant." Submit the remaining copies of the transmittal form along with two copies of the annual report to FDA. If any part of the annual report applies to more than one application, list in item 7 all other applications to which such parts apply			2. Report No. (FDA Complete)			Y- 0 1 4		
			APPLICANT NOTE Reference NDA and Y numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.					
4. APPLICANT			3. CFR SECTION NUMBER (Antibiotic only)					
Wendt Laboratories, Inc								
5. DRUG NAME			6. TYPE OF REPORT (Check one)					
Nitroflurazone Ointment, 0.25%			<input checked="" type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER					
7. OTHER NDA/ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)			8. PERIOD COVERED BY REPORT					
			FROM			TO		
			YEAR	MONTH	YEAR	MONTH		
			1993	July	1999	July	Fold Line	
REPORT INFORMATION REQUIRED (See § 314.81 for description)								
9. (Enter type of information attached under "Identification." If you have nothing to report, enter None.) (INFORMATION IN "9b" and "9c" IS ALWAYS REQUIRED.)								
TYPE OF INFORMATION			IDENTIFICATION (Volume No.(s)/Tab(s)/Page(s) of Report)					
a. SUMMARY OF SIGNIFICANT NEW INFORMATION			None					
b. DISTRIBUTION DATA			Has not been manufactured and distributed					
c. LABELING (Whether or not previously submitted)			Has not been manufactured or distributed					
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES			None Thru 7/99					
e. NONCLINICAL LABORATORY STUDIES			None					
f. CLINICAL DATA			None					
g. STATUS REPORT POST-MARKETING STUDIES			None					
h. STATUS OF OPEN REGULATORY BUSINESS (Optional)			None					
TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT			FDA USE ONLY					
			10. REPORT FILED IN NDA NUMBER					
Jennifer Eckhardt, Administrative Assistant			N	8	6	7	6	6
SIGNATURE AFD-630 <i>Jennifer Eckhardt</i>			11. DATE OF RECEIPT					
APPLICANT'S RETURN ADDRESS (Type within the window envelope tic marks)								
<p style="margin-left: 100px;">PO Box 128</p> <p style="margin-left: 100px;">Belle Plaine, MN 56011</p>								

NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug Application.

INSTRUCTIONS

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If any part of the annual report applies to more than one application, list in item 7 all other applications to which such parts apply.

1. NDA OR ANDA NUMBER			
N	8	7	081
2. Report No. (FDA Complete)			
Y-	0	1	1
APPLICANT NOTE Reference NDA and Y numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.			
3. CFR SECTION NUMBER (Antibiotic only)			
6. TYPE OF REPORT (Check one)			
<input checked="" type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER			
8. PERIOD COVERED BY REPORT			
FROM		TO	
YEAR	MONTH	YEAR	MONTH
1993	July	1999	July

4. APPLICANT
Wendt Laboratories, Inc.

5. DRUG NAME
Nitroflurazone Solution 0.2%

7. OTHER NDA/ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)

REPORT INFORMATION REQUIRED (See § 314.81 for description)
9. (Enter type of information attached under "Identification." If you have nothing to report, enter None.)
(INFORMATION IN "9b" and "9c" IS ALWAYS REQUIRED.)

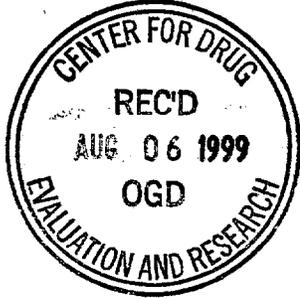
TYPE OF INFORMATION	IDENTIFICATION (Volume No.(s)/Tab(s)/Page(s) of Report)
a. SUMMARY OF SIGNIFICANT NEW INFORMATION	None
b. DISTRIBUTION DATA	Has not been manufactured or distributed
c. LABELING (Whether or not previously submitted)	Has not been manufactured or distributed
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES	None
e. NONCLINICAL LABORATORY STUDIES	None
f. CLINICAL DATA	None
g. STATUS REPORT POST-MARKETING STUDIES	None
h. STATUS OF OPEN REGULATORY BUSINESS (Optional)	None

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
Jennifer Eckhardt, Administrative Assistant

FDA USE ONLY			
10. REPORT FILED IN NDA NUMBER			
N	8	7	081

SIGNATURE
Jennifer Eckhardt

11. DATE OF RECEIPT



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PO Box 128
Belle Plaine, MN 55011

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4. APPLICANT
Wealth Laboratories, Inc.

5. DRUG NAME
Paralochol Phosphate Tablets, 10 mg

7. OTHER NDA/ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)

1. NDA OR ANDA NUMBER
 N 84185

2. Report No. (FDA Complete)
 Y- 001

APPLICANT NOTE
 Reference NDA and Y numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.

3. CFR SECTION NUMBER (Antibiotic only)

6. TYPE OF REPORT (Check one)
 ANNUAL OTHER

8. PERIOD COVERED BY REPORT
 FROM TO
 YEAR MONTH YEAR MONTH
1985 Oct. 1989 June

9. REPORT INFORMATION REQUIRED (See § 314.81 for description) (Enter type of information attached under "Identification." If you have nothing to report, enter None.) (INFORMATION IN "9b" and "9c" IS ALWAYS REQUIRED.)

TYPE OF INFORMATION	IDENTIFICATION (Volume No.(s)/Tab(s)/Page(s) of Report)
a. SUMMARY OF SIGNIFICANT NEW INFORMATION	<i>None</i>
b. DISTRIBUTION DATA	<i>Has not been manufactured or distributed.</i>
c. LABELING (Whether or not previously submitted)	<i>Has not been manufactured or distributed.</i>
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES	<i>None</i>
e. NONCLINICAL LABORATORY STUDIES	<i>None</i>
f. CLINICAL DATA	<i>None</i>
g. STATUS REPORT POST-MARKETING STUDIES	<i>None</i>
h. STATUS OF OPEN REGULATORY BUSINESS (Optional)	<i>None</i>

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
*Jennifer Eckhardt
 Administrative Assistant*

SIGNATURE
Jennifer Eckhardt

APPLICANT'S RETURN ADDRESS (Type within the window envelope tic marks)
*P.O. Box 158
 Bylin, Phoen AN 50011*

FDA USE ONLY
 10. REPORT FILED IN NDA NUMBER
 N 84185

11. DATE OF RECEIPT



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1. NDA OR ANDA NUMBER			
N	84	4	185
2. Report No. (FDA Complete)			
Y-	0	0	1
APPLICANT NOTE Reference NDA and Y numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report.			
3. CFR SECTION NUMBER (Antibiotic only)			
4. APPLICANT Wendt Laboratories, Inc.			
5. DRUG NAME Bethanechol Chloride Tablets, 25mg.			
6. TYPE OF REPORT (Check one) <input checked="" type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER			
7. OTHER NDA/ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)			
8. PERIOD COVERED BY REPORT			
FROM		TO	
YEAR	MONTH	YEAR	MONTH
1985	Oct.	1999	July

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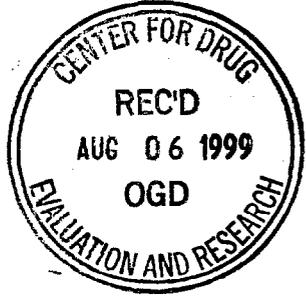
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f. CLINICAL DATA	None
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h. STATUS OF OPEN REGULATORY BUSINESS (Optional)	None

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
Jennifer Eckhardt, Administrative Assistant

SIGNATURE *Jennifer Eckhardt*

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Belle Plaine, MN 56011

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10. REPORT FILED IN NDA NUMBER			
N	8	4	186
11. DATE OF RECEIPT			
			

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No. Day Year	Military <input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Return Receipt Fee		Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Time In <input type="checkbox"/> AM <input type="checkbox"/> PM	Int'l Alpha Country Code	COD Fee	Insurance Fee	Delivery Date	Time <input type="checkbox"/> AM <input checked="" type="checkbox"/> PM	Employee Signature
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