

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 86-766

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date:

NDA NUMBER: 86-766

NAME AND ADDRESS OF APPLICANT

Wendt Laboratories, Inc.
Belle Plaine, MN 56001

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

DATE(s) of SUBMISSION:
11-15-78

PHARMACOLOGICAL CATEGORY

antibacterial

NAME OF DRUG

Nitrofurazone

HOW DISPENSED

RX OTC

DOSAGE FORM(S)

ointment

POTENCY(IES)

0.2%

RELATED IND/NDA/DMF

STERILIZATION

SAMPLES

LABELING

needs minor revision

BIOLOGIC AVAILABILITY

na

ESTABLISHMENT INSPECTION

requested

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

need clarification of actual tests

PACKAGING

Black PP ulined black pp cap

STABILITY

Protocol: not submitted

Exp. Date: none-- no data submitted

REMARKS AND

CONCLUSION: Rev w/f JTaylor

U.S. DEPARTMENT OF HEALTH, EDUCATION & WELFARE
FEDERAL BUREAU OF INVESTIGATION
DIVISION OF FOOD & DRUGS
U.S. DEPARTMENT OF HEALTH, EDUCATION & WELFARE
Abbreviated New Drug Application
or Supplement

Statement Date:

NDA NUMBER:

86-766

NAME AND ADDRESS OF APPLICANT

Wendt Labs., Inc. - Belle Plaine, MN 56001

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE ~~XXX~~
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

labeling & control info

DATE(s) of SUBMISSION
as per letters

PHARMACOLOGICAL CATEGORY

antibacterial

NAME OF DRUG

nitrofurazone

HOW DISPENSED

RX xxx OTC

DOSAGE FORM(S)

ointment

POTENCY(IES)

0.2%

RELATED IND/NDA/DME

87-081 solution
86-766 ointment

STERILIZATION

SAMPLES

LABELING

unsatisfactory per FR 3-29-73

BIOLOGIC AVAILABILITY

NA

ESTABLISHMENT INSPECTION

requested _____ (active ingredient) ok _____

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

see issued letter

PACKAGING

polypropylene jars and caps 8 & 15 oz.

STABILITY

Protocol: satisfactory

Exp. Date: firm asks for 2 yrs w/cycling data

REMARKS AND
CONCLUSION:

rev w/f CChang *l. cheng 3-5-80*

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date:

NDA # 86-766

NAME AND ADDRESS OF APPLICANT:

Wendt Labs. Inc.
Belle Plaine MN 56001

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION XXX
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT
Labeling information

DATE(s) of SUBMISSION(s)
as per letters

PHARMACOLOGICAL CATEGORY
antibacterial

NAME OF DRUG
Nitrofurazone

HOW DISPENSED
RX XXX OTC

DOSAGE FORM
Ointment

POTENCY(IES)
0.2%

RELATED IND/NDA/DMF
87-081 solution
86-766 ointment

STERILIZATION

SAMPLES

LABELING

Unsatisfactory per FR 3-29-73

BIOLOGIC AVAILABILITY

NA

ESTABLISHMENT INSPECTION

Wendt requested, (active ingredient) ok.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

see issued letter

PACKAGING

Polypropylene jars and caps 8 & 16 oz.

STABILITY: satisfactory

Protocol:

Exp. Date: Firm asks for 2 years w/cycling data

REMARKS & CONCLUSION: rev w/f CChang

ccy 9-17-80

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT		Statement Date:	NDA # 86-766
NAME AND ADDRESS OF APPLICANT: Wendt Labs., Inc. Belle Plaine, MN 56001		ORIGINAL AMENDMENT SUPPLEMENT RESUBMISSION xxx CORRESPONDENCE REPORT OTHER	
PURPOSE OF AMENDMENT/SUPPLEMENT labeling & stability info.		DATE(s) of SUBMISSION(s) as per letter	
PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED RX <u>xxxx</u> OTC <u> </u>	
antibacterial	nitrofurazone	RELATED IND/NDA/DMF	
DOSAGE FORM	POTENCY(IES)	87-081 solution 86-766 ointment	
ointment	0.2%		
STERILIZATION	SAMPLES		
LABELING			
unsatisfactory per FR 3-29-73			
BIOLOGIC AVAILABILITY			
na			
ESTABLISHMENT INSPECTION			
Wendt - unsatisfactory per HFD-322 (12-30-80) _____ (active ingredient) ok _____			
COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS see issued letter			
PACKAGING			
polypropylene jars and caps 8 & 16 oz.			
STABILITY:			
Protocol: satisfactory			
Exp. Date: firm asks for 2 yrs w/cycling data			
REMARKS & CONCLUSION:			
acknowledge CChang <i>ccy 1-21-81</i>			

NAME AND ADDRESS OF APPLICANT:

Wendt Laboratories Inc.
Belle Plaine, MN 56001

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION: XXXX
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

labeling information

DATE(s) of SUBMISSION(s)
as per letter

PHARMACOLOGICAL CATEGORY

antibacterial

NAME OF DRUG

nitrofurazone

HOW DISPENSED

RX XXXX OTC

DOSAGE FORM

ointment

POTENCY(IES)

0.2%

RELATED IND/NDA/DMF

87-081 solution
86-766 ointment

STERILIZATION

SAMPLES

LABELING

unsatisfactory per FR 3-29-73

BIOLOGIC AVAILABILITY

ESTABLISHMENT INSPECTION

Wendt - unsatisfactory per HFD-322 (12-30-80) satisfactory (5-81)
_____ (active ingredient) ok _____

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Satisfactory

PACKAGING

polypropylene jars and caps 8 & 16 oz.

STABILITY:

Protocol: Satisfactory

Exp. Date: Firm asks for 2 years w/cycling data

REMARKS & CONCLUSION: approval

CChang

C. Chang 5-7-81

Composition of the Drug

	mg./g.
Nitrofurazone	2.0
Polyethylene Glycol 4000	348
Polyethylene Glycol 400	650

Suppliers of the active ingredient:

1. _____

2. _____

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER
86-766

DATE APPROVAL LETTER ISSUED
MAY 11 1981

TO:

Press Relations Staff (HFI-40)

FROM:

Bureau of Drugs

Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publications only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION

ORIGINAL NDA

SUPPLEMENT
TO NDA

ABBREVIATED
ORIGINAL NDA

SUPPLEMENT
TO ANDA

CATEGORY

HUMAN

VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG.
Nitrofurazone

DOSAGE FORM

Ointment

HOW DISPENSED

RX

OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

Nitrofurazone 0.2%

NAME OF APPLICANT (Include City and State)

Wendt Laboratories Inc.
Belle Plaine, MN 56011

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

Antibacterial

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME

CChang

DATE

5-7-81

FORM APPROVED BY

NAME

JLMeyer

DATE