CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-288

Chemistry Review(s)

Summary of Chemistry Review of NDA 21-288
(Trelstar LA)

A. Drug Substances:

Triptorelin pamoate is an analog of GnRH for palliative treatment **of advanced prostate cancer,** and has been used for a previously approved drug (NDA 20-715). It is manufactured and supplied by (DMF) and its facility is **in compliance to cGMP**.

There has been no changes in DMF since it was reviewed for the approved NDA, and therefore it is still deemed adequate to support this NDA.

B. Drug Product:

This is an essentially the same product as the one approved for NDA 20-715 (1-month formulation), except that it has different composition of dl-lactide-glycolide polymer ; and higher strength (11.25mg vs 3.75mg) to make it a 3-month formulation.

This new formulation is manufactured, tested, packaged by **Debio Recherche Pharmaceutique S.A.**, Switzerland, sterilized at .

Raw material testing and **pyrogen testing** of final dosage form are done by .

Stability testing of sterile diluent is done by and the is manufactured by .

Final **sterilization** and **secondary packaging** is done by Pharmacia & Upjohn, Inc., MI.

All facilities involved are **in compliance with cGMP**.

The lyophilized microgranules in a vial contain contain 11.25mg of triptorelin (free base) as well as dl-lactide-glycolide polymer (145mg), mannitol (85mg), carboxymethylcellulose sodium (30mg), and polysorbate 80 (2mg).

The lyophilized microgranules are to be reconstituted with 2ml of **Sterile Water for Injection, USP** before intramuscular injection.

The **quality** of the lyophilized microgranules is **controlled** by the same specifications used for the 1-month formulation, except for dissolution acceptance criteria .

The microgranules are packaged in a . The vial is then packaged in a specially designed blister pack together with a prefilled syringe containing 2ml Sterile Water for Injection, USP.

The container/closure systems involved in vial as well as in prefilled syringe are considered to be **adequate for protecting** the product during the shelf life.

Based on available stability data, **month of expiry date** is granted.

The tradename, **Trelstar LA**, was accepted by OPDRA.

C. Conclusion and Recommendation:

As recommended by the primary reviewer, this NDA can be approved from chemistry point of view.

/S/ 6/27/01

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader
For the Division of reproductive and Urologic Drug Products
DNDC II, Office of New Drug Chemistry

DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG PRODUCTS - HFD-580

Review of Chemistry, Manufacturing and Controls

NDA #: 21-288

CHEMISTRY REVIEW #: 2 **DATE REVIEWED:** 25-JUNE-2001

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	29-JUN-00	29-JUN-00	30-JUN-00
Amendment	21-JUN-01	25-JUN-01	

NAME & ADDRESS OF SPONSOR:

Debio Recherche Pharmaceutique
Case Postale
Route du Levant 146
CH-1920 Martigny, Switzerland
US Agent: N. Peter Kostopulos
1747 Pennsylvania Ave., N.W., Suite 300
Washington, DC 20006

DRUG PRODUCT NAME:

Proprietary:	Trelstar LA
Nonproprietary/Established/USAN:	Triptorelin pamoate for Injectable Suspension
Code Name/#:	D-Trp6-LHRH
Chem.Type/Ther.Class:	3S

PARMACOLOGICAL CATEGORY/INDICATION: LHRH agonist/Palliative treatment for advanced prostate cancer

DOSAGE FORM: Lyophilized powder to be reconstituted (water for injection) for Injection

STRENGTHS: 11.25 mg

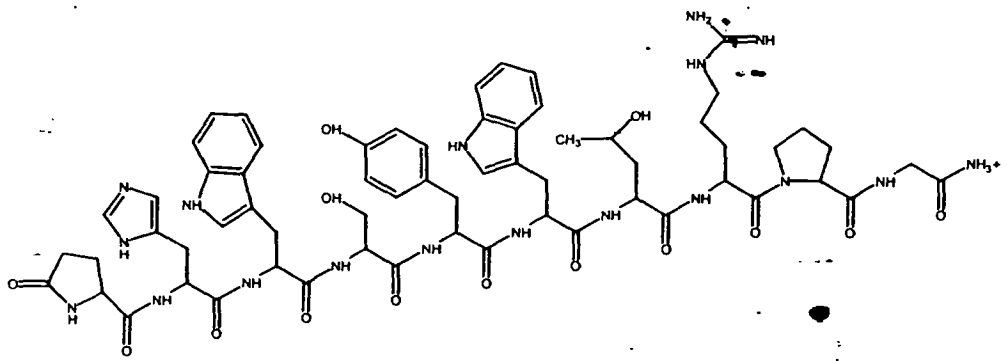
ROUTE OF ADMINISTRATION: Intramuscular (IM) injection

DISPENSED: ___x___ Rx _____ OTC

SPECIAL PRODUCTS: ___ Yes _x_ No

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-tryptophyl-L-leucyl-L-arginyl-L-prolylglycinamide (pamoate salt) [(pyro)Glu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH_2, pamoate salt]



$C_{64}H_{82}N_{18}O_{13} \bullet C_{23}H_{16}O_6$ (pamoic acid)

MW 1699.9 (triptorelin 1311.5 + pamoic acid 388.4)

SUPPORTING DOCUMENTS:

See Chemistry Review #1.

RELATED DOCUMENTS:
NDAs 20-715,

PATENT STATUS:
See Chemistry Review #1.

CONSULTS:
See Chemistry Review #1.

REMARKS/COMMENTS:
The only outstanding issues from Chemistry Review #1 pertained to physician package insert and the container/carton labels. The sponsor has responded to those CMC issues and agreed to make the recommended revisions (see 6/21/01 amendment).

CONCLUSIONS & RECOMMENDATIONS:
From a Chemistry, Manufacturing and Controls point of view this NDA may be approved.

cc:
Orig. NDA #21-288
HFD-580/Division File
HFD-580/JBest
HFD-580/MRhee/DLin

/S/

David T. Lin, Ph.D.
Review Chemist

R/D Init by:

Summary of Chemistry Review

A. Drug Substance:

1. **Description & Characterization:** Satisfactory. See Chem. Rev. #1.
2. **Manufacturers:** Satisfactory. See Chem. Rev. #1.
3. **Synthesis:** Satisfactory. See Chem. Rev. #1.
4. **Process Controls:** Satisfactory. See Chem. Rev. #1.
5. **Reference Standard:** Satisfactory. See Chem. Rev. #1.
6. **Specifications/Methods:** Satisfactory. See Chem. Rev. #1.
7. **Container:** Satisfactory. See Chem. Rev. #1.
8. **Stability:** Satisfactory. See Chem. Rev. #1.

B. Drug Product:

1/2. **Components/Composition:** Satisfactory. See Chem. Rev. #1.

3. **Specifications/Methods for Drug Product Components:** Satisfactory. See Chem. Rev. #1.
4. **Manufacturer:** Satisfactory. See Chem. Rev. #1.
5. **Methods of Manufacturing:** Satisfactory. See Chem. Rev. #1.
6. **Regulatory Specifications/Methods:** Satisfactory. See Chem. Rev. #1.
7. **Container/Closure System:** Satisfactory. See Chem. Rev. #1.
8. **Microbiology:** N/A
9. **Stability:** Satisfactory. See Chem. Rev. #1.

C. Investigational Formulations: Satisfactory. See Chem. Rev. #1.

D. Environmental Assessment: Satisfactory. See Chem. Rev. #1.

E. Methods Validation: *Pending*. The complete methods validation package will be submitted to FDA labs.

F. Labeling: Satisfactory. See Chem. Rev. #2.

G. Establishment Inspection: Satisfactory. See Chem. Rev. #1.

Chemist's Review Notes

Question 1: *In order to prevent confusion with the approved product, Trelstar Depot, the following statement should be displayed prominently in the package insert, and on the container/carton labels: "Give Once Every 84 Days (12 Weeks)". In addition, in the Precautions section, to prevent the chance that the symbol "µg" is mistaken for "mg", substitute it with "mcg" or "micrograms".*

Response: Satisfactory
The sponsor has complied with the recommendation.

Question 2: *The same storage statement that is printed on the vial label needs to be added to the pre-filled syringe label.*

Response: Satisfactory
The sponsor has complied with the recommendation.

Labeling:

The sponsor has agreed to revise the syringe labels from "Sterile Water for Injection" to "Sterile Water for Injection, USP, and add the requested storage statement. In addition, the container/carton labels have been revised to comply with OPDRA's request with addition of the following statement, "Give Once Every 84 Days (12 Weeks)".

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG PRODUCTS - HFD-580

Review of Chemistry, Manufacturing and Controls

NDA #: 21-288

CHEMISTRY REVIEW #: 1

DATE REVIEWED: 12-JUNE-2001

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	29-JUN-00	29-JUN-00	30-JUN-00
Amendment	23-AUG-00	24-AUG-00	
Amendment	05-FEB-01	06-FEB-01	
Amendment	05-FEB-01	07-FEB-01	
Amendment	14-MAY-01	15-MAY-01	
Amendment	21-MAY-01	22-MAY-01	
Amendment	01-JUN-01	04-JUN-01	
Amendment	01-JUN-01	04-JUN-01	

NAME & ADDRESS OF SPONSOR:

Debio Recherche Pharmaceutique
Case Postale
Route du Levant 146
CH-1920 Martigny, Switzerland
US Agent: N. Peter Kostopulos
1747 Pennsylvania Ave., N.W., Suite 300
Washington, DC 20006

DRUG PRODUCT NAME:

Proprietary:	Trelstar LA
Nonproprietary/Established/USAN:	Triptorelin pamoate for Injectable Suspension
Code Name/#:	D-Trp6-LHRH
Chem.Type/Ther.Class:	3S

PARMACOLOGICAL CATEGORY/INDICATION: LHRH agonist/Palliative treatment for advanced prostate cancer

DOSAGE FORM: Lyophilized powder to be reconstituted (water for injection) for Injection

STRENGTHS: 11.25 mg

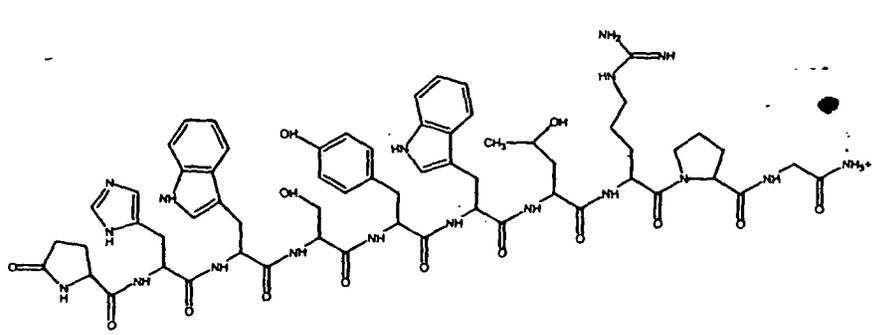
ROUTE OF ADMINISTRATION: Intramuscular (IM) injection

DISPENSED: __x__ Rx _____ OTC

SPECIAL PRODUCTS: ___ Yes _x_ No

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-tryptophyl-L-leucyl-L-arginyl-L-prolylglycinamide (pamoate salt) [(pyro)Glu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH_2, pamoate salt]



$C_{64}H_{82}N_{18}O_{13} \bullet C_{23}H_{16}O_6$ (pamoic acid)
MW 1699.9 (triptorelin 1311.5 + pamoic acid 388.4)

SUPPORTING DOCUMENTS:

Type/Number	Subject	Holder	Status	Review Date	Letter Date
NDA 20-715	Trelstar™ Depot (triptorelin pamoate for injectable suspension)	Debio R.P.	Approved	6/15/00	N/A
DMF			Adequate; Reviewed by Dr. D. Lin	7/16/99	N/A
DMF			Adequate; Reviewed by Dr. D. Lin	5/21/01	N/A
DMF	USP		Adequate; Reviewed by Dr. S. Tran	3/14/00	N/A
DMF	USP		Adequate; Reviewed by Dr. R. Barron	8/20/99	N/A
DMF			Adequate; Reviewed by Dr. D. Lin	5/3/00	N/A
DMF			Adequate; Reviewed by Dr. D. Lin	1/10/01	N/A
DMF			Adequate; Reviewed by Dr. P. Stinavage	7/21/00	N/A

RELATED DOCUMENTS:
NDAs 20-715,

PATENT STATUS:

Patent No.	Type	Expiration	Patent Owner
5,134,122	Drug process	7/20/2010	Debio R.P.
5,225,205	Drug product	7/20/2010	Debio R.P.
5,192,741	Drug product	3/9/2010	Debio R.P.

CONSULTS:

1. The Division of Biopharmaceutics was consulted for the dissolution specifications (see Biopharm. Review by Dr. Venkat Jarugula).
2. The EER was sent to Compliance on August 16, 2000 and a overall Acceptable recommendation was issued by the Office of Compliance on April 19, 2001 (see Appendix A).
3. The Microbiology section was consulted to the Microbiology Staff. Dr. David Hussong has recommended an Approval (see Microbiology Reviews #1 and #2 dated 11/17/00 and 5/21/01, respectively).
4. The proposed trademark, Trelstar LA, was consulted to OPDRA and determined to be acceptable (see review dated 3/1/01).

CONCLUSIONS & RECOMMENDATIONS:

From a Chemistry, Manufacturing and Controls point of view this NDA is approvable. The NDA may be approved pending satisfactory of the CMC labeling issues.

cc:
Orig. NDA #21-288
HFD-580/Division File
HFD-580/JBest
HFD-580/MRhee/DLin

S

David T. Lin, Ph.D.
Review Chemist

R/D Init by:

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pp. 4-25

21-MAY-2001 FDA CDER EES Page 1 of 4
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 21288/000
Stamp: 29-JUN-2000
Regulatory Due: 29-APR-2001
Applicant: DEBIO RECHERCHE
CH-1920
MARTIGNY, , SZ
Priority: S
Org Code:

Action Goal:
District Goal: 28-FEB-2001
Brand Name: TRELSTAR LA(TRIPTORELIN PAMOATE FOR INJ -
Estab. Name:
Generic Name: TRIPTORELIN PAMOATE FOR INJECTABLE SUSP

Dosage Form: (INJECTION)
Strength: 11.25 MG

FDA Contacts: J. BEST (HFD-580) 301-827-4260 , Project Manager
D. LIN (HFD-580) 301-827-4230 , Review Chemist
M. RHEE (HFD-580) 301-827-4237 , Team Leader

Overall Recommendation: ACCEPTABLE on 19-APR-2001 by M. GARCIA (HFD-322) 301-594-0095

Establishment:

DMF No:
Responsibilities:
Profile: CSN
Estab. Comment: (HFD-580) 301-827-4230)

AADA:
OAI Status: NONE
(on 30-JUN-2000 by D. LIN

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	24-AUG-2000	GMP			EGASM
INSPECTION SCHEDULED	18-DEC-2000		25-JAN-2001		IRIVERA
INSPECTION PERFORMED	06-FEB-2001		25-JAN-2001		EGASM
DO RECOMMENDATION	19-APR-2001			ACCEPTABLE INSPECTION	EGASM
OC RECOMMENDATION	19-APR-2001			ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

Establishment:

DMF No:
Responsibilities:
Profile: CTL
Estab. Comment: by D. LIN (HFD-580) 301-827-4230)

AADA:
OAI Status: NONE
(on 30-JUN-2000

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	24-AUG-2000	GMP			EGASM
INSPECTION SCHEDULED	16-OCT-2000		03-NOV-2000		IRIVERA
INSPECTION PERFORMED	07-NOV-2000		31-OCT-2000		EGASM
DO RECOMMENDATION	06-FEB-2001			ACCEPTABLE INSPECTION	EGASM
OC RECOMMENDATION	06-FEB-2001			ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

28-FEB-2001

29-APR-2001
DEBIO RECHERCHE
S
580
Priority:
Org Code:
Application Comment: THIS NDA IS SIMILAR TO NDA 20-715 EXCEPT THAT THE DOSAGE STRENGTH HAS INCREASED TO 11.25 MG AND IT IS A THREE MONTH FORMULATION. (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Establishment:

DMF No: AADA:
Responsibilities:
Profile: CTL OAI Status: NONE
Estab. Comment: (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	24-AUG-2000	GMP			EGASM
INSPECTION SCHEDULED	16-OCT-2000		07-NOV-2000		IRIVERA
INSPECTION PERFORMED	07-NOV-2000		03-NOV-2000		IRIVERA
DO RECOMMENDATION	12-FEB-2001			ACCEPTABLE	EGASM
				INSPECTION	
OC RECOMMENDATION	12-FEB-2001			ACCEPTABLE	EGASM
				DISTRICT RECOMMENDATION	

Establishment: 9614420
DEBIO RECHERCHE PHARMACEUTIQUE SA
CH-1920
MARTIGNY, , SZ
DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
Profile: SVS OAI Status: NONE
Estab. Comment: SITE OF ALL PRODUCTION OPERATIONS OF THE DRUG PRODUCT, INCLUDING ALL ANALYTICAL TESTING INVOLVED WITH FINISHED LYOPHILIZED DOSAGE FORM. (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	10D			DAMBROGIOJ
DO RECOMMENDATION	24-AUG-2000			ACCEPTABLE	EGASM
				BASED ON FILE REVIEW	
BASED ON EI OF 7/28/99					
OC RECOMMENDATION	24-AUG-2000			ACCEPTABLE	EGASM
				DISTRICT RECOMMENDATION	

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	10D			DAMBROGIOJ
DO RECOMMENDATION	12-SEP-2000			ACCEPTABLE. BASED ON FILE REVIEW	MROBINSO
GMP EI ENDING MARCH 31, 2000 WAS CLASSIFIED ACCEPTABLE FOR PROFILE CLASS SVS AND SVL.					
OC RECOMMENDATION	12-SEP-2000			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

Establishment:

DMF No: AADA:
Responsibilities:

Profile: SVS OAI Status: NONE
Estab. Comment: (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	10D			DAMBROGIOJ
DO RECOMMENDATION	01-SEP-2000			ACCEPTABLE BASED ON FILE REVIEW	EGASM
BASED ON EI OF 2/25/99					
OC RECOMMENDATION	05-SEP-2000			ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

Establishment:

DMF No: AADA:
Responsibilities:
Profile: RSP OAI Status: NONE
Estab. Comment: (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
SUBMITTED TO DO	17-AUG-2000	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	24-AUG-2000	GMP			EGASM
DO RECOMMENDATION	20-SEP-2000			ACCEPTABLE BASED ON FILE REVIEW	ADAMSS
BASED ON 8/19-20/99 CDRH INSPECTION.					
OC RECOMMENDATION	21-SEP-2000			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

Establishment:

DMF No: [ ] AADA:
Responsibilities:
Profile: CTL OAI Status: NONE
Estab. Comment: (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
OC RECOMMENDATION	17-AUG-2000			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment:

DMF No: AADA:
Responsibilities:
Profile: GSP OAI Status: NONE
Estab. Comment: (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
OC RECOMMENDATION	17-AUG-2000			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment:

DMF No: AADA:
Responsibilities:

Profile: CTL OAI Status: NONE
Estab. Comment: RELEASE AND STABILITY TESTER OF THE STERILE WATER FOR INJECTION. (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-AUG-2000				LINDAV
OC RECOMMENDATION	17-AUG-2000			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment: 1810189
PHARMACIA AND UPJOHN CO
7000 PORTAGE ROAD
KALAMAZOO, MI 49001
DMF No: [ ] AADA:
Responsibilities: FINISHED DOSAGE PACKAGER
Profile: SVS OAI Status: NONE
Estab. Comment: SECONDARY PACKAGING SITE FOR THE DRUG PRODUCT. (on 30-JUN-2000 by D. LIN (HFD-580) 301-827-4230)

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NDA 21-288
Trelstar® LA 11.25 mg (triptorelin pamoate for injectable suspension)
Debio Recherche Pharmaceutique S.A.

There was no Statistical Review for Dissolution/Stability for this NDA.

APPEARS THIS WAY
ON ORIGINAL

DMF: [ ] DMF Type [ ]

Title: PLGA75-Poly (DL-Lactide-co-Glycolide)

1. **CHEM REVIEW #** 1

2. **REVIEW DATE:** 21-MAY-2001

3. **ITEM REVIEWED**

A. IDENTIFICATION

USAN:

Ingredient Dictionary name: Poly(dl-lactide-co-glycolide)

Manufacturer's code: PLGA75

Chemical name: 1,4-dioxane-2,5-dione, polymer with 3,6-dimethyl-1,4-dioxane-2,5-dione

CAS number: 26780-50-7

B. LOCATION IN DMF

Type of Submission	Date of Submission	Location of Information
Annual update	11-Jan-2000	Vol. 1.1

4. **PREVIOUS DOCUMENTS:**

Type of Document	Date of Document	Comment
Original submission	17-Dec-1996	
Amendment	04-Feb-1998	

5. **NAME AND ADDRESS OF DMF HOLDER AND REPRESENTATIVE(S):**

Name:

Address:

Representative:

Representative or U.S. Agent:

Name:

Address:

Contact Person's Name:

Regulatory Affairs Manager

Address: same

Telephone:

6. **DMF REFERENCED FOR:**

NDA:	21-288	
APPLICANT:	Debio Recherche Pharmaceutique S.A.	
LOA:	1/24/00	
DRUG PRODUCT NAME:	Trelstar LA	
DOSAGE FORM:	Lyopholized powder for suspension	CODE: 834
STRENGTH:	11.25 mg	
ROUTE OF ADMINISTRATION:	Intramuscular injection	CODE: 005

7. **SUPPORTING DOCUMENTS:** None

8. **CURRENT STATUS OF DMF:**
DATE OF LAST UPDATE OF DMF: January 11, 2000
DATE OF MOST RECENT LIST OF COMPANIES FOR WHICH LOA's HAVE BEEN PROVIDED: only Debio Recherche Pharmaceutique S.A.

9. **CONSULTS:** None

10. **COMMENTS:**
Reviewed poly(dl-lactide-co-glycolide). This DMF is reviewed in support of NDA 21-288.

11. **CONCLUSION:**
This DMF is adequate to support the NDA.

/S/ 5/21/01
David T. Lin, Ph.D.
Review Chemist, HFD-580

cc:
Orig. DMF # (2 copies)
HFD-580/Div. File NDA 21-288
HFD-580/CSO/JBest
HFD-580/Chemist/MJRhee/DTLin
R/D Init

/S/ 5/22/01
Moo-Jhong Rhee, Ph.D.
Team Leader, HFD-580

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information

NDA 21-288
Trelstar® LA 11.25 mg (triptorelin pamoate for injectable suspension)
Debio Recherche Pharmaceutique S.A.

See Chemistry review #1, Pg. 23 for Categorical Exemption for Environment Assessment.

/S/

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL