CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-581

ADMINISTRATIVE DOCUMENTS

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: **ANDA 75581/000**
Stamp: **16-FEB-1999** Regulatory Due:
Applicant: **TEVA PHARMS**
1510 DELP DR
KULPSVILLE, PA 19443

Priority:
Org Code: **600**
Action Goal:
District Goal: **16-JAN-2000**
Brand Name:
Established Name: **KETOCONAZOLE**
Generic Name:
Dosage Form: **CRM (CREAM)**
Strength: **2%**

FDA Contacts: **J. BUCCINE (HFD-623) 301-827-5848 , Project Manager**
P. SCHWARTZ (HFD-629) 301-827-5848 , Team Leader

Overall Recommendation:

ACCEPTABLE on 30-MAR-1999 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment:
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities: **FINISHED DOSAGE OTHER - TESTER**

Establishment:
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities: **FINISHED DOSAGE OTHER TESTER**

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Establishment: ORATORIES INC
L 60062

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

F No:
DA No:

Profile: **OIN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **30-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment: **1826582**

DMF No: **12171**

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

ANDA APPROVAL SUMMARY

ANDA: 75-581

DRUG PRODUCT: Ketoconazole Cream 2%

FIRM: Teva Pharmaceuticals USA

DOSAGE FORM: Cream **STRENGTH:** 2%

CGMP: Statement/EIR Update Status:

EER is acceptable (OC recommendation, 3/30/99)

BIO: The bioequivalence study was found to be acceptable by the Division of Bioequivalence and Medical officer Dr. Mary Fanning. (reviewed by S Pradhan and Dr. Fanning, 1/27/00).

VALIDATION -(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

Method validation has been completed and found acceptable (7/26/99, Philadelphia District Laboratories in Philadelphia, PA.)

STABILITY: (Are containers used in study identical to those in container section?)

The containers used in the stability study are identical to those described in the container section.

LABELING:

Container, carton and insert labeling have been found satisfactory (Labeling approval summary 1/10/00, reviewed by L Golson)

STERILIZATION VALIDATION (IF APPLICABLE):

Not applicable

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):

The of the exhibit batch (bio batch) of the Ketoconazole Cream 2% (lot# RX0479-100) were manufactured. DMF Ketoconazole USP drug substance was found adequate (3/29/00, reviewed by Liang-Lii Huang, Ph.D.)

SIZE OF STABILITY BATCHES- (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):

The exhibit batch (lot# RX0479-100) was the stability batch.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:

The proposed production batch is of the Ketoconazole Cream 2%. The manufacturing process will be the same as was used for the exhibit batch.

CHEMIST: Liang-Lii Huang, Ph.D. **DATE:** March 29, 2000
SUPERVISOR: Paul Schwartz, Ph.D. **DATE:** March 29, 2000

3/29/00

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO (Division/Office): HFD-550, Dr Mary Fanning

FROM: OGD, Rx Support Branch (HFD-615)

E:	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
3/31/99	—	75-581	original application	Feb 12, 1999

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Ketoconazole Cream, 2%	medium	—	May 31, 1999

NAME OF FIRM: Teva

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY _____
- ☐ PRE NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICPENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER (specify below)

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER	☐ CHEMISTRY ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ PROTOCOL – BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ BIOAVAILABILITY STUDIES
- ☐ PHASE IV STUDIES

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSEMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS (Attach additional sheets if necessary): The firm has submitted an application for Ketoconazole Cream 2% with a multi-center, double-blind, three-way parallel design clinical study. Please review & comment.

Thanks,
Harvey

SIGNATURE OF REQUESTER: Harvey C. Manley — 827-5713

METHOD OF DELIVERY (Check one): ☐ MAIL ☐ HAND

SIGNATURE OF RECEIVER

SIGNATURE OF DELIVERER

APPROVAL SUMMARY

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-581 Date of Submission: September 20, 1999 (Amendment)

Applicant's Name: Teva Pharmaceuticals USA

Established Name: Ketoconazole Cream, 2%

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? Yes

Container Labels: (15 g, 30 g, and 60 g) - Satisfactory as of September 20, 1999 submission

Carton Labeling: (15 g, 30 g, and 60 g) – Satisfactory as of September 20, 1999 submission

Professional Package Insert Labeling: Satisfactory as of September 20, 1999 submission

Revisions needed post-approval:

DESCRIPTION – Your structural formula has an insufficient number of bonds. Please revise.

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Nizoral® Cream, 2%

NDA Number: 19-084

NDA Drug Name: Ketoconazole Cream, 2%

NDA Firm: Janssen Pharmaceutica Inc.

Date of Approval of NDA insert and supplement #019: April 16, 1996

Has this been verified by the MIS system for the NDA? Yes

Was this approval based upon an OGD labeling guidance? No

Basis of Approval for the Container Labels: Side-by-side comparison

Basis of Approval for the Carton Labeling: Side-by-side comparison

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book?		X	
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Insert for FTR? Immediate or individually cartoned? Light sensitive product which might require carton? Must the package insert accompany the product?		X	
Are there any other [illegible]		X	
Labeling			
Is the name of the [illegible] lacking in prominence? (Name should be the most prominent information [illegible]		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling(continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	

Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.			
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			
Bioequivalence Issues: (Compare bioequivalency values: Insert to study, List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues? FTR: Use the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

FOR THE RECORD:

1. **Labeling review based on the labeling for the RLD (Nizoral Cream, 2% - Janssen Pharmaceutica Inc.; revised July 1994; approved April 16, 1996).**

2. **This is the first generic for this drug product.**

3. Packaging
The RLD packages its product in 15 g, 30 g and 60 g tubes.

The applicant is proposing to package its product in 15 g, 30 g, and 60 g aluminum, blind ended tubes with white pointed or spiked closures.

4. Labeling
Firm has ensured that the established name and strength appear as the most prominent information.

5. Inactive Ingredients
There does not appear to be a discrepancy in inactives between the DESCRIPTION and the composition statement.

6. USP Issues
USP – This product is not the subject of a USP monograph
RLD – Store below 77°F (25°C).
ANDA – Same as RLD, but have reversed the order so that degrees Celsius appear first.

7. Bioequivalence Issues – Pending

8. Patent/Exclusivity Issues – Patent expired June 15, 1999.

Date of Review:
January 10, 2000

Date of Submission:
September 20, 1999 (Amendment)

Primary Reviewer:
[redacted]

Date:
1/10/2000

Secondary Reviewer:
[redacted]

Date:

Team Leader:
[redacted]

Date:
1/18/2000

cc

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-581 Date of Submission: February 12, 1999

Applicant's Name: Teva Pharmaceuticals USA

Established Name: Ketoconazole Cream, 2%

Labeling Deficiencies:

1. CONTAINER (15 g, 30 g, 60 g)

   a. Please ensure that the established name and strength appear as the most prominent information on the label.

   b. Revise the "Contains" statement to read, Each gram contains: ketoconazole 20 mg…sodium sulfite, anhydrous.

   c. Relocate "Rx only" to appear on the principal display panel.

   d. Reverse the storage temperature so that the degrees Celsius appear before Fahrenheit.

2. CARTON (15 g, 30 g, 60 g)

   See CONTAINER comments.

3. INSERT

   a. GENERAL COMMENT

      Throughout the text of your labeling, refer to the product by its established name "ketoconazole cream, 2%" rather than "ketoconazole 2% cream".

   b. DESCRIPTION

      i. Revise to read, …agent, ketoconazole 2%. Each gram, for topical administration, contains ketoconazole 20 mg and is formulated…sodium sulfite, anhydrous.

      ii. Include the molecular formula and molecular weight.

c. ADVERSE REACTIONS

Change "5.0%" to "5%" in the first sentence of the first paragraph.

d. HOW SUPPLIED

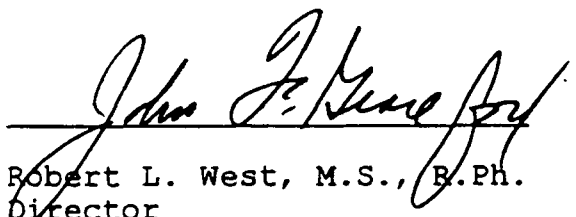
See CONTAINER comment (d).

Please revise your labels and labeling, as instructed above, and submit in final print.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following web site for any approved changes -

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.



Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-581 Date of Submission: February 12, 1999

Applicant's Name: Teva Pharmaceuticals USA

Established Name: Ketoconazole Cream, 2%

Labeling Deficiencies:

1. CONTAINER (15 g, 30 g, 60 g)

   a. Please ensure that the established name and strength appear as the most prominent information on the label.

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   c. Relocate "Rx only" to appear on the principal display panel.

   d. Reverse the storage temperature so that the degrees Celsius appear before Fahrenheit.

2. CARTON (15 g, 30 g, 60 g)

   See CONTAINER comments.

3. INSERT

   a. GENERAL COMMENT

      Throughout the text of your labeling, refer to the product by its established name "ketoconazole cream, 2%" rather than "ketoconazole 2% cream".

   b. DESCRIPTION

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      ii. Include the molecular formula and molecular weight.

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Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book?		X	
If not USP, has the product name been proposed in the PI?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).	X		
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling (continued)	Yes	No	N.A.
Does NLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.			
Scoring: Describe scoring configuration of NLD and applicant (page #) in the FTR			

Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FYR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FYR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?	-	X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FYR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

NOTES/QUESTIONS TO THE CHEMIST: None

FOR THE RECORD:

1. Labeling review based on the labeling for the RLD (Nizoral Cream, 2% - Janssen Pharmaceutica Inc.; revised July 1994; approved April 16, 1996).

2. This is the first generic for this drug product.

3. Packaging
   The RLD packages its product in 15 g, 30 g and 60 g tubes.

   The applicant is proposing to package its product in 15 g, 30 g, and 60 g aluminum, blind ended tubes with white pointed or spiked closures.

4. Labeling
Firm has been asked to ensure that the established name and strehgth appear as the most prominent information.

5. Inactive Ingredients
There does not appear to be a discrepancy in inactives between the DESCRIPTION and the composition statement.

6. USP Issues
USP - This product is not the subject of a USP monograph
RLD - Store below 77°F (25°C).
ANDA - Same as RLD, but have been asked to reverse the order so that degrees Celsius appear first.

7. Bioequivalence Issues - Pending

8. Patent/Exclusivity Issues - Patent expired June 15, 1999.

Date of Review:
July 27, 1999

Date of Submission:
February 12, 1999

Primary Reviewer:

Date:
7/27/99

Team Leader:

Date:
7/28/1999

cc:

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **ANDA 75581/000**
Stamp: **16-FEB-1999** Regulatory Due:
Applicant: **TEVA PHARMS**
1510 DELP DR
KULPSVILLE, PA 19443

Priority:
Action Goal:
Brand Name:
Established Name: **KETOCONAZOLE**
Generic Name:
Dosage Form: **CRM (CREAM)**
Strength: **2%**

Org Code: **600**
District Goal: **16-JAN-2000**

FDA Contacts: **J. BUCCINE (HFD-617) 301-827-5848 , Project Manager**
P. SCHWARTZ (HFD-629) 301-827-5848 , Team Leader

Overall Recommendation:

Establishment: **1**

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

F No:
DA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment: **1319349**

DMF No:

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

DMF No:
ESEAR AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

DMF No:
AADA No:

Profile: **OIN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment:

DMF No:

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date **16-MAR-1999**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**