CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89884

CHEMISTRY REVIEW(S)

JUL 7 1997

38. Chemistry Comments to be Provided to the Applicant

ANDA: 89-884, 89-885, 89-886

APPLICANT: Hercon Laboratories, Corporation.

DRUG PRODUCT: Nitroglycerin Transderml Patch, 0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr.

The deficiencies presented below represent Major deficiensies.

We await the response to our letter dated May 30, 1997, from the Division of Bioequivalence, which contained major deficiencies related to the bioequivalence portion of your applications.

Please be advised that the suitability of the proposed drug release specifications will be established upon completion of review by the Division of Bioequivalence and should be incorporated into the appropriate chemistry, manufacturing and controls sections of your applications. Any changes made to the chemistry, manufacturing and controls sections of your application as a result of responding to the outstanding bioequivalence deficiencies must be submitted for review. We further request that you do not respond to this communication until you have responded to all outstanding bioequivalence and labeling issues.

Sincerely yours,

/S/

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

CHEMIST'S REVIEW ANDA 89-886

3. NAME AND ADDRESS OF APPLICANT

Hercon Laboratories Corporation
South Plainfield, NJ

6. NAME OF DRUG

Nitroglycerin Transdermal

11. HOW DISPENSED

Rx

12. RELATED IND/NDA/DMF(s)

89-884, 885, 886

13. DOSAGE FORM(s) 14. POTENCY

Transdermal System 15 mg/24 hours

16. RECORDS AND REPORTS

Current - yes

17. COMMENTS

Bio to be added at a later date.
The firm currently holds approved ANDA 88-782 and 88-783.
5 and 15 mg per 24 hours patch.
The only difference for the current pending ANDAs is the vinyl backing (previously foam backing) which is sealed off by a lining, so it'll not be in contact with drug reserves.

18. CONCLUSIONS AND RECOMMENDATIONS

Not Approvable

19. REVIEWER: DATE COMPLETED:

Bart Ho BH 2/16/88

20. COMPONENTS AND COMPOSITION

See attached

21. FACILITIES AND PERSONNEL

Base liquid polymer made at the which was made into FD by the addition of Nitroglycerin at Brief description provided.

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Chem Review

1. CHEMISTRY REVIEW NO #2

2. ANDA 89-884
89-885
89-886

3. NAME AND ADDRESS OF APPLICANT
Hercon Laboratories Corporation
Attention: Joseph J. Sobecki
P.O. Box 786
York, PA 17405

4. LEGAL BASIS FOR SUBMISSION
Conditionally approved marketed transdermal nitroglycerin product (Transderm-Nitro, Summit Pharmaceuticals[Ciba]). Transderm-Nitro, release rate 0.2, 0.4 and 0.6 of nitroglycerin per h; Summit Pharmaceuticals (Ciba). NDA-20-144. The reference listed drug is not entitle to a period of exclusivity under section 505(j)(4)(D) of the FDC act. According to Hercon Lab. no patent information has not been filed claiming the product which is the subject of this application. Nitroglycerin is a DESI drug.

Hercon legal basis for submissions:
December 4, 1987 for Nitro-Bid Ointment-Marion Lab.
June 1, 1989 for NTS Nitroglycerin Transdermal-Bolar.
August 20, 1992 for Nitro-Dur-Key Pharmaceuticals.
April 27, 1993 for Transderm-Nitro-Summit Pharmaceuticals (Ciba). The product has been completely reformulated. The firm stated that this response makes all previously submitted material moot. Therefore, this represents an original application.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Hercon Nitroglycerin Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
November 12, 1987: Original Submission
December 4, 1987: New correspondence
March 10, 1988: New correspondence
March 11, 1988: Amendment for labeling
May 11, 1988: Amendment for labeling

June 1, 1989: new corres.(address change)
August 20, 1992: new corresp.
April 27, 1993: Major amendment

FDA:
December 8, 1987: Acknowledgement letter
February 17, 1988: deficiency letter
February 17, 1988: Letter for the review by HFN-180
April 25, 1988: labeling deficiency letter
May 18, 1988: information letter
August 31, 1988: labeling deficiency letter

10. PHARMACOLOGICAL CATEGORY
Coronary vasodilator

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
DMF#
DMF#
DMF#
DMF#
DMF#

13. DOSAGE FORM
Transdermal System

14. POTENCY
0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr

15. CHEMICAL NAME AND STRUCTURE
1,2,3-propanetriol, trinitrate. MW= 227.09
$C_3H_5N_3O_9$

$CH_2ONO_2 \cdot CHONO_2 \cdot CH_2ONO_2$

16. RECORDS AND REPORTS
Phone conversation between Hercon and V.Vashio on 8-19-92.
Phone conversation between Hercon and Cecilia Parise on 5-24-93.

17. COMMENTS
The following deficiencies found in the review
-Drug substance
-other ingredients
-DMF
-Manufacturing
-Container/closure
-Laboratory controls
-Method validation
-Stability
-Labeling
-Bioequivalence

18. CONCLUSIONS AND RECOMMENDATIONS
This application is considered as not approvable. The letter will be issued. The amendment will be considered

major.

19. REVIEWER: Sema Basaran Ph.D. DATE COMPLETED: 8-16-93

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Chem Review #2

1. CHEMISTRY REVIEW # 3

2. ANDA 89-884
89-885
89-886

3. NAME AND ADDRESS OF APPLICANT
Hercon Laboratories Corporation
Attention: Joseph J. Sobecki
P.O. Box 786
York, PA 17405

4. LEGAL BASIS FOR SUBMISSION
Conditionally approved marketed transdermal nitroglycerin product (Transderm-Nitro, Summit Pharmaceuticals[Ciba]). Transderm-Nitro, release rate 0.2, 0.4 and 0.6 of nitroglycerin per h; Summit Pharmaceuticals (Ciba). NDA-20-144. The reference listed drug is not entitle to a period of exclusivity under section 505(j)(4)(D) of the FDC act. According to Hercon Labs. patent information has not been filed claiming the product which is the subject of this application. Nitroglycerin is a DESI drug.

Hercon's legal basis for submissions:
December 4, 1987 for Nitro-Bid Ointment-Marion Lab.
June 1, 1989 for NTS Nitroglycerin Transdermal-Bolar.
August 20, 1992 for Nitro-Dur-Key Pharmaceuticals.
April 27, 1993 for Transderm-Nitro-Summit Pharmaceuticals (Ciba). The product has been completely reformulated. The firm stated that this response makes all previously submitted material moot. Therefore, this represents an original application.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Hercon Nitroglycerin Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
November 12, 1987: Original Submission
December 4, 1987: New correspondence

March 10, 1988: New correspondence
March 11, 1988: Amendment for labeling
May 11, 1988: Amendment for labeling
June 1, 1989: new corres.(address change)
August 20, 1992: new corresp.
April 27, 1993: Major amendment
April 29, 1994: Major amendment
December 8, 1994: Major amendment

FDA:
December 8, 1987: Acknowledgement letter
February 17, 1988: Deficiency letter
February 17, 1988: Letter for the review by HFN-180
April 25, 1988: labeling deficiency letter
May 18, 1988: information letter
August 31, 1988: labeling deficiency letter
October 29, 1993: Deficiency letter
August 18, 1994: Bio-major deficiency letter

10. PHARMACOLOGICAL CATEGORY
Coronary vasodilator

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
DMF#
DMF#
DMF#
DMF#
DMF#

13. DOSAGE FORM
Transdermal System

14. POTENCY
0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr

15. CHEMICAL NAME AND STRUCTURE
1,2,3-propanetriol, trinitrate. MW= 227.09
$C_3H_5N_3O_9$

$CH_2ONO_2 \cdot CHONO_2 \cdot CH_2ONO_2$

16. RECORDS AND REPORTS
Phone conversation between Hercon and V.Vashio on 8-19-92.
Phone conversation between Hercon and Cecilia Parise on 5-24-93.
Memo from Donald Hare to William Rickman on February 2, 1995, regarding the approval of Schering-Key's supplement which would grant unconditional approval to Nitro-Dur. Schering-Key has submitted a formulation patent which will be listed in the Orange Book at the time of approval. All firms with a pending 505 (b)(2) or 505 (j) application using

the Schering product as the reference drug will have to amend their

applications with an appropriate patent certification when the Orange Book displays this formulation patent on the approved Nitro-Dur transdermal patch.

Debarment certification is included in December 8, 1994, amendment.

17. COMMENTS
The following deficiencies found in the review
-DMF
-Manufacturing
-Laboratory controls
-Labeling
-New Bioequivalence studies pending
-EER-reinspection requested

18. CONCLUSIONS AND RECOMMENDATIONS
This application is considered as not approvable. The letter will be issued consistent with the letter for applications 88-782, 88-783 and 89-516 (reviewed by G.Smith). The amendment will be considered major.

19. REVIEWER: Sema Basaran Ph.D. DATE COMPLETED: 4-5-95

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commercial

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Chem Review #3

1. CHEMISTRY REVIEW # 4

2. ANDA 89-884
89-885
89-886

3. NAME AND ADDRESS OF APPLICANT
Hercon Laboratories Corporation
Attention: Joseph J. Sobecki
P.O. Box 786
York, PA 17405

4. LEGAL BASIS FOR SUBMISSION
Conditionally approved marketed transdermal nitroglycerin product (Transderm-Nitro, Summit Pharmaceuticals[Ciba]). Transderm-Nitro, release rate 0.2, 0.4 and 0.6 of nitroglycerin per h; Summit Pharmaceuticals (Ciba). NDA-20-144. The reference listed drug is not entitle to a period of exclusivity under section 505(j)(4)(D) of the FDC act. According to Hercon Labs. patent information has not been filed claiming the product which is the subject of this application. Nitroglycerin is a DESI drug.

Hercon's legal basis for submissions:
December 4, 1987 for Nitro-Bid Ointment-Marion Lab.
June 1, 1989 for NTS Nitroglycerin Transdermal-Bolar.
August 20, 1992 for Nitro-Dur-Key Pharmaceuticals.
April 27, 1993 for Transderm-Nitro-Summit Pharmaceuticals (Ciba). The product has been completely reformulated. The firm stated that this response makes all previously submitted material moot. Therefore, this represents an original application.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Hercon Nitroglycerin Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
November 12, 1987: Original Submission
December 4, 1987: New correspondence

March 10, 1988:	New correspondence
March 11, 1988:	Amendment for labeling
May 11, 1988:	Amendment for labeling
June 1, 1989:	new corres.(address change)
August 20, 1992:	new corresp.
April 27, 1993:	Major amendment
April 29, 1994:	Major amendment
December 8, 1994:	Major amendment
August 7, 1995:	Major amendment

FDA:

December 8, 1987:	Acknowledgement letter
February 17, 1988:	Deficiency letter
February 17, 1988:	Letter for the review by HFN-180
April 25, 1988:	labeling deficiency letter
May 18, 1988:	information letter
August 31, 1988:	labeling deficiency letter
October 29, 1993:	Deficiency letter
August 18, 1994:	Bio-major deficiency letter
June 14, 1995:	Deficiency letter
November 30, 1995:	Bio-major deficiency letter

10. PHARMACOLOGICAL CATEGORY
Coronary vasodilator

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
DMF#
DMF#
DMF#
DMF#
DMF#
DMF#

13. DOSAGE FORM
Transdermal System

14. POTENCY
0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr

15. CHEMICAL NAME AND STRUCTURE
1,2,3-propanetriol, trinitrate. MW= 227.09
$C_3H_5N_3O_9$

$CH_2ONO_2 \cdot CHONO_2 \cdot CH_2ONO_2$

16. RECORDS AND REPORTS
Phone conversation between Hercon and V.Vashio on 8-19-92.
Phone conversation between Hercon and Cecilia Parise on 5-24-93.
Memo from Donald Hare to William Rickman on February 2, 1995, regarding the approval of Schering-Key's supplement which would grant unconditional approval to Nitro-Dur.

Schering-Key has submitted a formulation patent which will be listed in the Orange Book at the time of approval. All firms with a pending 505 (b)(2) or 505 (j) application using the Schering product as the reference drug will have to amend their applications with an appropriate patent certification when the Orange Book displays this formulation patent on the approved Nitro-Dur transdermal patch.

Debarment certification is included in December 8, 1994, amendment.

17. COMMENTS
The following deficiencies found in the review
-Laboratory controls
-Labeling
-New Bioequivalence studies pending
-EER-reinspection requested

18. CONCLUSIONS AND RECOMMENDATIONS
This application is considered as not approvable. The letter will be issued consistent with the letter for applications 88-782, 88-783 and 89-516 (reviewed by G.Smith). The amendment will be considered major.

19. REVIEWER: DATE COMPLETED:
Sema Basaran Ph.D. 1-4-96
3-4-96 (Labeling)

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Chem Review #4

1. CHEMISTRY REVIEW # 5

2. ANDA 89-884
89-885
89-886

3. NAME AND ADDRESS OF APPLICANT
Hercon Laboratories Corporation
Attention: Joseph J. Sobecki
P.O. Box 786
York, PA 17405

4. LEGAL BASIS FOR SUBMISSION
Conditionally approved marketed transdermal nitroglycerin product (Transderm-Nitro, Summit Pharmaceuticals [Ciba]). Transderm-Nitro, release rate 0.2, 0.4 and 0.6 of nitroglycerin per h; Summit Pharmaceuticals (Ciba).
NDA-20-144. The reference listed drug is not entitle to a period of exclusivity under section 505(j)(4)(D) of the FDC act. According to Hercon Labs. patent information has not been filed claiming the product which is the subject of this application. Nitroglycerin is a DESI drug.

Hercon's legal basis for submissions:
December 4, 1987 for Nitro-Bid Ointment-Marion Lab.
June 1, 1989 for NTS Nitroglycerin Transdermal-Bolar.
August 20, 1992 for Nitro-Dur-Key Pharmaceuticals.
April 27, 1993 for Transderm-Nitro-Summit Pharmaceuticals (Ciba). The product has been completely reformulated. The firm stated that this response makes all previously submitted material moot. Therefore, this represents an original application.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Hercon Nitroglycerin Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
November 12, 1987: Original Submission
December 4, 1987: New correspondence

March 10, 1988: New correspondence
March 11, 1988: Amendment for labeling
May 11, 1988: Amendment for labeling
June 1, 1989: new corresp.(address change)
August 20, 1992: new corresp.
April 27, 1993: Major amendment
April 29, 1994: Major amendment
December 8, 1994: Major amendment
August 7, 1995: Major amendment
October 10, 1996: Major Amendment
October 10, 1996: Bioequivalency Amendment
November 22, 1996: New Correspondence
November 27, 1996: New Correspondence

FDA:
December 8, 1987: Acknowledgment letter
February 17, 1988: Deficiency letter
February 17, 1988: Letter for the review by HFN-180
April 25, 1988: Labeling deficiency letter
May 18, 1988: Information letter
August 31, 1988: Labeling deficiency letter
October 29, 1993: Deficiency letter
August 18, 1994: Bio-major deficiency letter
June 14, 1995: Deficiency letter
November 30, 1995: Bio-major deficiency letter
March 29, 1996: Deficiency letter

10. PHARMACOLOGICAL CATEGORY
Coronary vasodilator

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
DMF#
DMF#
DMF#
DMF#
DMF#
DMF#

13. DOSAGE FORM
Transdermal System

14. POTENCY
0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr

15. CHEMICAL NAME AND STRUCTURE
1,2,3-propanetriol, trinitrate. MW= 227.09
$C_3H_5N_3O_9$

$CH_2ONO_2 \cdot CHONO_2 \cdot CH_2ONO_2$

16. RECORDS AND REPORTS

Phone conversation between Hercon and V. Vashio on 8-19-92. Phone conversation between Hercon and Cecilia Parise on 5-24-93. Memo from Donald Hare to William Rickman on February 2, 1995, regarding the approval of Schering-Key's supplement which would grant unconditional approval to Nitro-Dur. Schering-Key has submitted a formulation patent which will be listed in the Orange Book at the time of approval. All firms with a pending 505 (b)(2) or 505 (j) application using the Schering product as the reference drug will have to amend their applications with an appropriate patent certification when the Orange Book displays this formulation patent on the approved Nitro-Dur transdermal patch.

Debarment certification is included in December 8, 1994, amendment.

17. COMMENTS

The following deficiencies found in the review
-Labeling
-New Bioequivalence studies pending

18. CONCLUSIONS AND RECOMMENDATIONS

These applications can be approved based on acceptable Bioequvalency and labeling. The letter will not be issued until Bioequivalency and labeling issues resolved.(The amendment will be considered major).

19. REVIEWER: DATE COMPLETED:

Sema Basaran Ph.D. 4-14-96

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Chem Review #5

8. Chemistry Comments to be Provided to the Applicant

ANDA: 89-884, 89-885, 89-886

APPLICANT: Hercon Laboratories Corporation.

DRUG PRODUCT: Nitroglycerin Transdermal Patch, 0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr.

FACSIMILE

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

* Please update your patent certification and resubmit.

B. In addition to responding to the deficiency presented above, please note and acknowledge the following comments in your response:

The Division of Chemistry has no further questions at this time. Please be advised that the suitability of the proposed drug release specifications will be established upon completion of review by the Division of Bioequivalence. Any changes made to the chemistry, manufacturing and controls section of your application as a result of outstanding bioequivalence deficiencies must be submitted and could result in the response being considered a MAJOR Amendment. We further request that you do not respond to this communication until all outstanding bioequivalence and labeling issues have been resolved.

Sincerely yours,

/S/ 5/6/97

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

1. CHEMISTRY REVIEW # 6

2. ANDA 89-884
89-885
89-886

3. NAME AND ADDRESS OF APPLICANT
Hercon Laboratories Corporation
Attention: Joseph J. Sobecki
P.O. Box 786
York, PA 17405

4. LEGAL BASIS FOR SUBMISSION
Conditionally approved marketed transdermal nitroglycerin product (Transderm-Nitro, Summit Pharmaceuticals[Ciba]). Transderm-Nitro, release rate 0.2, 0.4 and 0.6 of nitroglycerin per h; Summit Pharmaceuticals (Ciba).
NDA-20-144. The reference listed drug is not entitle to a period of exclusivity under section 505(j)(4)(D) of the FDC act. According to Hercon Labs. patent information has not been filed claiming the product which is the subject of this application. Nitroglycerin is a DESI drug.

Hercon's legal basis for submissions:
December 4, 1987 for Nitro-Bid Ointment-Marion Lab.
June 1, 1989 for NTS Nitroglycerin Transdermal-Bolar.
August 20, 1992 for Nitro-Dur-Key Pharmaceuticals.
April 27, 1993 for Transderm-Nitro-Summit Pharmaceuticals (Ciba). The product has been completely reformulated. The firm stated that this response makes all previously submitted material moot. Therefore, this represents an original application.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Hercon Nitroglycerin Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
November 12, 1987: Original Submission
December 4, 1987: New correspondence

March 10, 1988:	New correspondence
March 11, 1988:	Amendment for labeling
May 11, 1988:	Amendment for labeling
June 1, 1989:	new corres.(address change)
August 20, 1992:	new corresp.
April 27, 1993:	Major amendment
April 29, 1994:	Major amendment
December 8, 1994:	Major amendment
August 7, 1995:	Major amendment
October 10, 1996:	Major Amendment
October 10, 1996:	Bioequivalency Amendment
November 22, 1996:	New Correspondence
November 27, 1996:	New Correspondence
June 5, 1997:	Facsimile amendment

FDA:

December 8, 1987:	Acknowledgement letter
February 17, 1988:	Deficiency letter
February 17, 1988:	Letter for the review by HFN-180
April 25, 1988:	labeling deficiency letter
May 18, 1988:	information letter
August 31, 1988:	labeling deficiency letter
October 29, 1993:	Deficiency letter
August 18, 1994:	Bio-major deficiency letter
June 14, 1995:	Deficiency letter
November 30, 1995:	Bio-major deficiency letter
March 29, 1996:	Deficiency letter
May 30, 1997:	Bio-fatal deficiency letter
May 7, 1997:	Facsimile Deficiency letter

10. PHARMACOLOGICAL CATEGORY
Coronary vasodilator

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
DMF#
DMF#
DMF#
DMF#
DMF#
DMF#

13. DOSAGE FORM
Transdermal System

14. POTENCY
0.2 mg/hr, 0.4 mg/hr and 0.6 mg/hr

15. CHEMICAL NAME AND STRUCTURE
1,2,3-propanetriol, trinitrate. MW= 227.09
$C_3H_5N_3O_9$

16. RECORDS AND REPORTS

Phone conversation between Hercon and V.Vashio on 8-19-92.
Phone conversation between Hercon and Cecilia Parise on 5-24-93.
Memo from Donald Hare to William Rickman on February 2, 1995, regarding the approval of Schering-Key's supplement which would grant unconditional approval to Nitro-Dur. Schering-Key has submitted a formulation patent which will be listed in the Orange Book at the time of approval. All firms with a pending 505 (b)(2) or 505 (j) application using the Schering product as the reference drug will have to amend their applications with an appropriate patent certification when the Orange Book displays this formulation patent on the approved Nitro-Dur transdermal patch.

Debarment certification is included in December 8, 1994, amendment.

Please refer our leter dated of May 7, 1997. Updated patent Certification requested.

The firm's comment: Their original patent certification dated April 16, 1993, is enclosed as Attachment 1. Based on 21 CFR 314.94 (a) (12) (vi) pertaining to ▒Late Submission of Patent Information▒, they are not required to re-certify against the Ciba patents that first appeared in the Orange Book in the January `96 to December ▒96Cumulative Supplement (copy of page enclosed as Attachment 2). The approval of Ciba's Transderm Nitro first appeared in the Orange Book in the January `96 to February ▒96 Cumulative Supplement (copy pages enclosed aAttachment 3). The patents appeared in the Orange Book a full ten months after the Ciba Transderm Nitro approval appeared in the Orange Book. Satisfactory.

17. COMMENTS

The following deficiencies found in the review
-Labeling
-New Bioequivalence studies required.

18. CONCLUSIONS AND RECOMMENDATIONS

These applications can be approved based on acceptable Bioequvalency and labeling. The approval letter will not be issued until Bioequivalency and labeling issues resolved. (The amendment will be considered minor).

19. REVIEWER: DATE COMPLETED:

Sema Basaran Ph.D. 6-30-97

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Chem Review #6

CDER Establishment Evaluation Report for April 14, 1997

Application: **ANDA 89886/000**
Stamp: **16-NOV-1987** Regulatory Due:
Applicant: **HERCON LABS**
200 B CORPORATE CT
SOUTH PLAINFIELD, NJ 07080

Priority:
Org Code: **600**
Action Goal:
District Goal: **16-JAN-1989**
Brand Name:
Established Name: **NITROGLYCERIN**
Generic Name:
Dosage Form: **FLM (TRANSDERMAL SYSTEM)**
Strength: **0.6 MG/HR**

FDA Contacts: **T. AMES** **(HFD-617)** **301-594-0305 , Project Manager**
S. BASARAN **(HFD-647)** **301-594-0305 , Review Chemist**

Overall Recommendation:

Establishment: **2522638**
HERCON LABORATORIES CORP SU
ABERDEEN RD AND SINKING SPRIN
EMIGSVILLE, PA 17318

DMF No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC** **14-APR-1997**

Responsibilities:
FINISHED DOSAGE MANUFACTURER

Establishment:

DMF No: __

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC** **14-APR-1997**

Responsibilities:
DRUG SUBSTANCE MANUFACTURER

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC** **14-APR-1997**

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

ESTABLISHMENT EVALUATION REQUEST

1.8054

REQUEST TYPE (Check One)	DATE	PHONE NO.
☒ Original ☒ FollowUp ☐ FUR	May 4, 1995	(301) 594-0305
REQUESTORS NAME: Sema Basaran	DIVISION: Office of Generic Drugs	MAIL CODE: HFD-647
APPLICATION AND SUPPLEMENT NUMBER: ANDA 89-884, 89-885, 89-886		
BRAND NAME:	ESTABLISHED NAME: Nitroglycerin Transdermal Delivery System	
DOSAGE STRENGTH: 0.2 mg/hr, 0.4 mg/hr, 0.6 mg/hr	STERILE ☐Yes ☒ No	
PROFILE CLASS:: NEC (Transdermal Patch)	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)	
APPLICANT'S NAME: Hercon Laboratories Corporation		
APPLICANT'S ADDRESS: Sinking Spring Lane Emigsville, Pennsylvania 17318		

COMMENTS : Note that the transdermal patches are identical in all aspects with those submitted under ANDA's 88-782, 88-783 and 89-516 except for the area (size) of the patch for a specified release rate. This raises serious concerns regarding the ability to distinguish or segregate different products (e.g. the 0.2 mg/hr patch for ANDA 88-782 from the 0.2 mg/hr patch for ANDA 89-884). Please confirm adequate controls are in place. Note also that themanufacturing operations are identical to those previously provided, except for provisions made to incorporate the reduced patch size.

FACILITIES TO BE EVALUATED
(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	FOR CDER USE ONLY
Hercon Laboratories Corporation Sinking Springs Lane Emigsville, Pennsylvania 17318	Manufacture of drug product (Transdermal Patch)	NEC Transdermal Patch		
2.	Manufacture of drug substance			
3.				
4.				
5.				

FOR CFTO USE ONLY	

1 FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
NDA 89-884, 89-885, 89-886 HFD-647/Div File, HFD-617/JWilson, HFD-617/TAmes, HFD-647/JSimmons HFD-647/SBasaran