CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 86-766

ADMINISTRATIVE DOCUMENTS

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 12-8-78
FROM: J. Taylor (thru J.L. Meyer)		OFFICE HFD-330
TO: Mr. David H. Bryant, Office of Compliance		DIVISION HFD-322

SUBJECT: Inspection Request

SUMMARY

In conncetion with ANDA 86-766

for: Nitrofurazone Ointment, 0.2%

Applicant: Wendt Laboratories, Inc.
100 Main Drive
Belle Plaine, Minnesota 56011

AF -

REQUESTED:

[X] 1. Evaluation of compliance with CGMP for:

[X] a. The applicant

[ ] b. Others

[X] 2. Recommendation for approval/disapproval of the application/communication/supplement, based on your evaluation of compliance with CGMP

REMARKS:

SIGNATURE

DOCUMENT NUMBER 86-766

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Director,
Division of Generic Drug Monographs (HFD-530)
Attn: Ross/ Chang

DATE: September 12, 1979

FROM : Chief, Manufacturing Review Branch (HFD-322)
Division of Drug Manufacturing

SUBJECT: GMP Evaluation Requests dated 12/8/78, 7/12/79, & 8/1/79
Re: ANDA's 86-766, ——— & 87-081

A telephone conversation with Minneapolis District Office on 8/20/79 confirmed that the applicant of the above ANDA's, Wendt Labs, Belle Plaine, MN., only manufactures veterinary drugs.

Since we do not provide evaluations of vet drug manufacturers, your request is considered withdrawn as of 8/20/79.

W. T. Lampkin
for David H. Bryant

cc: HFD-300 R/F
HFD-322 Firm Files
HFD-530 (ANDA Orig)
HFD-320 R/F
MMO'Rourke:ljh:9/12/79

9-17-79

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Division of Drug Manufacturing (HFD-320)
Associate Directorate for Compliance
Attn: Ms. Peg. O'Rourke

DATE: 2-27-80

FROM : Division of Generic Drugs (HFD-530)
C. CHANG, ext. 3- 4040, 4080

SUBJECT: GMP EVALUATION REQUEST
Chemist C. CHANG
NDA/ANDA/IND # : 86-766, 87-081, &
FORM 5/6 # :

DRUG: Nitrofurazone 0.2% Oint, Solution 0.2%, &

DRUG CLASSIFICATION: NA

PRODUCT CLASSIFICATION CODE: 61N, L10, 4C-1

180 DAY DATE: NA

APPLICANT: Wendt LABS
Belle Plaine, Minnesota 56011

FACILITIES TO BE EVALUATED(Name,Address,& Operations to be performed for Applica:

Wendt LABS
For [ ]
of [ ] prpoms [ ]
test.

ADDITIONAL INFORMATION:

FOR HFD-320 USE ONLY

CONTROL #:

Date Received:

Date Completed:

cc: HFD-320(original)
HFD-___ (2 copies)

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Division of Drug Manufacturing, HFD-320 DATE: 9-15-80

FROM : Division of Generic Drug Monograph, HFD- 530

Requester's Name: C. CHANG Phone: 3-4040

SUBJECT: GMP EVALUATION REQUEST

NDA,ANDA, and SUPPLEMENT NUMBER: 86-766, 87-081, [solution]

DRUG Trade Name: Nitrofurazone Ointment, 0.2% & [ ]

DRUG Non-Proprietary Name: Same

DRUG CLASSIFICATION: ___ A or B ___ 1C ___ Other

PRODUCT CODE: OIN (description of dosage form, e.g., compressed tablet;coated tablet; soft gelatin capsule;liquid;See Table)

180 DAY DATE: As soon as possible.

APPLICANT'S NAME: Wendt LABs, Inc.

ADDRESS: 100 Nancy Drive, Belle Plaine, MN 56011

FACILITIES TO BE EVALUATED: (Name, Address, and Responsibility)

① Wendt LABs Inc at Minnesota

② For [ ] of [ ] performs - [ ] test

FOR HFD-320 USE ONLY

Date Received: _____ Date Completed: _____

cc: HFD-320 (Orig)
HFD- (2 Copies)

ADDITIONAL COMMENTS CONCERNING THIS REQUEST SHOULD BE DESCRIBED ON AN ATTACHED SHEET

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Division of Generic Drug Monographs
ATTN: Charles Chang (HFD-530)

DATE: December 31, 1980

FROM : Manufacturing Review Branch (HFD-322)
Division of Drug Manufacturing

SUBJECT: ANDA's 86-766; 87-081; ———
Nitrofurazone Ointment, Nitrofurazone Solution, ———

FIRM: Wendt Labs
Belle Plaine, MN.

An inspection of Wendt Labs on 7/16/80 to 8/1/80 revealed that this firm only manufactures veterinary drugs. Although the firm has submitted human drug ANDA's, the inspection revealed that the firm is not yet operational in the manufacture of human drugs. Therefore, no evaluation of the firm as to compliance with human drug CGMP's can be made at this time.

Seymour Fishman

cc:
HFD-300
HFD-322
HFD-530 (Orig)
MIN-DO (HFR-5400)
SFishman/lh/12/31/80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date

From Manufacturing Review Branch, HFD-322
Division of Drug Manufacturing

Subject APPROVABLE ANDA's 86-766, 87-081 — NITROFURAZONE OINT, SOLN

To Director
Division of GENERIC DRUG MONOGRAPHS
Drug Products
Attn: DAVID ROSEN

APPLICANT: WERNER LABS, BELLE PLAINE MN

APPEARS THIS WAY ON ORIGINAL

We have evaluated the operations of WERNER LABS as they relate to compliance with Current Good Manufacturing Practice Regulations (21 CFR Part 211) with the exception of expiration dating (211.137) and stability testing (211.166) for the referenced application(s). Since you evaluate the applicants' submission of stability data and proposed expiration date, you should make the determination that the stability testing is adequate to support the proposed expiration date. If you desire, you can include appropriate references to (211.137) and (211.166) as deviations directly into your non-approvable letter if you conclude the stability testing is inadequate. Otherwise, we conclude there is no reason to withhold approval of the subject application(s) insofar as CGMP compliance of this/these firm(s) is concerned for the type of operations as specified in this/these pending application(s).

Our evaluation is based in part on Establishment Inspection and Quality Assurance Profile information.

Seymour Fishman

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 86-766

CORRESPONDENCE

Minneapolis, Minn. 612-445-5272
Belle Plaine, Minn. 612-873-2288
Cable Address: WENDT, Mpls., USA

WENDT LABORATORIES

100 Nancy Drive
Belle Plaine, Mn. 56011

10100 Colorado Rd.
Minneapolis, Mn. 55437

A Family of Pharmaceutical Manufacturers,
Since 1927

86-766

ABBREVIATED
NEW DRUG APPLICATION

November 15. 1978

Dept. of Health, Education, and Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen:

With reference to the Federal Regulations published in the Federal Register of April, 1970 (35 FR 6574), we are herewith submitting an Abbreviated New Drug Application for a topical preparation, Nitrofurazone Ointment 0.2%.

In addition, we request a waiver of any bioavailability requirements based upon the Federal Register publication.

You may address all correspondence and inquires to my attention.

Sincerely,

WENDT LABORATORIES, INC.

Gregory P. Bergt

Gregory P. Bergt
100 Nancy Drive
Belle Plaine, Minn. 56011

COPY
OF
COVER LETTER MADE

GPB/aq

Enclosures

RECEIVED
NOV 17 1978
BUREAU OF DRUGS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

Form Approved
OMB No. 57-R0003

NEW DRUG APPLICATION *(DRUGS FOR HUMAN USE)*

(Title 21, Code of Federal Regulations, § 130.4)

Name of applicant Wendt Laboratories, Inc.

Address 100 Nancy Drive, Belle Plaine, Minnesota 56011

Date November 15, 1978

Name of new drug Nitrofurazone Ointment 0.2%

- ☐ Original application (regulation § 130.4).
- ☐ Amendment to original, unapproved application (regulation § 130.7).
- ☒ Abbreviated application (regulation § 130.4(f)).
- ☐ Amendment to abbreviated, unapproved application (regulation § 130.7).
- ☐ Supplement to an approved application (regulation § 130.9).
- ☐ Amendment to supplement to an approved application.

The undersigned submits this application for a new drug pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act. It is understood that when this application is approved, the labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application; and if the article is a prescription drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the drug will contain the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant warnings, hazards, contraindications, side effects, and precautions, as that contained in the labeling which is part of this application in accord with §1.106(b) (21 CFR 1.106(b)). It is understood that all representations in this application apply to the drug produced until an approved supplement to the application provides for a change or the change is made in conformance with other provisions of §130.9 of the new-drug regulations.

Attached hereto, submitted in the form described in §130.4(g) of the new-drug regulations, and constituting a part of this application are the following:

1. Table of contents. The table of contents should specify the volume number and the page number in which the complete and detailed item is located and the volume number and the page number in which the summary of the item is located (if any).

2. Summary. A summary demonstrating that the application is well-organized, adequately tabulated, statistically analyzed (where appropriate), and coherent and that it presents a sound basis for the approval requested. The summary should include the following information: (In lieu of the outline described below and the evaluation described in Item 3, an expanded summary and evaluation as outlined in §130.4(d) of the new-drug regulations may be submitted to facilitate the review of this application.)

a. Chemistry.

i. Chemical structural formula or description for any new-drug substance.

ii. Relationship to other chemically or pharmacologically related drugs.

iii. Description of dosage form and quantitative composition.

b. Scientific rationale and purpose the drug is to serve.

c. Reference number of the investigational drug notice(s) under which this drug was investigated and of any notice, new-drug application, or master file of which any contents are being incorporated by reference to support this application.

d. Preclinical studies. (Present all findings including all adverse experiences which may be interpreted as incidental or not drug-related. Refer to date and page number of the investigational drug notice(s) or the volume and page number of this application where complete data and reports appear.)

i. Pharmacology (pharmacodynamics, endocrinology, metabolism, etc.).

ii. Toxicology and pathology: Acute toxicity studies; subacute and chronic toxicity studies; reproduction and pathology studies; miscellaneous studies.

e. Clinical studies. (All material should refer specifically to each clinical investigator and to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found.)

i. Special studies not described elsewhere.

ii. Dose-range studies.

iii. Controlled clinical studies.

iv. Other clinical studies (for example, uncontrolled or incompletely controlled studies).

v. Clinical laboratory studies related to effectiveness.

vi. Clinical laboratory studies related to safety.

vii. Summary of literature and unpublished reports available to the applicant.

3. Evaluation of safety and effectiveness. a. Summarize separately the favorable and unfavorable evidence for each claim in the package labeling. Include references to the volume and page number in the application and in any documents incorporated by reference where the complete data and reports may be found.

b. Include tabulation of all side effects or adverse experience, by age, sex, and dosage formulation, whether or not considered to be significant, showing whether administration of the drug was stopped and showing the investigator's name with a reference to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found. Indicate those side effects or adverse experiences considered to be drug-related.

4. Copies of the label and all other labeling to be used for the drug (a total of 12 copies if in final printed form, 4 copies if in draft form):

a. Each label, or other labeling, should be clearly identified to show its position on, or the manner in which it accompanies, the market package.

b. If the drug is to be offered over the counter, labeling on or within the retail package should include adequate directions for use by the layman under all the conditions for which the drug is intended for lay use or is to be prescribed, recommended, or suggested in any labeling or advertising sponsored by or on behalf of the applicant and directed to the layman. If the drug is intended or offered for uses under the professional supervision of a practitioner licensed by law to administer it, the application should also contain labeling that includes adequate information for all such uses, including all the purposes for which the over-the-counter drug is to be advertised to, or represented for use by, physicians.

c. If the drug is limited in its labeling to use under the professional supervision of a practitioner licensed by law to administer it, its labeling should bear information for use under which such practitioners can use the drug for the purposes for which it is intended, including all the purposes for which it is to be advertised or represented, in accord with §1.106(b) (21 CFR 1.106(b)). The application should include any labeling for the drug intended to be made available to the layman.

d. If no established name exists for a new-drug substance, the application shall propose a nonproprietary name for use as the established name for the substance.

e. Typewritten or other draft labeling copy may be submitted for preliminary consideration of an application. An application will not ordinarily be approved prior to the submission of the final printed label and labeling of the drug.

f. No application may be approved if the labeling is false or misleading in any particular.

(When mailing pieces, any other labeling, or advertising copy are devised for promotion of the new drug, samples shall be submitted at the time of initial dissemination of such labeling and at the time of initial placement of any such advertising for a prescription drug (see §130.13 of the new-drug regulations). Approval of a supplemental new-drug application is required prior to use of any promotional claims not covered by the approved application.)

5. A statement as to whether the drug is (or is not) limited in its labeling and by this application to use under the professional supervision of a practitioner licensed by law to administer it.

6. A full list of the articles used as components of the drug. This list should include all substances used in the synthesis, extraction, or other method of preparation of any new-drug substance, and in the preparation of the finished dosage form, regardless of whether they undergo chemical change or are removed in the process. Each substance should be identified by its established name, if any, or complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

7. A full statement of the composition of the drug. The statement shall set forth the name and amount of each ingredient, whether active or not, contained in a stated quantity of the drug in the form in which it is to be distributed (for example, amount per tablet or per milliliter) and a batch formula representative of that to be employed for the manufacture of the finished dosage form. All components should be included in the batch formula regardless of whether they appear in the finished product. Any calculated excess of an ingredient over the label declaration should be designated as such and percent excess shown. Reasonable variations may be specified.

8. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug. Included in this description should be full information with respect to any new-drug substance and to the new-drug dosage form, as follows, in sufficient detail to permit evaluation of the adequacy of the described methods of manufacture, processing, and packing and the described facilities and controls to determine and preserve the identity, strength, quality, and purity of the drug:

a. A description of the physical facilities including building and equipment used in manufacturing, processing, packaging, labeling, storage, and control operations.

b. A description of the qualifications, including educational background and experience, of the technical and professional personnel who are responsible for assuring that the drug has the safety, identity, strength, quality, and purity it purports or is represented to possess, and a statement of their responsibilities.

c. The methods used in the synthesis, extraction, isolation, or purification of any new-drug substance. When the specifications and controls applied to such substance are inadequate in themselves to determine its identity, strength, quality, and purity, the methods should be described in sufficient detail, including quantities used, times, temperatures, pH, solvents, etc., to determine these characteristics. Alternative methods or variations in methods within reasonable limits that do not affect such characteristics of the substance may be specified.

d. Precautions to assure proper identity, strength, quality, and purity of the raw materials, whether active or not, including the specifications for acceptance and methods of testing for each lot of raw material.

e. Whether or not each lot of raw materials is given a serial number to identify it, and the use made of such numbers in subsequent plant operations.

f. If the applicant does not himself perform all the manufacturing, processing, packaging, labeling, and control operations for any new-drug substance or the new-drug dosage form, his statement identifying each person who will perform any part of such operations and designating the part; and a signed statement from each such person fully describing, directly or by reference, the methods, facilities, and controls in his part of the operation.

g. Method of preparation of the master formula records and individual batch records and manner in which these records are used.

h. The instructions used in the manufacturing, processing, packaging, and labeling of each dosage form of the new drug, including any special precautions observed in the operations.

i. Adequate information with respect to the characteristics of and the test methods employed for the container, closure, or other component parts of the drug package to assure their suitability for the intended use.

j. Number of individuals checking weight or volume of each individual ingredient entering into each batch of the drug.

k. Whether or not the total weight or volume of each batch is determined at any stage of the manufacturing process subsequent to making up a batch according to the formula card and, if so, at what stage and by whom it is done.

l. Precautions to check the actual package yield produced from a batch of the drug with the theoretical yield. This should include a description of the accounting for such items as discards, breakage, etc., and the criteri used in accepting or rejecting batches of drugs in the event of an unexplained discrepancy.

m. Precautions to assure that each lot of the drug is packaged with the proper label and labeling, including provisions for labeling storage and inventory control.

n. The analytical controls used during the various stages of the manufacturing, processing, packaging, and labeling of the drug, including a detailed description of the collection of samples and the analytical procedures to which they are subjected. The analytical procedures should be capable of determining the active components within a reasonable degree of accuracy and of assuring the identity of such components. If the article is one that is represented to be sterile, the same information with regard to the manufacturing, processing, packaging, and the collection of samples of the drug should be given for sterility controls. Include the standards used for acceptance of each lot of the finished drug.

o. An explanation of the exact significance of the batch control numbers used in the manufacturing, processing, packaging, and labeling of the drug, including the control numbers that appear on the label of the finished article. State whether these numbers enable determination of the complete manufacturing history of the product. Describe any methods used to permit determination of the distribution of any batch if its recall is required.

p. A complete description of, and data derived from, studies of the stability of the drug, including information showing the suitability of the analytical methods used. Describe any additional stability studies underway or contemplated. Stability data should be submitted for any new-drug substance, for the finished dosage form of the drug in the container in which it is to be marketed, including any proposed multiple-dose container, and if it is to be put into solution at the time of dispensing, for the solution prepared as directed. State the expiration date(s) that will be used on the label to preserve the identity, strength, quality, and purity of the drug until it is used. (If no expiration date is proposed, the applicant must justify its absence.)

q. Additional procedures employed which are designed to prevent contamination and otherwise assure proper control of the product.

(An application may be refused unless it includes adequate information showing that the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity in conformity with good manufacturing practice and identifies each establishment, showing the location of the plant conducting these operations.)

9. Samples of the drug and articles used as components, as follows: a. The following samples shall be submitted with the application or as soon thereafter as they become available. Each sample shall consist of four identical, separately packaged subdivisions, each containing at least three times the amount required to perform the laboratory test procedures described in the application to determine compliance with its control specifications for identity and assays:

i. A representative sample or samples of the finished dosage form(s) proposed in the application and employed in the clinical investigations and a representative sample or samples of each new-drug substance, as defined in §130.1(g), from the batch(es) employed in the production of such dosage form(s).

ii. A representative sample or samples of finished market packages of each dosage form of the drug prepared for initial marketing and, if any such sample is not from a commercial-scale production batch, such a sample from a representative commercial-scale production batch; and a representative sample or samples of each new-drug substance as defined in §130.1(g), from the batch(es) employed in the production of such dosage form(s).

iii. A sample or samples of any reference standard and blank used in the procedures described in the application for assaying each new-drug substance and other assayed components of the finished drug: *Provided, however,* That samples of reference standards recognized in the official U.S. Pharmacopeia or The National Formulary need not be submitted unless requested.

b. Additional samples shall be submitted on request.

c. Each of the samples submitted shall be appropriately packaged and labeled to preserve its characteristics, to identify the material and the quantity in each subdivision of the sample, and to identify each subdivision with the name of the applicant and the new-drug application to which it relates.

d. There shall be included a full list of the samples submitted pursuant to Item 9a; a statement of the additional samples that will be submitted as soon as available; and, with respect to each sample submitted, full information with respect to its identity, the origin of any new-drug substance contained therein (including in the case of new-drug substances, a statement whether it was produced on a laboratory, pilot-plant, or full-production scale) and detailed results of all laboratory tests made to determine the identity, strength, quality, and purity of the batch represented by the sample, including assays. Include for any reference standard a complete description of its preparation and the results of all laboratory tests on it. If the test methods used differed from those described in the application, full details of the methods employed in obtaining the reported results shall be submitted.

e. The requirements of Item 9a may be waived in whole or in part on request of the applicant or otherwise when any such samples are not necessary.

f. If samples of the drug are sent under separate cover, they should be addressed to the attention of the Bureau of Medicine and identified on the outside of the shipping carton with the name of the applicant and the name of the drug as shown on the application.

10. Full reports of preclinical investigations that have been made to show whether or not the drug is safe for use and effective in use. a. An application may be refused unless it contains full reports of adequate preclinical tests by all methods reasonably applicable to a determination of the safety and effectiveness of the drug under the conditions of use suggested in the proposed labeling.

b. Detailed reports of the preclinical investigations, including all studies made on laboratory animals, the methods used, and the results obtained, should be clearly set forth. Such information should include identification of the person who conducted each investigation, a statement of where the investigations were conducted, and where the underlying data are available for inspection. The animal studies may not be considered adequate unless they give proper attention to the conditions of use recommended in the proposed labeling for the drug such as, for example, whether the drug is for short- or long-term administration or whether it is to be used in infants, children, pregnant women, or women of child-bearing potential.

c. Detailed reports of any pertinent microbiological and *in vitro* studies.

d. Summarize and provide a list of literature references (if available) to all other preclinical information known to the applicant, whether published or unpublished, that is pertinent to an evaluation of the safety or effectiveness of the drug.

11. List of investigators. a. A complete list of all investigators supplied with the drug including the name and post office address of each investigator and, following each name, the volume and page references to the investigator's report(s) in this application and in any documents incorporated by reference, or the explanation of the omission of any reports.

b. The unexplained omission of any reports of investigations made with the new drug by the applicant, or

submitted to him by an investigator, or the unexplained omission of any pertinent reports of investigations or clinical experience received or otherwise obtained by the applicant from published literature or other sources, whether or not it would bias an evaluation of the safety of the drug or its effectiveness in use, may constitute grounds for the refusal or withdrawal of the approval of an application.

12. Full reports of clinical investigations that have been made to show whether or not the drug is safe for use and effective in use. a. An application may be refused unless it contains full reports of adequate tests by all methods reasonably applicable to show whether or not the drug is safe and effective for use as suggested in the labeling.

b. An application may be refused unless it includes substantial evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

c. Reports of all clinical tests sponsored by the applicant or received or otherwise obtained by the applicant should be attached. These reports should include adequate information concerning each subject treated with the drug or employed as a control, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, full information concerning any other treatment given previously or concurrently, and a full statement of adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation and a statement of where the underlying data are available for inspection. Ordinarily, the reports of clinical studies will not be regarded as adequate unless they include reports from more than one independent, competent investigator who maintains adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated and comparable records on any individuals employed as controls. An application for a combination drug may be refused unless there is substantial evidence that each ingredient designated as active makes a contribution to the total effect claimed for the drug combination. Except when the disease for which the drug is being tested occurs with such infrequency in the United States as to make testing impractical, some of the investigations should be performed by competent investigators within the United States.

d. Attach as a separate section a completed Form FD-1639, Drug Experience Report (obtainable, with instructions, on request from the Department of HEW. Food and Drug Administration. Bureau of Drugs *(BD-200)* Rockville, Maryland 20852), for each adverse experience or, if feasible, for each subject or patient experiencing one or more adverse effects, described in Item 12c, whether or not full information is available. Form FD-1639 should be prepared by the applicant if the adverse experience was not reported in such form by the investigator. The Drug Experience Report should be cross-referenced to any narrative description included in Item 12c. In lieu of a FD Form 1639, a computer-generated report may be submitted if equivalent in all elements of information with the identical enumerated sequence of events and methods of completion; all formats proposed for such use will require initial review and approval by the Food and Drug Administration.

e. All information pertinent to an evaluation of the safety and effectiveness of the drug received or otherwise obtained by the applicant from any source, including information derived from other investigations or commerical marketing (for example, outside the United States), or reports in the scientific literature, involving the drug that is the subject of the application and related drugs. An adequate summary may be acceptable in lieu of a reprint of a published report which only supports other data submitted. Reprints are not required of reports in designated journals, listed in §130.38 of the new-drug regulations, about related drugs; a bibliography will suffice. Include any evaluation of the safety or effectiveness of the drug that has been made by the applicant's medical department, expert committee, or consultants.

f. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigation and experience with its components, including all reports received or otherwise obtained by the applicant suggesting side effects, contraindications, and ineffectiveness in use of such components. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference information concerning such components previously submitted by the applicant to the Food and Drug Administration.

g. The complete composition and/or method of manufacture of the new drug used in each submitted report of investigation should be shown to the extent necessary to establish its identity, strength, quality, and purity if it differs from the description in Item 6, 7, or 8 of the application.

13. If this is a supplemental application, full information on each proposed change concerning any statement made in the approved application.

Observe the provisions of §130.9 of the new-drug regulations concerning supplemental applications.

Wendt Laboratories, Inc.
(Applicant)

Per Gregory P. Bergt
(Responsible official or agent)

Gregory P. Bergt, Chemist
(Indicate authority)

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

NOTE: This application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of and must be countersigned by an authorized attorney, agent, or official residing or maintaining a place of business within the United States.

DEC 5 1978

NDA 86-766

Wendt Laboratories, Inc.
Attention: Gregory P. Bergt
100 Nancy Drive
Belle Plaine, Minnesota 56011

Gentlemen:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NAME OF DRUG: Nitrofurazone Ointment, 0.2%

DATE OF APPLICATION: November 15, 1978

DATE OF RECEIPT: November 17, 1978

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the NDA number shown above.

Sincerely yours,

Marvin Seife 12/5/78

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

KAN city-DO DUP HFD-614
JLMeyer/cjb/12-2-78 ack
JLMeyer 12/4/78

JAN 29 19

NDA 86-766

Wendt Laboratories, Inc.
Attention: Gregory P. Bergt
100 Nancy Drive
Belle Plaine, Minnesota 56011

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrofurazone Ointment, 0.2%.

We have completed the review of this abbreviated new drug application and have the following comments:

1. Container labeling: Revise to indicate actual temperature storage conditions and include "Protect from Light".

2. Insert: Revise the format by deleting "———" and include the complete chemical formula under "Description".

3. [redacted]

4.

5.

6.

Please let us have your response promptly.

Sincerely yours,

for R. Bugler 1/26/79

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc: MINN-DO DUP HFD-614
JRCarr/JMeyer/JTaylor 1/24/79
r/d/ initl JMeyer/MSeife 1-26-79
f/t/wlh/1-26-79
rev w/f 1/24/79

JMeyer 1/26/79

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

NDA 86-766

JUL 11 1979

Wendt Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrofurazone Ointment, 0.2%.

Reference is also made to your communication dated March 27, 1979, relating to the labeling and control information.

We have completed the review of this abbreviated new drug application and have the following comments regarding the proposed labeling:

1. Container label: submit twelve copies of the final printed labeling identical in content to the draft copies.

2. Package insert: The Animal Toxicology section should be placed after HOW SUPPLIED as in the Federal Register statement of 3-29-73.

Other information required by 314.1(f) of the regulations:

1.

2.

3.

4.

5. [redacted]

The manufacturer of the active ingredient is currently under review by our Division of Drug Manufacturing. We will correspond with you when the review becomes available.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Minneapolis, Minn. 612-445-5272
Belle Plaine, Minn. 612-873-2288
Cable Address: WENDT, Mpls., USA

Drug

WENDT LABORATORIES

100 Nancy Drive
Belle Plaine, Mn. 56011

10100 Colorado Rd.
Minneapolis, Mn. 55437

A Family of Pharmaceutical Manufacturers,
Since 1927

October 15, 1979

NDA 86-766

Dr. Marvin Seife
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Seife:

In response to your letter dated July 17, 1979 concerning our NDA 86-766 for Nitrofurazone Ointment, 0.2%, I am enclosing the requested information. In order to facilitate your review, this submission is being presented in the same sequential format as your letter.

We hope this will complete all necessary information required for approval. Please contact me if you have any questions.

Sincerely,

WENDT LABORATORIES, INC.

Gregory P. Bergt

Gregory P. Bergt
100 Nancy Drive
Belle Plaine, Minn. 56011

GPB/aq

Enclosures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

NDA 86-766

MAR 6 1980

Wendt Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

Gentlemen:

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Reference is also made to your communication dated October 15, 1979 relating to the labeling and control information.

We have completed the review of this abbreviated new drug application and have the following comments regarding the proposed labeling:

Revise container labels in accord with the Federal Register Statement of 3-29-73.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

to the foreign article for such purposes as this article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

B. BLANKENHEIMER,
Acting Director,
Officer of Import Programs.

[FR Doc.73-6042 Filed 3-28-73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. FDA-D-239; Various NDA's]

NEW DRUG APPLICATIONS

Notice of Withdrawal of Approval; Correction

In FR Doc. 71-11136 appearing on page 18893 in the issue of the FEDERAL REGISTER dated September 23, 1971, the listing of new drug applications being withdrawn is corrected by deleting the entry "13-538, Decadrontopoint" from the NDA numbers and drug names listed under Merck Sharp and Dohme, Division Merck & Co., West Point, Pa. 19486.

Dated: March 23, 1973.

MARY A. MCENIRY,
Assistant to the Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc.73-5992 Filed 3-28-73;8:45 am]

[DESI 5795]

NITROFURAZONE SOLUBLE DRESSING

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug for topical use: Furacin Soluble Dressing containing nitrofurazone 0.2 percent in a water-soluble base of polyethylene glycols; Norwich Pharmacal Co., Division of Morton-Norwich Products, Inc., 13-27 Eaton Avenue, Norwich, NY 13815 (NDA 5-795).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An abbreviated new drug application is required from any person marketing such drug without approval.

Other dosage forms containing nitrofurazone and dosage forms containing furazolidone have also been reviewed in the drug efficacy study. The oral administration of nitrofurazone and furazolidone has been shown to induce mammary neoplasia in rats. Having considered the available information and the availability on the market of alternative effective drugs associated with less potential risk, the Commissioner has concluded that there is a lack of proof of safety of these nitrofurazone products. Accordingly there is published elsewhere in this issue of the FEDERAL REGISTER a notice proposing to withdraw approval of all other new drug applications for nitrofurazone-containing preparations.

However, the Commissioner has further concluded that nitrofurazone soluble dressing, because of a more favorable benefit-risk relationship, should remain on the market under the limited labeling conditions described below. In particular, this product has a fairly broad antimicrobial spectrum, and may be effective in important medical uses when there is bacterial resistance to other agents. Other products which would be substituted for it, if it were not available, are preferably reserved for specific, life-threatening infections.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that nitrofurazone in the form of a soluble dressing is effective for adjunctive therapy of patients with second- and third-degree burns when bacterial resistance to other agents is a real or potential problem. It is also effective for use in skin grafting where bacterial contamination may cause graft rejection and/or donor site infection, particularly in hospitals with historical resistant-bacteria epidemics.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Nitrofurazone soluble dressing preparations are in water-soluble ointment form suitable for topical administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal Law prohibits dispensing without prescription."

b. Each container of the drug, including any individually wrapped unit package, bears as part of the permanently affixed label information, prominently and conspicuously placed, and in legible type size, the following: (1) The statement, "For use only as adjunctive therapy of patients with second- and third-degree burns when bacterial resistance to other agents is a real or potential problem; or in skin grafting where bacterial contamination may cause graft rejection and/or donor site infection, particularly in hospitals with historical resistant-bacteria epidemics." and (2) a reference to the "Warnings" section of the full disclosure labeling that accompanies the package.

c. The drug is labeled to comply with all requirements of the Act and regulations promulgated thereunder and those parts of its labeling indicated below are substantially as follows: (Optional additional information, applicable to the drug, may be proposed under other appropriate paragraph headings and should follow the information set forth below.)

DESCRIPTION

Chemically (name of drug product) is nitrofurazone, 5-nitro-2-furaldehyde semicarbazone with the following structure: (To be supplied by manufacturer). (Additional descriptive information to be included by the manufacturer or distributor should be confined to an appropriate description of the physical and chemical properties of the drug and the formulation.)

ACTIONS

Nitrofurazone is a synthetic nitrofuran with a broad antibacterial spectrum. It is bactericidal against most bacteria commonly causing surface infections, including many that have become antibiotic resistant.

It acts by inhibiting enzymes necessary for carbohydrate metabolism in bacteria. This action occurs in both the aerobic and analrobic cycles of carbohydrate metabolism, explaining its bactericidal effect in aerobic, anaerobic, and facultative bacteria. Topically it is without appreciable toxicity to human cells.

INDICATIONS

Nitrofurazone is a topical antibacterial agent indicated for adjunctive therapy of patients with second and third-degree burns when bacterial resistance to other agents is a real or potential problem.

It is also indicated in skin grafting where bacterial contamination may cause graft rejection and/or donor site infection particularly in hospitals with historical resistant-bacteria epidemics.

There is no known evidence of effectiveness of this product in the treatment of minor burns or surface bacterial infections involving wounds, cutaneous ulcers or the varlous pyodermas.

CONTRAINDICATIONS

Known prior sensitization is a contraindication to the use of nitrofurazone.

WARNINGS

Nitrofurazone has been shown to produce mammary tumors when fed at high doses to female Sprague-Dawley rats. The relevance of this to topical use in humans is unknown.

USAGE IN PREGNANCY

Safe use of nitrofurazone during pregnancy has not been established. Therefore, the drug is not recommended for the treatment of women of child-bearing potential, unless the need for the therapeutic benefit of nitrofurazone is, in the attending physician's judgment, greater than the possible risk.

PRECAUTIONS

Use of topical antimicrobials occasionally allows overgrowth of nonsusceptible organisms including fungi. If this occurs or if irritation, sensitization or superinfection develop, treatment with nitrofurazone should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

Nitrofurazone has not been significantly toxic in man by topical application. In quantitative studies published in the period 1945-70, 206 instances of clinical skin reaction were reported out of 18,249 patients treated with nitrofurazone topical formulations, an overall incidence of 1.1 percent.

The treatment of nitrofurazone sensitization is not distinctive; general measures commonly used for a variety of sensitization reactions are adequate, except for the rare instance of severe contact dermatitis in

which steroid administration may be indicated.

DOSAGE AND ADMINISTRATION

BURNS. Apply directly to the lesion as with a spatula, or first place on gauze. Impregnated gauze may be used. Reapply once daily or once weekly, depending on the preferred dressing technique.

SKIN GRAFTS. The dressing is used both to prepare burns and other lesions for grafting, and postoperatively as a prophylactic measure. By rapid eradication of the infection, it can produce clean, firm granulation tissue. Because it is water-soluble and has negligible tissue toxicity, it does not interfere with successful takes. Flushing the gauze with sterile saline facilitates removal.

HOW SUPPLIED

(To be supplied by manufacturer.)

ANIMAL TOXICOLOGY

The oral administration of nitrofurazone for 7 days to rats at extremely high dosage levels of 240 mg/kg/day produced severe hepato-renal lesions whereas only renal changes were seen when the dosage level was reduced to 60 mg/kg/day for 60 days.

Dosage levels of 60 and 30 mg/kg/day shortened the time of appearance of the typical mammary gland tumor associated with older female rats. These tumors exhibited the same histological characteristics seen in the spontaneously occurring tumors and were seen only in the female animals. No mammary tumors were seen in rats treated with nitrofurazone orally for 1 year at levels of approximately 11 mg/kg/day. Spermatogenic arrest was noted in the male rats at dosage levels of 30 mg/kg/day and above.

Dogs treated orally with nitrofurazone for 400 days at levels of 11 mg/kg/day showed no toxic effects related to drug treatment. The single intravenous administration in dogs of 20, 35, or 75 mg/kg nitrofurazone produced clinical signs of lacrimation, salivation, emesis, diarrhea, excitation, weakness, ataxia and weight loss, whereas 100 mg/kg produced convulsions and death.

There was no evidence of toxicosis in rhesus monkeys treated with doses of nitrofurazone as high as 68 mg/kg/day for 10 weeks and 23 mg/kg/day for 63 weeks.

Finally, when 30 mg/kg of nitrofurazone was administered to pregnant rabbits once daily on days 7 through 15 of pregnancy there was a slight increase in the frequency of stillbirths, but no teratogenetic effects were seen.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER July 14, 1970 (35 FR 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and an abbreviated supplement for updating information as described in paragraphs (a)(1) (i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new drug application, the submission of an abbreviated new drug application as described in paragraph (a)(3)(i) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 5795, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Original abbreviated new drug applications: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-66), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application reviewed and are subject to this notice. See 21 CFR 130.40 (37 FR 23185, Oct. 31, 1972). For example, the Food and Drug Administration regards nitrofurazone in either soluble powder form or solution form intended for the conditions of use described herein to be subject to this notice. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355), and the Administrative Procedure Act (5 U.S.C. 554), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: March 22, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-5991 Filed 3-28-73;8:45 am]

[DESI 7358; Docket No. FDC-D-520; NDA 5-795 et al.]

NORWICH PHARMACAL CO.

Certain Nitrofuran Drugs; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

Notice is hereby given to Norwich Pharmacal Co., Division of Morton-Norwich Products, Inc., 13-27 Eaton Avenue, Norwich, NY 13815, and to any interested person who may be adversely affected, that the Commissioner of Food and Drugs proposes to issue an order under the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the following new drug applications, or pertinent parts thereof, and all amendments and supplements thereto held by the Norwich Pharmacal Co.:

NDA No.	*Drug Name*
NDA 5-795	That part of the application providing for Furacin (nitrofurazone) Vaginal Suppositories and Ear Solution.
NDA 7-358	Furacin (nitrofurazone with ephedrine) Nasal Drops.
NDA 11-065	Tricofuron (furazolidone and nifuroxime) Vaginal Powder and Suppositories.
NDA 11-270	Furoxone (furazolidone) Tablets.
NDA 11-323	Furoxone (furazolidone with kaolin and pectin) liquid.
NDA 12-403	Furacin (nitrofurazone and nifuroxime with diperodon hydrochloride) Otic Drops.

With the exception of Furacin Ear Solution, Nasal Drops, and Otic Drops, the above-listed drug products were reviewed by the National Academy of Sciences-National Research Council, Drug Efficacy Study Group and classified as less than effective.

It is proposed to withdraw approval of these new drug applications on the grounds that (1) new information with respect to the drugs, evaluated together with the evidence available at the time of approval of the applications, shows there is a lack of substantial evidence that the drugs will have all the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling; and (2) tests by methods not deemed reasonably applicable when such applications were approved, evaluated together with the evidence available when the applications were approved, show that such drugs containing either nitrofurazone or furazolidone for human use, are not shown to be safe for use under the conditions of use upon the basis of which the applications were approved. Specifically, the oral administration of nitrofurazone and of furazolidone has been shown to induce mammary neoplasia in rats. None of the nitrofurazone and furazolidone—containing drugs have been adequately tested for absorption in humans. Inadequate animal data exist on topical use. A serious question of safety regarding the use of nitrofurazone and furazolidone in humans is therefore raised. Other equally effective drugs having less potential risk are available. The subject drugs are not specific for use in life-threatening or other important medical uses. Accordingly, the Food and Drug Administration concludes that, because of the unfavorable benefit-to-risk ratio associated with use of these drug products, there is a lack of proof of safety.

DUPLICATE MAR 6 1980

NDA 86-766

Wendt Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrofurazone Ointment, 0.2%.

Reference is also made to your communication dated October 15, 1979 relating to thellabeling and control information.

We have completed the review of this abbreviated new drug application and have the following comments regarding the proposed labeling:

Revise container labels in accord with the Federal Register Statement of 3-29-73.

Please let us have your response promptly.

Sincerely yours,

for Marvin Seife, M.D. 3/6/80
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

MINN-DO DUP
JRCarr/JLMeyer/CChang o.c.c. 3-6-80
R/DinitJMeyer/MSeife 2-28-80
ft/cjl/3-3-80 rev w/f

JRCarr 3/5/80 JLMeyer 3/5/80

Minneapolis, Minn. 612-445-5272
Belle Plaine, Minn. 612-873-2288
Cable Address: WENDT, Mpls., USA

Drug

WENDT LABORATORIES

100 Nancy Drive
Belle Plaine, Mn. 56011

10100 Colorado Rd.
Minneapolis, Mn. 55437

A Family of Pharmaceutical Manufacturers,
Since 1927

May 16, 1980

NDA 86-766

RESUBMISSION
NDA DATA ASSIGNMENT
FPL

James Morrison
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

Pursuant to the enclosed letter dated March 6, 1980 concerning our abbreviated new drug application for Nitrofurazone Ointment, 0.2%, enclosed herewith are twelve (12) revised container labels in accord with the Federal Register Statement of 3-29-73.

I trust that this submission will enable you to act favorably for approval of the application.

Sincerely,

WENDT LABORATORIES, INC.

Gregory P. Bergt

Gregory P. Bergt
100 Nancy Drive
Belle Plaine, Minn. 56011

GPB/aq

Enclosures

RECEIVED
MAY 19 1980
GENERIC DRUGS

DUPLICATE

DEPARTMENT OF HEALTH EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

NDA 86-766

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Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

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Please let us have your response promptly.

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

NDA 86-766

Wendt Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

SEP 18 1980

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrofurazone Ointment, 0.2%.

Reference is also made to your communication dated May 16, 1980 relating to the labeling information.

We have completed the review of this abbreviated new drug application and have the following comments regarding the proposed labeling:

Package insert:

1. The package insert lacks chemical name and structural formula in the description section.

2. In animal toxicology 1st line last column should be 240 mg./kg./day instead of 210 mg./kg/day.

Other information required by 314.1(f) of the regulations:

Your status and contract facility (———————) are under review by our Division of Drug Manufacturing. We will correspond with you when this review becomes available.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

DUPLICATE

SEP 18 1980

NDA 86-766

Wendt Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

Gentlemen:

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Package insert:

1. The package insert lacks chemical name and structural formula in the description section.

2. In animal toxicology 1st line last column should be 240 mg./kg./day instead of 210 mg./kg/day.

Other information required by 314.1(f) of the regulations:

Your status and contract facility ([redacted]) are under review by our Division of Drug Manufacturing. We will correspond with you when this review becomes available.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife 9/18/80

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
MINN-DO

HFD-614
HFD-616
AStandard/JLMeyer/CBerg c-e 9-17-80
R/D init JLMeyer/MSeife/9/16/80
pb/9/16/80
rev w/f

JLMeyer 9/17/80

Minneapolis, Minn. 612-445-5272
Belle Plaine, Minn. 612-873-2288
Cable Address: WENDT, Mpls., USA

WENDT LABORATORIES

100 Nancy Drive
Belle Plaine, Mn. 56011

10100 Colorado Rd.
Minneapolis, Mn. 55437

A Family of Pharmaceutical Manufacturers,
Since 1927

December 2, 1980

NDA 86-766

Dr. Marvin Seife
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Seife:

In reply to your letter dated September 18, 1980 regarding our abbreviated new drug application for Nitrofurazone Ointment, 0.2%, I am enclosing twelve copies of the revised package insert per your comments for review. However, due to the fact that previous communications from your office did not request chemical and structural formula in the description section but rather requested final printed labeling as submitted (refer to attached letters dated July 17, 1979 and March 6, 1980), I would request that we be allowed to use the inserts as submitted previously until exhausted. We would of course use the enclosed inserts, if approvable, upon stock depletion.

Additionally, I trust our most recent inspection conducted on October 31 and November 3-6, 1980 will enable you to act favorably for approval of this application. In order to expedite any further questions that you might have, I am willing to meet with you or anyone else that would require further information.

Sincerely,

WENDT LABORATORIES, INC.

Gregory P. Bergt

Gregory P. Bergt
100 Nancy Drive
Belle Plaine, Minn. 56011

GPB/aq
Enclosures

JAN 22 1981

NDA 86-766

Wendt Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrofurazone Ointment, 0.2%.

Reference is also made to your communication dated December 2, 1980.

Our Division of Drug Manufacturing has made the following comments in regard to your compliance with CGMP regulations:

> An inspection of Wendt Labs on 7/16/80 to 8/1/80 revealed that this firm only manufactures veterinary drugs. Although the firm has submitted human drug ANDA's, the inspection revealed that the firm is not yet operational in the manufacture of human drugs. Therefore, no evaluation of the firm as to compliance with human drug CGMP's can be made at this time.

Therefore, before we can take further action on this abbreviatdd new drug application we should have a satisfactory inspection report. Your submission of December 2, 1980 will not be reviewed at this time.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 1/22/81

Marvin Seife, M.D.
Director
Division of Ganeric Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
DET-DO DUP HFD-614
JMeyer/CChang 1-21-80
r/d/ iit JMeyer/MSeife 1-21-81
f/t/wh/1-21-81 JMeyer 1/21/81
ack.

file

Minneapolis, Minn. 612-445-5272
Belle Plaine, Minn 612-873-2288
Cable Address: WENDT, Mpls., USA

WENDT LABORATORIES

100 Nancy Drive
Belle Plaine, MN 56011

10100 Colorado Rd.
Minneapolis, MN 55437

A Family of Pharmaceutical Manufacturers,
Since 1927

March 2, 1981

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: ANDA 86-766 (Nitrofurazone Ointment, 0.2%), Your letter dated 1/22/81

Dear Dr. Seife:

We have been advised by the Minneapolis District FDA office (Mr. Joseph R. Baca) that our plant is now in compliance with the Current Good Manufacturing Practices for Human and Veterinary Drugs. A letter to this effect is being sent to Rockville by the District Office.

Accordingly, we request your office be aware of these developments and act on this pending application at an early date. I would be pleased to meet with you and/or staff to discuss this in greater detail on March 19, 1981.

Please contact me at (612)-873-2288 if additional information is needed at this time.

Sincerely,

WENDT LABORATORIES, INC

Gregory P. Beret

Gregory P. Beret
100 Nancy Drive
Belle Plaine, MN 56011

RECEIVED
MAR 06 1981
GENERIC DRUGS

GPB/jas

Minneapolis, Minn. 612-445-5272
Belle Plaine, Minn. 612-873-2288
Cable Address: WENDT, Mpls., USA

WENDT LABORATORIES

100 Nancy Drive
Belle Plaine, Mn. 56011

10100 Colorado Rd.
Minneapolis, Mn. 55437

A Family of Pharmaceutical Manufacturers,
Since 1927

March 23, 1981

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: ANDA 86-766 (Nitrofurazone Ointment, 0.2%)

Dear Dr. Seife:

Please find enclosed a copy of the letter from the Minneapolis FDA office which regards the latest inspection at our facilities. As you review the letter you will note that the agency has determined Wendt Labs. to be in substantial compliance with CGMP's. Additionally, we wish to point out that there is not two separate CGMP regulations published for human and veterinary drug manufacturers. There is only one published CGMP for drug manufacturing and it applies to both human and veterinary drug products.

We believe that your letter of January 22, 1981 is in error with regard to "evaluation of the firm as to compliance with human drug CGMP's."

I would again offer to discuss any questions that you might still have regarding this application in your office at your earliest convenience. We are quite anxious to hear from you on this matter since it appears that this is only remaining question prior to approval.

Sincerely,

Wendt Laboratories, Inc.

Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

GPB/jas
Enclosure