CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-387

LABELING REVIEW(S)

REVIEW OF PROFESSIONAL LABELING - #1
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 76387

Date of Submission: March 28, 2002

Applicant's Name: Roxane Laboratories, Inc.

Established Name: Clotrimazole Lozenges, USP 10 mg

Labeling Deficiencies:

1. **GENERAL COMMENT**

   The established name for this product is "Clotrimazole Lozenges". Please revise your labels and labeling accordingly.

2. **CONTAINER** - 10 mg tablet (bottles of 70, 140, and 500)

   Refer to (1) general comment

3. **UNIT DOSE BLISTER CARTON** (7 x 10 unit dose tablets)

   - Revise the quantity statement "10x7 unit dose tablets" to read "7 x 10 unit dose tablets" (include spacing in between the "x"). Please note that the first number represents the number of strips and the second number represents the number of tablets.
   - Add the statement "For institutional use only".
   - Refer to (1) general comment

4. **BLISTER LABEL**

   Refer to (1) general comment

5. **INSERT**

   a. **GENERAL COMMENTS**

      i. Refer to (1) general comment

      ii. Please use the full establish name, "Clotrimazole Lozenges" in the following sections:

      - DESCRIPTION
      - INDICATION AND USAGE
      - CONTRAINDICATIONS
      - DOSAGE AND ADMINISTRATION
      - HOW SUPPLIED

b. HOW SUPPLIED

Please revise the description of the unit dose tablets to read "10 mg white tablets, 7 x 10 unit dose tablets" instead of " 10 mg white tablets, blister pack 10x7".

Please revise your labeling, as instructed above, and submit 12 final printed copies for approval.

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

website 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 the differences annotated and explained.

Wm Peter Rickman
Acting 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 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? 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 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.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
			X

Is the scoring configuration different than the RLD?			
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.		X	
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: 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.		X	

NOTES/QUESTIONS TO THE CHEMIST: NONE

FOR THE RECORD:

1. **MODEL LABELING**
   This review was based on the labeling for Mycelex by Bayer Corporation; NDA 18-713/S011; approved December 30, 1991.

2. **INACTIVE INGREDIENTS**
   There does not appear to be a discrepancy in inactives between the DESCRIPTION and the composition statement.
   [Vol. A1.3 page 516]

3. PATENTS/EXCLUSIVITIES

Patent Data – NDA 18-713

Patent No.	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
NONE	NONE	NONE	NONE	II	NONE

Exclusivity-Data – NDA 18-713

Code	Reference	Expiration	Labeling Impact
NONE	NONE	NONE	NONE

4. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON

- USP: Preserve in well-closed containers
- RLD: Stored below 86°F (30°C)
  Avoid freezing
- ANDA: Same as RLD.

5. DISPENSING STATEMENT COMPARISON

- USP: None.
- RLD: None.
- ANDA: None.

6. PACKAGE CONFIGURATION

- RLD: Packaged in bottles of 70 and 140 with CRC, and blister pack 7 X 10 unit dose tablets.
- ANDA: Packaged in HDPL bottles of 70, 140 with CRC and bottles of 500. In addition to blister pack 7 X 10 unit dose tablets. [Vol. A1.3 page 1253]

7. FINISHED DOSAGE FORM

- RLD:
  White discoid uncoated tablets supplied in bottles of 70 and 140 in addition to 7 X 10 unit dose tablets.
- ANDA:
  White, round, flat face beveled edge troche with product identification 54552 on one side and Plain on the other, supplied in bottles of 70, 140, 500 in addition to 7 X 10 unit dose tablets.
  [Vol. A1.3 page 1152]

8. MANUFACTURING FACILITY OF FINISHED DOSAGE FORM

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228
[Vol. A1.2 page 797]

Date of Review: **Date of Submission: February 28, 2002**

Primary Reviewer: Beverly Weitzman Beverly Weitzman **Date:** 10/21/02

Team Leader: **Date:** 10/22/2002

cc:
ANDA: 76-369
DUP/DIVISION FILE
HFD-613/Jgrace (no cc) .
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Review

APPROVAL SUMMARY

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

ANDA Number: 76-387

Date of Submission: November 15, 2002

Applicant's Name: Roxane Laboratories, Inc.

Established Name: Clotrimazole Lozenges, USP 10 mg

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: 10 mg tablet (bottles of 70, 140, and 500) - Satisfactory in FPL as of November 15, 2002 submission [Vol. 2.1; Code # 10001775/01 (70's); code # 10001773/01 (140's); code # 10001774/01(500's)]
- Unit Dose Blister Label: (7 x 10 unit dose tablets) - Satisfactory in FPL as of November 15, 2002 submission [Vol. 2.1; Code # 0054-8146-22]
- Unit Dose Blister Carton - (7 x 10 unit dose tablets) – Satisfactory in FPL as of November 15, 2002 submission [Vol. 2.1; Code # 10001790/01]
- Professional Package Insert Labeling: Satisfactory in FPL as of November 15, 2002 submission. [Vol. 2.1; code # 10001777/01; Revised November 2002]

BASIS OF APPROVAL:

- Was this approval based upon a petition? No
- What is the RLD on the 356(h) form: Mycelex Troche, 10mg
- NDA Number: 18-713
- NDA Drug Name: Clotrimazole Lozenges,10mg
- NDA Firm: Bayer Corporation
- Date of Approval of NDA Insert: December 30, 1991 /S011
- 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
- Revisions needed post-approval: No
- Patents/Exclusivities: Refer to chart below.

Patent Data – NDA 18-713

Patent No.	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
			There are no unexpired patents for this product in the Orange Book Database.		NONE

Exclusivity-Data – NDA 18-713

Code	Reference	Expiration	Labeling Impact
	There is no unexpired exclusivity for this product.		NONE

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? 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 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.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
			X

Is the scoring configuration different than the RLD?			
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.		X	
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: 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.		X	

NOTES/QUESTIONS TO THE CHEMIST: NONE

FOR THE RECORD:

1. **MODEL LABELING**
   This review was based on the labeling for Mycelex by Bayer Corporation; NDA 18-713/S011; Approved December 30, 1991; Revised 6/98.

2. **INACTIVE INGREDIENTS**
   There does not appear to be a discrepancy in inactives between the DESCRIPTION and the composition statement.
   [Vol. A1.3 page 516]

3. PATENTS/EXCLUSIVITIES

Patent Data – NDA 18-713

Patent No.	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
NONE	NONE	NONE	NONE	II	NONE

Exclusivity-Data – NDA 18-713

Code	Reference	Expiration	Labeling Impact
NONE	NONE	NONE	NONE

4. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON

- USP: Preserve in well-closed containers
- RLD: Stored below 86°F (30°C)
  Avoid freezing
- ANDA: Same as RLD.

5. DISPENSING STATEMENT COMPARISON

- USP: None.
- RLD: None.
- ANDA: None.

6. PACKAGE CONFIGURATION

- RLD: Packaged in bottles of 70 and 140 with CRC, and blister pack 7 X 10 unit dose tablets.
- ANDA: Packaged in HDPL bottles of 70, 140 with CRC and bottles of 500. In addition to blister pack 7 X 10 unit dose tablets.

7. FINISHED DOSAGE FORM

- RLD:
  White discoid uncoated tablets supplied in bottles of 70 and 140 in addition to 7 X 10 unit dose tablets.
- ANDA:
  White, round, flat face beveled edge troche with product identification 54552 on one side and Plain on the other, supplied in bottles of 70, 140, 500 in addition to 7 X 10 unit dose tablets.
  [Vol. A1.3 page 1152]

8. MANUFACTURING FACILITY OF FINISHED DOSAGE FORM

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228
[Vol. A1.2 page 797]

Date of Review: **Date of Submission:** November 15, 2002

Primary Reviewer: Beverly Weitzman **Date:** 11/25/02

Team Leader: John J. Grace **Date:** 11/26/2002

cc:

ANDA: 76-389
DUP/DIVISION FILE
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Review

APPROVAL SUMMARY #2

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH
Supercedes November 15, 2002 submission

ANDA Number: 76-387

Date of Submission: December 30, 2002

Applicant's Name: Roxane Laboratories, Inc.

Established Name: Clotrimazole Lozenges, USP 10 mg

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: 10 mg tablet (bottles of 70, 140, and 500) - Satisfactory in FPL as of November 15, 2002 submission [Vol. 2.1; Code # 10001775/01 (70's); code # 10001773/01 (140's); code # 10001774/01(500's)]
- Unit Dose Blister Label: (7 x 10 unit dose tablets) - Satisfactory in FPL as of November 15, 2002 submission [Vol. 2.1; Code # 0054-8146-22]
- Unit Dose Blister Carton - (7 x 10 unit dose tablets) – Satisfactory in FPL as of November 15, 2002 submission [Vol. 2.1; Code # 10001790/01]
- Professional Package Insert Labeling: Satisfactory in FPL as of December 30, 2002 submission. [Vol. 2.1;Revised December 2002; code # 10001777/02]

BASIS OF APPROVAL:

- Was this approval based upon a petition? No
- What is the RLD on the 356(h) form: Mycelex Troche, 10mg
- NDA Number: 18-713
- NDA Drug Name: Clotrimazole Lozenges,10mg
- NDA Firm: Bayer Corporation
- Date of Approval of NDA Insert: December 15, 2002 /S019
- 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
- Revisions needed post-approval: No
- Patents/Exclusivities: Refer to chart below.

Patent Data – NDA 18-713

Patent No.	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
			There are no unexpired patents for this product in the Orange Book Database.		NONE

Exclusivity-Data – NDA 18-713

Code	Reference	Expiration	Labeling Impact
	There is no unexpired exclusivity for this product.		NONE

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? 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 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.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
			X

Is the scoring configuration different than the RLD?			
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.		X	
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: 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.		X	

NOTES/QUESTIONS TO THE CHEMIST: NONE

FOR THE RECORD:

1. MODEL LABELING

This review was based on the labeling for Mycelex by Bayer Corporation; NDA 18-713/S019; Approved December 15, 2002. This supplement provides for a labeling revision to add a Geriatric Use subsection to the PRECAUTIONS section of the package insert.

2. INACTIVE INGREDIENTS

There does not appear to be a discrepancy in inactives between the DESCRIPTION and the composition statement.
[Vol. A1.3 page 516]

3. **PATENTS/EXCLUSIVITIES**

Patent Data – NDA 18-713

Patent No.	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
NONE	NONE	NONE	NONE	II	NONE

Exclusivity-Data – NDA 18-713

Code	Reference	Expiration	Labeling Impact
NONE	NONE	NONE	NONE

4. **STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON**
   - USP: Preserve in well-closed containers
   - RLD: Stored below 86°F (30°C)
     Avoid freezing
   - ANDA: Same as RLD.

5. **DISPENSING STATEMENT COMPARISON**
   - USP: None.
   - RLD: None.
   - ANDA: None.

6. **PACKAGE CONFIGURATION**
   - RLD: Packaged in bottles of 70 and 140 with CRC, and blister pack 7 X 10 unit dose tablets.
   - ANDA: Packaged in HDPL bottles of 70, 140 with CRC and bottles of 500. In addition to blister pack 7 X 10 unit dose tablets.

7. **FINISHED DOSAGE FORM**
   - RLD:
     White discoid uncoated tablets supplied in bottles of 70 and 140 in addition to 7 X 10 unit dose tablets.
   - ANDA:
     White, round, flat face beveled edge troche with product identification 54552 on one side and Plain on the other, supplied in bottles of 70, 140, 500 in addition to 7 X 10 unit dose tablets.
     [Vol. A1.3 page 1152]

8. **MANUFACTURING FACILITY OF FINISHED DOSAGE FORM**
   Roxane Laboratories, Inc.
   1809 Wilson Road
   Columbus, OH 43228
   [Vol. A1.2 page 797]

Date of Review: **Date of Submission: December 30, 2002**

Primary Reviewer: Beverly Weitzman **Date:**

Team Leader: John J. Gu **Date:** 1/10/2003

cc:

ANDA: 76-387
DUP/DIVISION FILE
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Review