

**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 Transdermal Patch, 0.2 mg/hr, 0.4 mg/hr  
and 0.6 mg/hr.

The deficiencies presented below represent Major deficiencies.

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

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)

Transdermal System

14. POTENCY

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:

Bart Ho

DATE COMPLETED:

BH 2/16/88

20. COMPONENTS AND COMPOSITION

See attached

21. FACILITIES AND PERSONNEL

Base liquid polymer made at the

✓ Nitroglycerin at provided.

which was made into FD by the addition of  
Brief description

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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 entitled 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  
 $C_3H_5N_3O_9$



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: DATE COMPLETED:  
Sema Basaran Ph.D. 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 entitled 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

ANDA 89-884/885/886  
Review#3

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  
 $C_3H_5N_3O_9$



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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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

ANDA 89-884/885/886

Review#4

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  
 $C_3H_5N_3O_9$



16. RECORDS AND REPORTS

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 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:

Sema Basaran Ph.D.

DATE COMPLETED:

1-4-96

3-4-96 (Labeling)

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Chem Review #7

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 entitled 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

ANDA 89-884/885/886

Review#4

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<sub>3</sub>H<sub>5</sub>N<sub>3</sub>O<sub>9</sub>



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 Bioequivalency and labeling. The letter will not be issued until Bioequivalency and labeling issues resolved. (The amendment will be considered major).

|                      |                        |
|----------------------|------------------------|
| 19. <u>REVIEWER:</u> | <u>DATE COMPLETED:</u> |
| 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/

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

L, 5/6/97

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 entitled 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.

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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

ANDA 89-884/885/886  
Review#6

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 letter 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 '96 Cumulative 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 as Attachment 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 Bioequivalency and labeling. The approval letter will not be issued until Bioequivalency and labeling issues resolved. (The amendment will be considered minor).

19. REVIEWER:

Sema Basaran Ph.D.

DATE COMPLETED:

6-30-97

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Chem Review #6

CDER Establishment Evaluation Report  
for April 14, 1997

Page 1 of 1

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

Priority:  
Action Goal:  
Brand Name:  
Established Name: NITROGLYCERIN  
Generic Name:  
Dosage Form: FLM (TRANSDERMAL SYSTEM)  
Strength: 0.6 MG/HR

Org Code: 600

District Goal: 16-JAN-1989

FDA Contacts: T. AMES (HFD-617)  
S. BASARAN (HFD-647)

301-594-0305 , Project Manager  
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

## ESTABLISHMENT EVALUATION REQUEST