CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 74-754

ADMINISTRATIVE DOCUMENTS

CDER Establishment Evaluation Report for July 21, 1997

Application: **ANDA 74754/000**
Stamp: **25-SEP-1995** Regulatory Due:
Applicant: **LEMMON**
650 CATHILL RD
SELLERSVILLE, PA 18960

Priority:
Org Code: **600**
Action Goal:
District Goal: **25-NOV-1996**
Brand Name:
Established Name: **KETOROLAC TROMETHAMINE**
Generic Name:
Dosage Form: **TAB (TABLET)**
Strength: **10 MG**

FDA Contacts:

Overall Recommendation:

ACCEPTABLE on 31-OCT-1996 by S. FERGUSON (HFD-324) 301-827-0062
ACCEPTABLE on 28-FEB-1997 by DOLESKI

Establishment:
IF No:
AADA No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment:
S INC
DMF No:
AADA No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment:
DMF No:
AADA No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment:
No:

AADA No:

INC

Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 19-SEP-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment:

DMF No:

AADA No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 28-FEB-1997**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment

DMF No:

AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 03-JUN-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON FILE REVIEW**

Responsibilities:
DRUG SUBSTANCE MANUFACTURER

Establishment

DMF No:

AADA No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDAT 06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment

MF No:

AADA No:

Profile: **NEC** OAI Status: **NONE**

Responsibilities:

Last Milestone: **OC RECOMMENDAT 06-FEB-1996** **FINISHED DOSAGE RELEASE TESTER**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment:

DMF No:

A / L

AADA No:

Profile: **TCM** OAI Status: **NONE** Responsibilities:
Last Milestone: **OC RECOMMENDAT 31-OCT-1996** **FINISHED DOSAGE MANUFACTURER**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

ANDA/AADA OFFICE LEVEL APPROVAL ROUTING SUMMARY

ANDA # 74-754
AADA #
Drug KETOROLAC TROMETHAMINE
Dosage Form TABLET
Strength 10mg
Applicant LEMMON COMPANY
Proposed Action AP TA

REVIEWER:	RECEIPT	ACTION
1. Project Manager Review Support Branch	Date 4/11/97 Initials	Date 4/11/97 Initials

Original Rec'd date SEPT. 21, 1995
Date Acceptable for Filing
Open Amendment Date(s) MAY 14, 1996 MARCH 14, 1997
Chemistry Reviewer J. SMITH
Supervisor V. SAVGOO
Bio Reviewer N. TRAN
Supervisor S. NERURKAR
Date of Office Level Bio Review 9/27/96
Pending Legal Case Yes ___ No ✓
Comments:

EER Status 2/28/97 OK
OAI Status Yes ___ No ✓
Patent Certification MAY 16 1997
Citizen Petition Yes ✓ No ___ If YES attach Email from Project Manager to Petition Coordinator of pending approval 97-033

2. Director of Chem. (I) or II Office of Generic Drugs	Date 4/11/97 Initials	Date 4/14/97 Initials

Comments:
Chem section is satisfactory based on the FIRST Generic APPROVAL AUDIT completed.

Office Level Chem Review (1st Generic Only) Div. Dir. of Chem I or II	Date 4/14/97 Initials	Date 4/19/97 Initials

Comments:
C/C Patent Exp: May 16, 1997

4. P. Rickman Supv., Reg. Support Branch	Date ? Initials	Date 5/13/97 Initials

Contains certification required by the GDEA if sub after 6/1/92
Yes ✓ No ___ //// Determination of involvement? Yes ___ No ✓
Paragraph 4 Certification ___ Yes ✓ No (checklist)
Comments:
Patent '969 (use patent for treatment of pain) expires 5/16/97 V-55
No exclusivity issues
Citizen petition issue needs resolution for full approval letter
* returned to Project manager

5. J. Phillips Director Division of LPS Office of Generic Drugs	Date 5/15/97 Initials	Date 5/16/97 Initials

Comments:
I think injectable only?
I = V TTT: 19 months
- Previous TA on 2/28/97 by Roger Williams; 1st Generic
- Approval - Patent Expires Today (5/16/97): Labeling is Satisfactory
- EER acceptable; C.P. covers the injectable.

Satisfactory for Approval.

6. G.Johnston
Deputy Director
Office of Generic Drugs
Patent Cert - P_4 - Yes___ No___
Petition status none
Pend. Legal Actions - Yes___ No___
Comments:

Date 5/16/97 Initials
Date 5/16/97 Initials
OK for approval

7. D. Sporn
Director
Office of Generic Drugs

Date 5/16/97 Initials
Date 5/16/97 Initials

R. Williams, MD
1st Generic _____
PD or clinical for BE _____
Special Scientific or Reg Issues ____
Comments:

8. Project Manager Tim Welsh

Date 5/16/97 Initials
Date 5/16/97 Initials

Company Notified
1000 Time notified of approval via telephone
1000 Time notified of approval via facismile

LETTER SIGNED: D. Sporn 5/16/97
(Name and Date)

(revision date 8-14-96) (X:\wpfile\welsh\rout2.rec)

CDER Establishment Evaluation Report
for April 09, 1997

Application: **ANDA 74754/000**
Stamp: **25-SEP-1995** Regulatory Due:
Applicant: **LEMMON**
650 CATHILL RD
SELLERSVILLE, PA 18960

Priority:
Action Goal:
Brand Name:
Established Name: **KETOROLAC TROMETHAMINE**
Generic Name:
Dosage Form: **TAB (TABLET)**
Strength: **10 MG**

Org Code: **600**
District Goal: **25-NOV-1996**

FDA Contacts:

Overall Recommendation:

ACCEPTABLE on 31-OCT-1996 by S. FERGUSON (HFD-324) 301-827-0062
ACCEPTABLE on 28-FEB-1997 by DOLESKI

Establishment:
DMF No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI** **06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment:
DMF No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI** **06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment: **2517175**
LEMMON CO SUB TAG PHARMACE
650 CATHILL RD
SELLERSVILLE, PA 18960
DMF No:

Profile: **TCM** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI** **31-OCT-1996**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities:
FINISHED DOSAGE MANUFACTURER

Establishment:
DMF No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI** **06-FEB-1996**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:
FINISHED DOSAGE RELEASE TESTER

Establishment: DMF No:
INC

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI 19-SEP-1996**
Responsibilities: Decision: **ACCEPTABLE**
FINISHED DOSAGE RELEASE TESTER Reason: **BASED ON PROFILE**

Establishment: DMF No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI 28-FEB-1997**
Responsibilities: Decision: **ACCEPTABLE**
FINISHED DOSAGE RELEASE TESTER Reason: **DISTRICT RECOMMENDATION**

Establishment:

NEC OAI Status: **NONE**
tone: OC RECOMMENDATI 06-FEB-1996
Responsibilities: Decision: **ACCEPTABLE**
FINISHED DOSAGE RELEASE TESTER Reason: **BASED ON PROFILE**

Establishment: No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATI 06-FEB-1996**
Responsibilities: Decision: **ACCEPTABLE**
FINISHED DOSAGE RELEASE TESTER Reason: **BASED ON PROFILE**

Establishment: F No:

ofile: CSN OAI Status: **NONE**
st Milestone: OC RECOMMENDATI 03-JUN-1996
Responsibilities: **Decision: ACCEPTABLE**
DRUG SUBSTANCE MANUFACTURER Reason: **BASED ON FILE REVIEW**

ANDA APPROVAL SUMMARY

ANDA: 74-754 DRUG PRODUCT: Ketorolac Tromethamine Tablets USP, 10 mg

FIRM: Lemmon DOSAGE FORM: Tablet STRENGTH: 10 mg

CGMP STATEMENT/EIR UPDATE STATUS:

CGMP statement on p. 1679. EER OK as of 02/28/97.

BIO STUDY: Acceptable 9/27/96.

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

USP drug product (methods validation not required). Description of dosage form is same as innovator's.

STABILITY - (ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?):

The container closure systems used in stability testing were identical to those described in the CONTAINER section.

LABELING: Acceptable 7/19/96

STERILIZATION VALIDATION (IF APPLICABLE): N/A

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.?):

units (lot RX 0293-117); firm's source of drug substance (Syntex Ireland) is OK.

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

bio batch = stability batch

PROPOSED PRODUCTION BATCH - (MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?):

units; same process as bio/stability

CHEMIST: J. L. Smith DATE: 4/8/97

TEAM LEADER: V. Sayeed DATE:

Department of Health and Human Services
Public Health Service
Food and Drug Administration
ESTABLISHMENT EVALUATION REPORT
for February 28, 1997

Requestor's Name: **Phone:**

pplication: ANDA 74754 **Brand Name:**
Established Name: KETOROLAC TROMETHAMINE
Sponsor: LEMMON **Strength:** 10 MG **Org Code:** **Dosage Form:**
Office:
Street: 650 CATHILL RD
City / State: SELLERSVILLE, PA 18960 **District Goal:** 25-NOV-96
Action Goal: **User Fee Goal:**

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTE		NEC	AC	28-FEB-97

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	06-FEB-96

Establishment: **Name:** .ES

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	06-FEB-96

Establishment: **Name:**

Responsibilities	if No	Profile	Status	Date
DRUG SUBSTANCE MANUFACTURER		CCS	AC	03-JUN-96

CSO	Date	Recommendation
DOLESKI	28-FEB-97	ACCEPTABLE

Department of Health and Human Services
Public Health Service
Food and Drug Administration
ESTABLISHMENT EVALUATION REPORT
for February 28, 1997

CSO	Date	Recommendation
FERGUSONS	31-OCT-96	ACCEPTABLE

Department of Health and Human Services
Public Health Service
Food and Drug Administration
ESTABLISHMENT EVALUATION REPORT
for February 28, 1997

Requestor's Name: **Phone:**

pplication: ANDA 74754 **Brand Name:**
Established Name: KETOROLAC TROMETHAMINE
Sponsor: LEMMON **Strength:** 10 MG **Org Code:** [illegible] **Dosage Form:** [illegible]
Office:
Street: 650 CATHILL RD
City / State: SELLERSVILLE, PA 18960 **District Goal:** 25-NOV-96
Action Goal: **User Fee Goal:**

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		[illegible]	PN	05-NOV-96

Establishment **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	06-FEB-96

Establishment **me:** LABORATORIES

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	06-FEB-96

Establishmen: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
DRUG SUBSTANCE MANUFACTURER		CCS	AC	03-JUN-96

CSO	Date	Recommendation
FERGUSONS	31-OCT-96	ACCEPTABLE

Department of Health and Human Services
Public Health Service
Food and Drug Administration
ESTABLISHMENT EVALUATION REPORT
for February 28, 1997

Requestor's Name: **Division:** **Phone:**

pplication: ANDA 74754 **Brand Name:**
Established Name: KETOROLAC TROMETHAMINE
Strength: 10 MG **Dosage Form:** TAB

Sponsor: LEMMON **Org Code:** 600 **Priority:**
Office:
Street: 650 CATHILL RD
City / State: SELLERSVILLE, PA 18960 **District Goal:** 25-NOV-96
Action Goal: **User Fee Goal:**

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	06-FEB-96

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER			AC	06-FEB-96

Establishment: **Name:** \L INC

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE MANUFACTURER			AC	31-OCT-96

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	06-FEB-96

Establishment: **Name:**

Responsibilities	Dmf No	Profile	Status	Date
FINISHED DOSAGE RELEASE TESTER		NEC	AC	19-SEP-96

E L E C T R O N I C M A I L M E S S A G E

Date: 25-Feb-1997 09:33am EST
From: John Podsadowski
JPODSADO@FDAEM@SSWMBX@FDAOC
Dept:
Tel No:

TO: LYNCHM@A1@FDACD

Subject: Oneida Labs (BUF) 74-754 Lemmon Ketorolac

Forwarded to: SSWGATE@FDA-SSW@Servers[FDACD.LYNCHM]
cc: Russ Davis@BUF.DOMESTIC@FDAORANER
Joseph Vannelli@BUF.DOMESTIC@FDAORANER
Comments by: John Podsadowski@BUF.DOMESTIC@FDAORANER
Comments:

Mark:

inspection should have started Mon. 2/24/97. As soon as I receive results of this inspection, I'll send you the BUF-DO recommendation.

********JAP

---------- [Original Message] ----------
I told Bob West we might be in a position to give OGD a verbal OK if we could talk to the investigator or their superior or J. Podsadowski at the completion of this inspectional coverage as the end of the month approaches.

John, try to advise us when you know the results of that inspection. Their involvment was limited to x-ray diffraction of bulk drug substance periodically?

E L E C T R O N I C M A I L M E S S A G E ....

Date: 18-Feb-1997 03:02pm EST
From: Robert West
WESTR
Dept: HFD-611 MPN2 273
Tel No: 301-594-1837 FAX 301-594-0183

TO: Mark Lynch (LYNCHM)

CC: Joseph David Doleski (DOLESKI)
CC: James Wilson (WILSONJ)
CC: Vilayat Sayeed (SAYEEDV)
CC: Kassandra Sherrod (SHERRODK)

Subject: ANDA 74-754 for Lemmon's Ketorolac Tromethamine Tablets

Mark:

We have received an acceptable recommendation in the EES for ANDA 74-754 for Lemmon's Ketorolac Tromethamine Tablets. It's dated 10/31/96.

Since then, Lemmon has amended the application to provide for as a contract facility to form X-ray diffraction testing on the active ingredient. The establishment number is

Last summer, we had an acceptable EER for this facility and approved ANDA 73-524/S-003 and ANDA 70-541/S-022 which utilized this facility for the same purpose.

Unfortunately, we have been informed that the normal 2-year inspectional cycle has been exceeded, and the facility is in need of a routine CGMP inspection.

ANDA is otherwise ready for tentative approval. Previously, in similar circumstances, we would NOT withhold approval of an application if the contract testing facility had exceeded its normal inspection cycle, but was acceptable at the time it became overdue for inspection. Can we follow the same procedure in this situation.

Thanks in advance for your input,

Bob

E L E C T R O N I C M A I L M E S S A G E

Sensitivity: COMPANY CONFIDENTIAL

Date: 25-Feb-1997 12:37pm EST
From: Mark Lynch
LYNCHM
Dept: HFD-324 MPN1 265
Tel No: 301-827-0062 FAX 301-827-0145

Subject: FWD: Oneida Labs (BUF) 74-754 Lemmon Ketorolac

FYI it's OK to approve verbally if you get a clear signal from John in order to make end of month cut-off.

E L E C T R O N I C M A I L M E S S A G E ----

Date: 19-Feb-1997 10:53am EST
From: Joseph David Doleski
DOLESKI
Dept: HFD-324 MPN1 265
Tel No: 301-827-0062 FAX 301-827-0145

TO: Robert West (WESTR)

Subject: FWD: ANDA 74-754 for Lemmon's Ketorolac Tromethamine Tablets

Bob,

Regarding Oneida Labs, the inspection will begin Monday.

Dave

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

J

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE *(Check One)*	DATE	PHONE NO.	EER ID #
Original ☐ FollowUp ☐ FUR	January 24, 1996	594-0310	9485

REQUESTORS NAME: John Smith	DIVISION: Office of Generic Drugs	MAIL CODE: HFD-623
APPLICATION AND SUPPLEMENT NUMBER: ANDA 74-754		
BRAND NAME: Toradol	ESTABLISHED NAME: Ketorolac Tromethamine Tablets	
DOSAGE STRENGTH: 10 mg		STERILE ☐Yes ☒ No
PROFILE CLASS:: TCM	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*	
APPLICANT'S NAME: Lemmon Company		
APPLICANT'S ADDRESS: 650 Cathill Road Sellersville PA 18960		
COMMENTS :	Top 200	

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY-	
1.	Manufacturer of NDS	CCS	SYLC 23192	AC	2/10/95
2. Lemmon Company 650 Cathill Road Sellersville, PA 18960	Manufacture, processing, packaging labeling, handling of the finished drug product	TCM	LEPS 23193	AC	10/4/96 10/26/94
3.	Testing lab	NEC	NLNJ 23194	AC	4/24/95
4.	Testing lab	NEC	SOAS 23195	AC	11/23/92
5.	Testing lab	NEC	LALL 23196	AC	11/26/95
6. abs, Inc.	Testing lab	NEC	SOTW 23197	AC	9/29/93
7. nc.	Testing lab	NEC	ARDO 23198	AC	1/29/95
8. s, Inc.	Testing lab	NEC	NALC 23199	AC	8/10/93

FOR HFD-324 USE ONLY:	CSO	DATE RECEIVED
	CGMP COMPLIANCE STATUS: Acceptable	DATE

1/25/96
10/31/96

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: ANDA 74-754 HFD-/Div File, HFD-617/JWilson, HFD-617/TAmes, HFD-/JSimmons HFD-/GJSmith x:\wpfile\eerforms\74754

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE *(Check One)*	DATE	PHONE NO.	EER ID #
☐ Original ☒ FollowUp ☐ FUR	October 31, 1996	594-0310	

REQUESTORS NAME: John Smith	DIVISION: Office of Generic Drugs	MAIL CODE: HFD-623

APPLICATION AND SUPPLEMENT NUMBER: ANDA 74-754

BRAND NAME: Toradol	ESTABLISHED NAME: Ketorolac Tromethamine Tablets

DOSAGE STRENGTH: 10 mg	STERILE ☐Yes ☒ No

PROFILE CLASS:: TCM	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*

APPLICANT'S NAME: Lemmon Company

APPLICANT'S ADDRESS: 650 Cathill Road
Sellersville PA 18960

COMMENTS : see new item #9

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD 324 USE ONLY
1.	Manufacturer of NDS	3240		
		CCS		
2. Lemmon Company 650 Cathill Road Sellersville, PA 18960	Manufacture, etc. of the finished drug product			
c.	Testing lab			
		NEC		
4.	Testing lab			
		NEC		
5.	Testing lab			
		NEC		
6. abs, Inc.	Testing lab			
		NEC		
7. c.	Testing lab			
		NEC		
8. , Inc.	Testing lab			
		NEC		
9. INC.	Testing Lab			
		NEC		

HFD-324 USE ONLY:	DATE RECEIVED
CGMP COMPLIANCE STATUS	DATE

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: ANDA 74-754 HFD-/Div File, HFD-617/JWilson, HFD-617/TAmes, HFD-/JSimmons HFD-/GJSmith
X:\NEW\FIRMSAM\LEMMON\EER\74754.3

ANDA/AADA OFFICE LEVEL APPROVAL ROUTING SUMMARY

ANDA # 74-754
AADA #
ug Cefaclor AC Trimethoprim Tablets, USP
sage Form Tablets
Strength 10 mg
Applicant Lemmon Company
Proposed Action AP TA

REVIEWER:	RECEIPT	ACTION
1. Project Manager Review Support Branch	Date ____ Initials ____	Date 10/30/96 Sent for Review Initials ____

Original Rec'd date September 25, 1995
Date Acceptable for Filing ~~November 25, 1995~~ 10-25-96
Open Amendment Date(s) 10/28/96, 9/30/96
Chemistry Reviewer J. Smith
Supervisor V. Sayeed
Bio Reviewer N. Trehan
Supervisor S. Nazzal
Date of Office Level Bio Review 10/28/96 (R. Williams)
Pending Legal Case Yes ____ No (X)
Comments:
Tentative Approval; First Generic

EER Status Pending
OAI Status Yes ____ No ____
Patent Certification P III Expires 5/10/97
Citizen Petition Yes ____ No (X) If YES attach Email from Project Manager to Petition Coordinator of pending approval

2. Director of Chem I or II
Office of Generic Drugs
Comments:

Date 12/6
Initials 12/6

Date 12/6
Initials 12/6

3. Office Level Chem Review
(1st Generic Only)
Div. Dir. of Chem I or II
Comments: First Generic CMC specification satisfactory

Date ____
Initials ____

Date 1/31/97
Initials for R. Reed

4. P. Rickman
Supv., Reg. Support Branch

Date 2/4/97
Initials

Date 2/10/97
Initials

Contains certification required by the GDEA if sub after 6/1/92
Yes ✓ No ____ //// Determination of involvement? Yes ____ No ✓
Paragraph 4 Certification ____ Yes ✓ No
Comments:
Applicant has made a P III patent cert. for # 4089969 (use patent) which expires 5/10/97. Applicant will not market product until patent has expired. No Exclusivity

5. J. Phillips
Director Division of LPS
Office of Generic Drugs
Comments:

Date 2/27/97
Initials FP

Date 2/27/97
Initials FP

TTTA: 17 months:

EER - Acceptable per S. Ferguson on 10/31/96; Overall EES also acceptable - however an amendment for a new contract facility has been added & is now pending (11/5/96); Office Level (K. Chan) OK per 2/27/96 & R. Williams on 10/28/96); No C.P or Legal Cases; 1st Generic CMC audit complete; P III certification; Labeling Satisfactory

Satisfactory, pending EER EER Acceptable (EES) 2/28/97 Reed

6. G.Johnston
Deputy Director
Office of Generic Drugs
Patent Cert - P_4 - Yes___ No___
Petition status _____
Pend. Legal Actions - Yes___ No___
Comments:

Date_____ Initials_____ Date_____ Initials_____

7. ~~D. Sporn~~
Director
Office of Generic Drugs

R. Williams, MD
1st Generic Yes.
PD or clinical for BE _____
Special Scientific or Reg Issues_____
Comments:

Date_____ Initials_____ Date_____ Initials_____

8. Project Manager J. Wilson for

Date 2-28-97 Initials [illegible] Date 2/28/97 Initials [illegible]

Company Notified
12:50 Time notified of approval via telephone
12:55 Time notified of approval via facsimile

LETTER SIGNED: [signature] 2/28/97
(Name and Date)

(revision date 8-14-96) (X:\wpfile\welsh\rout2.rec)

December 13, 1996 (RMP) for ANDA 74-754, Ketorolac Tromethamine Tablets, USP 10mg.

RMP called Phillip Erickson of Lemmon company at 215-256-8400 and asked PE why there is not blend uniformity specification in the production scale batch record (item 11, page 6/12 of the 6/19/1996 amendment). PE said, it is on page 1882. RMP thanked him and terminated the conversation.

Rashmi

APPROVAL SUMMARY

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

Date of Review: July 19, 1996

ANDA Number: 74-754 Review Cycle: #2

Date of Submission: June 19, 1996

Applicant's Name [as seen on 356(h)]: Lemmon Company

Manufacturer's Name (If different than applicant):

Proprietary Name: None

Established Name: Ketorolac Tromethamine Tablets USP, 10 mg

Reviewer: C. Park

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

A. Do you have 12 Final Printed Labels and Labeling? Yes

CONTAINER LABELS (100's, 500's and 1000's)

Satisfactory in final print as of 6/19/96

PROFESSIONAL PACKAGE INSERT LABELING:

Satisfactory in final print as of 6/19/96

B. REVISIONS NEEDED POST-APPROVAL:

We encourage you to include the NDC numbers for each package size in the HOW SUPPLIED section at next printing or revision.

C. BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Toradol® Tablets

NDA Number: 19-645

NDA Drug Name: Toradol® Tablets

NDA Firm: Syntex Labs.

Date of Approval of NDA Insert and supplement #: December 7, 1994/SLR-004

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: CFR, USP AND Side-by-side comparison

Other Comments:

REVIEW OF PROFESSIONAL LABELING CHECKLIST

Applicant's 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. [SUPP.1]	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?			
Error Prevention Analysis			
PROPRIETARY NAME			
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?			
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?			
PACKAGING -See applicant's packaging configuration in FTR			
Is this a new packaging configuration, never been approved by an ANDA or NDA for this drug product? 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	
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 (p. #) 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 p. # 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? [see FTR]	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. [See FTR]	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.			

NOTES/QUESTIONS TO THE CHEMIST:

FOR THE RECORD:

1. MODEL:

   Toradol injection/oral by Syntex [NDA 19645/19698]; approved 12/7/94

2. PACKAGING:

   RLD - 100's & unit dose 100's
   ANDA- 100's, 500's & 1000's

3. SCORING:

   RLD - unscored
   ANDA- unscored

4. INACTIVES:

   The inactive ingredients listed in the DESCRIPTION section are consistent with the firm's composition statement [Vol. 1.6, p.1565].

5. USP ISSUE (USP description and solubility)

   Neither the RLD nor the ANDA list the USP description and solubility information. We did not request the ANDA to include this information in their DESCRIPTION section. [Copied from FTR in the previous review]

6. STORAGE recommendations:

   USP- Preserve in well-closed containers at controlled room temperature, protected from light and excessive humidity.

RLD- Store bottles at controlled room temperature, 15° to 30° C(59° to 86°F). Protect from excessive humidity and light.

ANDA- Store at controlled room temperature, 15°-30°C (59°-86°F).

In the last chemistry/labeling letter we have asked the firm to change the storage statement to read "Store at controlled room temperature 20 - 25º C according to the USP recommendation. However, during the tele-conference of April 17, 1996 between Andy Shapiro, Manager, Professional Affairs and Jerry Phillips, then Acting Director of Labeling and Program Support, Jerry Phillips stated that the requested temperature range (20 - 25º C) was part of a proposed guideline and not a requirement, therefore, the temperature range the firm originally proposed (15 - 30º C) is acceptable. The firm decided to maintain the originally proposed storage statement (15 - 30º C) on the container label and in the package insert labeling.

7. DISPENSING RECOMMENDATIONS:

USP- none
RLD- Insert: none
Container: none [However, they have the statement, PACKAGE NOT CHILD RESISTANT printed on the front panel of their container label of 100's **non**-unit dose].
ANDA- Insert: Dispense contents in a tight, light-resistant container, as defined in the USP, with a child-resistant closure (as required).
Container: Dispense contents in a tight, light-resistant container, as defined in the USP, with a child-resistant closure (as required).

8. PATENT AND EXCLUSIVITY:

Toradol by Syntex: -Patent expires 7/4/98 (U.S.Patent No. 4089969).
The Lemmon company certified in the correspondence dated June 19, 1996 that the firm will not engage in the commercial manufacture, use, or sale of the drug product until the expiration of U.S. Patent No. 4089969.

9. Table 3 under CLINICAL PHARMACOLOGY section provides information pertaining "Incidence of clinically serious G.I. bleeding as related to age, total daily dose, and history of G.I. perforation, ulcer, bleeding (PUB) after up to 5 days of treatment with Ketorolac Tromethamine-IV/IM." Even though this information is not directly related to the Ketorolac **Tromethamine Tablets**, it appears to be very important information to the consumers, particularly to those who have a history of PUB. Hence, we (Charlie Hoppes and Chan Park) decided not to ask the firm to delete this Table 3 from the package insert.
[Note: We did not ask the firm to delete this from the package insert in the previous review.]

/S/ 7/23/96

Chan Park Date
Primary Reviewer

/S/ 7/23/96

Date
Acting Team Leader
Labeling Review Branch

cc:

.1

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

Date of Review: February 27, 1996

Date of Submission: September 21, 1995

Primary Reviewer: Jacqueline White, Pharm.D.

ANDA Number: 74-754 **Review Cycle: 1st[Draft]**

Applicant's Name [as seen on 356(h)]: Lemmon Company

Manufacturer's Name (If different than applicant):

Established Name: Ketorolac Tromethamine Tablets, USP

LABELING DEFICIENCIES, WHICH ARE TO BE INCORPORATED WITH THE CHEMISTRY COMMENTS TO THE FIRM:

[NOTE: These deficiencies can be located on the x-drive as detailed in notes from Ted Sherwood regarding the New X-Drive]

A. CHEMISTRY DEFICIENCIES

B. LABELING DEFICIENCIES

1. CONTAINER: 10 mg - 100's, 500's and 1000's

Revise the storage statement to read as follows:

Store at controlled room temperature
20-25°C(68-77°F)
[See USP]

2. INSERT

a. GENERAL COMMENTS

i. When referring to micrograms use the abbreviation "mcg" instead of "μg".

ii. Delete USP following the established name, except in the TITLE, DESCRIPTION and HOW SUPPLIED sections.

iii. Delete terminal zeros following decimal points.

b. Boxed WARNING

i. Delete the subsection, INTRATHECAL OR EPIDURAL ADMINISTRATION

ii. LABOR, DELIVERY AND NURSING

Revise the first sentence to read:

> The use of ketorolac tromethamine in labor and delivery is CONTRAINDICATED because ...

c. DESCRIPTION

Revise the first sentence of the second paragraph to read:

> Ketorolac tromethamine is a racemic ...

d. INDICATIONS AND USAGE

Delete the second paragraph.

e. CONTRAINDICATIONS

Delete the following sentence:

> Ketorolac tromethamine IV/IM is CONTRAINDICATED for neuraxial (epidural or

intrathecal) administration due to its alcohol content.

f. PRECAUTIONS

i. Drug Interactions

A) Change the proprietary names of the antiepileptic and psychoactive drugs to their corresponding established names.

B) Delete the penultimate paragraph.

ii. Use in the Elderly (≥ 65 years of age)

Revise this subsection to read:

... the elderly with ketorolac tromethamine. The incidences and severity of ...

g. ADVERSE REACTIONS (The adverse reactions listed below were reported in clinical trials as probably related to ketorolac tromethamine).

Incidence Greater Than 1%

Delete the last sentence: ~~X~~Injection-site pain was reported by 2% of patients in multi-dose studies.

h. DOSAGE AND ADMINISTRATION

Delete the subsection heading "Ketorolac Tromethamine-IV/IM" and revise to read:

Ketorolac Tromethamine-IV/IM may ... exceed 5 days.

Ketorolac Tromethamine Tablets are indicated ONLY ...

~~[Delete paragraphs two through seven, "When administering ...from solution"]~~.

i. HOW SUPPLIED

i. Please indicate that your tablet is unscored.

ii. Please refer to our comment under CONTAINER.

Please revise your labels and labeling, as instructed above, and submit in final print. Please note that we reserve the right to request further changes in your labels and labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

NOTE TO THE CHEMIST:

Note the patent and exclusivity status for the referenced listed drug, Toradol by Syntex has been revised. [See Supplement 11 of the Approved Drug Products with therapeutic equivalence evaluations 15th edition]. Please ask the firm to update their patent and exclusivity certification statements accordingly.

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

Do you have 12 Final Printed Labels and Labeling? Yes No
If no, list why:

Container Labels:

Carton Labeling:

Unit Dose Blister Label:

Unit Dose Carton Label:

Professional Package Insert Labeling:

Patient Package Insert Labeling:

Auxiliary Labeling:

Revisions needed post-approval:

BASIS OF APPROVAL:

Was this approval based upon a petition? Yes No

What is the RLD on the 356(h) form:

NDA Number:

NDA Drug Name:

NDA Firm:

Date of Approval of NDA Insert and supplement #:

Has this been verified by the MIS system for the NDA?
Yes No

Was this approval based upon an OGD labeling guidance?
Yes No

If yes, give date of labeling guidance:

Basis of Approval for the Container Labels:

Basis of Approval for the Carton Labeling:

Other Comments:

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Applicant's 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. SUPP.1	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			
PROPRIETARY NAME			
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 -See applicant's packaging configuration in FTR			
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.			
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	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	
Error Prevention Analysis: *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? [See comment under Container]			
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			
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? [See FTR].			

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 bioeqivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable) [pending]			
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.			

FOR THE RECORD:

1. MODEL:

   a. Insert - Toradol injection/oral by Syntex [NDA 19645/19698]; approved 12/7/94
   b. Container - Toradol by Snytex; approved 4/24/92

2. PACKAGING:

   RLD - 100's & unit dose 100's
   ANDA- 100's, 500's & 1000's

3. SCORING:

   RLD - unscored
   ANDA- See comment under INSERT (HOW SUPPLIED). [No score was indicated in description of the finished dosage form. Vol. 1.6,p.1975].

4. INACTIVES:

   The inactive ingredients listed in the DESCRIPTION section are consistent with the firm's composition statement [Vol. 1.6, p.1565].

5. USP ISSUE:

   Neither the RLD nor the ANDA list the USP description and solubility information. We will **not** request the ANDA to include this information in their DESCRIPTION section.

6. STORAGE recommendations:

USP- Preserve in well-closed containers at controlled room temperature, protected from light and excessive humidity.

RLD- Store bottles at controlled room temperature, 15°to30°C(59°to86°F). Protect from excessive humidity and light.
[See comment under CONTAINER & insert (HOW SUPPLIED)].

ANDA- Store at controlled room temperature, 15°-30°C(59°-86°F).

7. DISPENSING RECOMMENDATIONS:

USP- none

RLD- Insert: none
Container: none [However, they have the statement, PACKAGE NOT CHILD RESISTANT printed on the front panel of their container label of 100's **non**-unit dose].

ANDA- Insert: Dispense contents in a tight, light-resistant container, as defined in the USP, with a child-resistant closure (as required).
Container: Dispense contents in a tight, light-resistant container, as defined in the USP, with a child-resistant closure (as required).

8. PATENT AND EXCLUSIVITY:

Toradol by Syntex: -Patent expires 7/4/98 [note, was previously scheduled to expire on 5/16/97]
-Exclusivity expires 12/7/97 for Treatment of pain (U-55) & New route (NR)
[See NOTE TO THE CHEMIST]

Primary Reviewer _____ Date 3-21-96

Team Leader, Labeling Review Branch Date 3/25/96

cc:

3/25/96
4nal.1

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

LEMMON
650 CATHILL RD
[illegible]ERSVILLE PA 18960

ANDA #: N074754

Dear Sir/Madam:

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

NAME OF DRUG:
KETOROLAC TROMETHAMINE USP
Dosage Form: TAB Potency: 10 MG USP: Y

DATE OF APPLICATION: 21-SEP-95

DATE OF RECEIPT: 25-SEP-95

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

However, in the interim, please submit three additional copies of the analytical methods and descriptive information needed to perform the tests on the samples (both the bulk active ingredient(s) and finished dosage form) and validate the analytical methods. Please do not send samples unless specifically requested to do so. If samples are required for validation, we will inform you where to send them in a separate communication.

If the above methodology is not submitted, the review of the application will be delayed.

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

Sincerely yours,

Richard Rondorf
HFD-623

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research