CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 86-766

LABELING REVIEW(S)

REVIEW OF ANDA

DATE COMPLETED: 12-15-78 ANDA #: 86-766

F.R. DATE: 3-29-73

CO. NAME: Wendt Labs., Inc.
Belle Plains, MN 56011
Minneapolis, MN 55437

NAME OF DRUG: Nitrofurazone Ointment 0.2%

DATE OF SUBMISSION: 11-15-78

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of studies: Bioavailability is not required for this drug.

2. Review of Labeling:

a. Container Labels: draft copies for

1 lb and 8 oz containers - add "Protect from light."
The draft labeling states these are "proposed —— labels".
This amount would probably not be marketed in —— form.

b. Package Insert: draft copy

1. Delete "———" and substitute "Description" including the chemical formula as in the FR statement of 3-29-73.

2. It is preferable to place the animal toxicology data at the end of the insert as in the F.R. statement.

CONCLUSION: 1. The proposed container labels should have the warning "Protect from light."
2. The draft copy of the package insert needs revision as noted above.

RECOMMENDATIONS: The company is to be so notified.

JR Carr
John R. Carr, D.D.S

cc:
DUP
JRC/cjb/12-19-78

REVIEW OF RESUBMISSION

DATE COMPLETED: 2-12-80

ANDA #: 86-766

CO. NAME: Wendt Laboratories
Minneapolis, MN 55437

APPROVAL DATE: none

NAME OF DRUG: Nitrofurazone Ointment 0.2%

DATE OF SUBMISSION: 10-15-79

RECEIVED FOR REVIEW: 2-12-80

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION

1. Review of Studies: For chemists review.

2. Review of Labeling:

   Container labels for 8 oz. and 1 lb. containers - satisfactory.

   Package insert: Satisfactory.

CONCLUSION: The labeling is acceptable.

RECOMMENDATIONS: The company is to be so notified.

J.R. Carr, D.D.S.

cc:dup
JRC/wh/2-12-80

REVIEW OF ANDA, RESUBMISSION, FPL

DATE COMPLETED: 6-18-80

ANDA #: 86-766

CO. NAME: Wendt Labs., Inc.
Belle Plaine, MN 56011

F.R. DATE: 3-29-73

NAME OF DRUG: Nitrofurazone Ointment 0.2%

DATE OF SUBMISSION: 5-16-80 (Original application 11-15-78)

TYPE OF SUBMISSION: Resubmission of ANDA

CLINICAL EVALUATION:

1. Review of Studies: None submitted.

2. Review of Labeling:

a) Container labeling - FPL -- has been revised to contain information as designated in the FR notice 3-29-73. It also includes prescription legend, warnings, size, ingredients, storage instructions, directions for use, lot #, expiration date and manufacturer's name.

b) Package insert - FPL - dated 10-78 -- The description section lacks the chemical name and structural formula

Typographical error in animal toxicology 1st line last column should be 240 mg/kg/day instead of 240 mg./kg/day.

The rest of the labeling conforms to the Federal Register notice as published 3-29-73.

The original ANDA submission for this drug was dated 11-15-78. It contained ingredients and amounts, designation as a prescription item, certification from the firm as being in compliance with GMP, certification that the drug dosage form and components are in compliance with the official compendium specifications of USP monograph or NF, and quality control procedures. All packaging procedures and all manufacturing, processing, packaging, labeling and control operations for this drug are noted as performed by Wendt Labs., Inc. Labels for the containers are described in the quality control procedures as stamped with the appropriate lot # before the packaging process begins.

No biologic availability data were available at the time of this original submission. Adverse reactions were noted as being included in the labeling. Exemption from an environmental impact statement was requested based on FR notice vol. 42, #73, 4-15-77, p. 19990.

Resubmission 3-27-79 in response to FDA 1-29-79 letter included draft container labeling for 8 oz. and 1# size; package insert - draft labeling; & controls data.

Resubmission 10-15-79 in response to FDA 7-17-79 incomplete letter includes:

FPL for package insert and container labeling.
Controls data.
Stability data - change in request of expiration dating from [redacted] to 2 years due to insufficient supportive data. Testing thru [redacted] cycles of 4°C and 45°C were without effect on physical characteristics of the drug. Drug described as light sensitive. [redacted].

Conclusions:
1. This is the third resubmission for this application.
2. The container labeling is satisfactory and incorporates information in accord with the Federal Register notice of 3-29-73.
3. The package insert lacks chemical name and structural formula in the description section and has a typographical error in the Animal Toxicology section (see Review of Labeling).

Recommendations:
1. Approval unless there are deficiencies based on chemist's review.
2. Labeling revision as noted above under review of labeling in 180 days or at the time of the next printing - whichever occurs first.

A. Standard
A. Standard, M.D.

cc:dup
AS/wh/8-19-80