CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-137

Chemistry Review(s)

07-JUN-2002

CHEMISTRY REVIEW

NDA 21-137

Levolet® (Levothyroxine sodium tablets, USP)

Vintage Pharmaceuticals, Inc.

David B. Lewis, Ph.D.

Division of Metabolic and Endocrine Drug Products
(DMEDP, HFD-510)

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APPEARS THIS WAY
ON ORIGINAL

Chemistry Review Data Sheet

1. NDA 21-137

2. REVIEW #: 4

3. REVIEW DATE: 06/06/02

4. REVIEWER: David B. Lewis, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
ORIGINAL NDA	30/04/99
AMENDMENT	09/02/00
CMC REVIEW NO. 1	09/02/00
IR/DEFICIENCY LETTER	18/01/00
CMC REVIEW NO. 2	15/02/00
AE LETTER	10/03/00
AMENDMENT	25/09/00
AMENDMENT	17/10/00
AMENDMENT	19/21/00
CMC REVIEW NO. 3	17/03/01
NA LETTER	27/03/01

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
AMENDMENT	17/12/01
AMENDMENT	01/03/02
AMENDMENT	05/04/02
AMENDMENT	02/05/02
AMENDMENT	10/05/02
AMENDMENT	31/05/02

- The amendment dated December 17th, 2001 constituted the re-submission (official response to the NA Letter of March 17th, 2001).
- The amendment dated March 1st, 2002 provided updated stability data for nine lots of Levolet (levothyroxine sodium tablets, USP).
- The amendment dated April 5th, 2002 provided updated stability data for the 25-mcg tablets (23 month test station).
- The amendment dated May 2nd, 2002 provided the updated regulatory drug product specifications (release and shelf life).
- The amendment dated May 10th, 2002 provided representative container labels.
- The amendment dated May 31st, 2002 provided corrected regulatory drug product specifications and clarification of the dissolution methodology.

7. NAME & ADDRESS OF APPLICANT:

Name:	Vintage Pharmaceuticals, Inc.
Address:	3241 Woodpark Blvd., Charlotte, NC 28206
Representative:	Christopher J. Nascone
Telephone:	(256) 859-2222

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Levolet
b) Non-Proprietary Name (USAN): Levothyroxine sodium tablets, USP
c) Code Name/# (ONDC only): none (N/A)
d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 5
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505 (b) (2) with reference to NDA 21-210 (Unithroid®, Jerome Stevens Pharmaceuticals, Bohemia, NY). Unithroid® is an immediate-release solid oral dosage form marketed in the following strengths: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg/tablet.

10. PHARMACOL. CATEGORY: Thyroid

11. DOSAGE FORM: Immediate-release solid oral tablets

12. STRENGTH/POTENCY: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg per tablet

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: _X_ Rx ___OTC

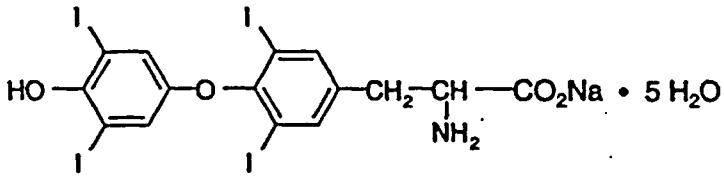
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note27]:

_____SPOTS product – Form Completed

__x__Not a SPOTS product

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

- Established name (USAN/INN): **Levothyroxine sodium**
- Inverted IUPAC Name: **L-Tyrosine, *O*-(4-hydroxy-3,5-diiodophenyl)-3',5'-diiodo-, monosodium salt, hydrate.**
- Molecular formula: **$C_{15}H_{10}I_4NNaO_4 \cdot 5H_2O$**
- Molecular weight(s): **888.96 g/mol (pentahydrate) and 798.86 g/mol (anhydrous material).**
- The chemical structure is as follows:



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II		Levothyroxine sodium, USP	3	Adequate	11/10/01	Drug substance
	III			3	Adequate	15/04/96	
	III			3	Adequate	29/06/94	
	III			3	Adequate	01/12/97	
	III			3	Adequate	24/07/94	
	III			3	Adequate	27/06/95	
	III			3	Adequate	03/09/98	
	III			3	Adequate	14/02/95	

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

Chemistry Review Data Sheet

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics			
EES	Acceptable	26/03/02	J. D. Ambrogio
Pharm/Tox	Approvable with proper labeling	14/02/00	R. Steigerwalt, Ph.D.
Biopharm	Acceptable	05/04/02	S. Johnson, Pharm. D.
LNC			
Methods Validation			
ODS (DMETS)	Acceptable*	04/06/02	A. Mahmud, R.Ph.
EA	Acceptable (Categorical exclusion)	08/02/00	D. Lewis, Ph.D.
Microbiology			

* The proposed proprietary name "Levolet" was judged acceptable; minor revisions to the container labels were suggested (ONDC concurred with these suggestions).

APPEARS THIS WAY
ON ORIGINAL

The Chemistry Review for NDA 21-137

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is recommended for approval from the standpoint of chemistry, manufacturing and controls. All product-specific cGMP inspections were satisfactory.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

Two revisions to the container labels should be made per ODS suggestion and ONDC concurrence: The designation of tablet strength should be highlighted according to a color code corresponding to the actual color of the tablets and the print size of the designation of strength should be larger than that used for the numerical count of tablets per container. See Draft Letter of Comments at the end of the review.

II. Summary of Chemistry Assessments

NDA 21-137 was originally submitted on April 30th, 1999. The first review cycle (CMC review No. 1) resulted in an IR letter (January 18th, 2000), to which a response was submitted (February 9th, 2000). CMC Review No. 2 (February 15th, 2000) resulted in an AE Letter (March 10th, 2000). The response(s) to the AE Letter were contained in three amendments (September 25th, October 17th, and December 19th, 2000), which were addressed in CMC Review No. 3 (March 17th, 2001). The 3rd CMC review resulted in the submission of a NA Letter (March 27th, 2001). The basis of the NA judgment was the Office of Compliance's (OC) WITHHOLD recommendation regarding the manufacturing facility. The amendment dated December 17th, 2001 constituted a re-submission and provided requested bioequivalence data (covered in a separate Biopharmaceutics review) and statements regarding the carried out run on the manufacturing site in conjunction with the 4th review cycle. While there were no outstanding CMC-related deficiencies remaining after CMC review No. 3, this review (CMC Review No. 4) addresses updated stability data and the current cGMP inspection status.

A. Description of the Drug Product(s) and Drug Substance(s)

The drug product is an immediate-release solid oral tablet, marketed in eleven (11) strengths, ranging from 25 to 300 mcg per tablet. The drug product is packaged in plastic bottles (100- and 1000-ct presentations). The drug substance (levothyroxine sodium, USP)

is manufactured and supplied by [ ] CMC information on the substance is contained in DMF — which was reviewed three times and found adequate to support NDA's for levothyroxine sodium tablets (Most recent review dated October 11th, 2001, D. Lewis, Ph.D., reviewer). The drug product contains the following excipients: microcrystalline cellulose, potassium iodide, croscarmellose sodium, magnesium stearate, and various FD&C and D&C aluminum lake dyes (colorants). The use of potassium iodide [ ], is addressed in the clinical review, and in the package insert (under warnings); [ ] The manufacturing process involves [ ] The key physico-chemical review issue associated with the drug product is chemical stability. The original NDA submission contained deficient primary stability data and the noted deficiencies were addressed in the amendments submitted between September 25th, 2000 through March 1st, 2002. The Vintage manufacturing facility was resubmitted for product-specific cGMP inspection; the site was found ACCEPTABLE by the District Office (DO), and by the OC.

B. Description of How the Drug Product is Intended to be Used

Levothyroxine sodium tablets are typically prescribed once daily, with a typical dose ranging from 12.5 to 200 mcg. Levothyroxine sodium has a narrow therapeutic index, and patients have their daily dose revisited periodically. Levolet (levothyroxine sodium tablets, USP) is proposed for marketing in the following strengths: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg per tablets. The drug product is packaged in 100-ct and 1000-ct bottles (HDPE plastic containers). The proposed expiration dating period is 24 months with storage at controlled room temperature (ca. 25°C, see USP 24, General Comments, pp. 11-12). The accumulated ICH stability data supports an expiry of 24 months for all proposed market strengths (100- and 1000-ct bottles). The 25-mcg tablets were supported by — months of acceptable ICH long-term stability data, due to time clock issues (impending user fee date); however, since the percent labeled claim after — months storage was approximately — %, 24 months of expiry was assigned to the 25-mcg tablets. The submission of — months of acceptable intermediate ICH stability studies (30°C and 60 % RH) supports the excursion range on the storage statement (15-30°C permitted).

C. Basis for Approvability or Not-Approval Recommendation

The application is recommended for approval for the following reasons:

- Adequate responses to the deficiencies noted in the IR letter (January 18th, 2000) and the AE Letter (March 10th, 2000).
- Acceptable cGMP status for the manufacturing facility located in Charlotte, NC.
- Submission of acceptable stability data for three lots apiece of 25-, 100-, and 300-mcg tablets, released without overage.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block: N/A

Signed off in DFS

C. CC Block: N/A

CC'd through DFS

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CHEMISTRY REVIEW

Chemistry Assessment Section

Application: NDA 21137/000
Stamp: 03-MAY-1999 Regulatory Due: 18-JUN-2002
Applicant: VINTAGE PHARMS
3241 WOODPARK BLVD
CHARLOTTE, NC 28206

Priority: 5S Org Code: 510
Action Goal: District Goal: 25-JAN-2001
Brand Name: LEVOLET(LEVOTHYROXINE SODIUM)25/30 MCG T
Established Name:
Generic Name: LEVOTHYROXINE SODIUM
Dosage Form: TAB (TABLET)
Strength: 25 - 300 MICROGRAMS

FDA Contacts:			
S. MCCORT	(HFD-510)	301-827-6415	, Project Manager
D. LEWIS	(HFD-510)	301-827-6420	, Review Chemist
D. WU	(HFD-510)	301-827-6375	, Team Leader

Overall Recommendation:

ACCEPTABLE on 10-APR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062
ACCEPTABLE on 26-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062
ACCEPTABLE on 17-DEC-2001 by J. D AMBROGIO (HFD-324) 301-827-0062
WITHHOLD on 13-FEB-2001 by S. FERGUSON (HFD-324) 301-827-0062
ACCEPTABLE on 19-JAN-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment:
DMF No:
AADA No:

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 03-JUN-1999
Decision: ACCEPTABLE
Reason: BASED ON PROFILE
Responsibilities: DRUG SUBSTANCE MANUFACTURER

Establishment:
DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-SEP-1999
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Responsibilities: DRUG SUBSTANCE OTHER TESTER

Establishment: 1038197
VINTAGE PHARMACEUTICALS INC
3241 WOODPARK BLVD
CHARLOTTE, NC 28206
DMF No:
AADA No:

Profile: TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 10-APR-2002
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Responsibilities: FINISHED DOSAGE MANUFACTURER

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Lewis
6/7/02 11:44:53 AM
CHEMIST
the application can be approved from the standpoint of chemistry.

David Lewis
6/7/02 11:47:59 AM
CHEMIST
Acting for S. Markofsky. Dr. Markofsky had done a partial secondary review of the application in May.

APPEARS THIS WAY
ON ORIGINAL

12-MAR-2001

DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #:21-137 **DATE REVIEWED:** 3-07-01

REVIEW #: 3 **REVIEWER:** David B. Lewis

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
AMENDMENT	09-25-00	09-26-00	
AMENDMENT	10-17-00	10-18-00	
AMENDMENT	12-19-00	12-21-00	

NAME & ADDRESS OF APPLICANT: Vintage Pharmaceuticals, Inc.
3241 Woodpark Boulevard
Charlotte, North Carolina 28206
(704) 596-0516 (Phone)
(704) 598-6237 (FAX)

DRUG PRODUCT NAME
Proprietary: Levolet™
Established: levothyroxine sodium tablets, USP
Code Name/#:
Chem.Type/Ther.Class:

PHARMACOL. CATEGORY/INDICATION: Treatment of hypothyroidism

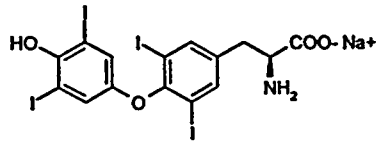
DOSAGE FORM: Oral tablet
STRENGTHS: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg

ROUTE OF ADMINISTRATION: Oral

Rx/OTC: X Rx __ OTC

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

Levothyroxine sodium



O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-*L*-tyrosine monosodium salt

$C_{15}H_{10}I_4NNaO_4$ 798.86 g/mol

SUPPORTING DOCUMENTS: See cover page for Chemistry Reviews No. 1 and 2.

RELATED DOCUMENTS (if applicable): See DMF table on page 2 of Chemistry Reviews # 1 and 2.

CONSULTS: None

REMARKS: Chemistry Review # 3 covers the Vintage Pharmaceuticals, Inc. responses to the Approvable (AE) Letter submitted to the firm on March 10th, 2000. The AE letter included five (5) deficiencies/requests for information. The response to the AE letter was provided in the amendment dated September 25th, 2000. This amendment included stability data (accelerated, intermediate, and long-term) for nine lots (3 apiece of 25, 100, and 300-mcg tablets). The 25-mcg lots were released with an [redacted] % of label claim. The amendment dated October 17th, 2000 provided a response to a telephone request dated October 10th, and includes stability data on three additional lots of 25-mcg tablets, released with T_4 assay values closer to 100 % (average of [redacted] % of label claim). The 10-17-00 amendment also provided information, regarding analytical methods for determining impurities. This information was not requested in the AE letter, and is not covered in the review. The amendment dated December 19th, 2000 provided updated stability data on the three lots of 25-mcg tablets provided in the 10-17-00 amendment. As of February 13th, 2001, the Office of Compliance has withheld approval of the Vintage manufacturing facility (Charlotte, NC), with the following comment: [redacted]

CONCLUSIONS & RECOMMENDATIONS: FROM A CHEMISTRY STANDPOINT, THIS NDA CAN NOT BE APPROVED. Although the responses to the deficiencies outlined in the AE letter dated 3-10-00 are adequate, regarding chemistry, manufacturing and controls information, the Office of Compliance has recommended withholding of approval of the NDA due to an unacceptable cGMP status (see attached EES printout). The NDA can not be approved until the compliance issues have been addressed by the firm to the satisfaction of the Atlanta District Office, and to the Office of Compliance. The firm should be reminded that the stability data for the new lots submitted in the amendments dated 9-25-00 and 10-17-00 should be updated in the resubmission.

cc:
Org. NDA 21-137
HFD-510/ Division File
HFD-820/Chemist/D Lewis/DGWu
HFD-510/S. McCort

R/D Init by:
Filename: NDA 21-137 CR # 3.doc

/S/

David B. Lewis, Ph.D.
Review Chemist

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DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-137 **DATE REVIEWED:** 2-10-00

REVIEW #: 1 **REVIEWER:** David B. Lewis

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	04-30-99	05-05-99	05-20-99
AMENDMENT	02-09-00		

NAME & ADDRESS OF APPLICANT: Vintage Pharmaceuticals, Inc.
3241 Woodpark Boulevard
Charlotte, North Carolina
28206
(704) 596-0516 (Phone)
(704) 598-6237 (FAX)

DRUG PRODUCT NAME
Proprietary: Levolet™
Established: levothyroxine sodium, USP
Code Name/#:
Chem.Type/Ther.Class: 55

PHARMACOL. CATEGORY/INDICATION: Treatment of hypothyroidism

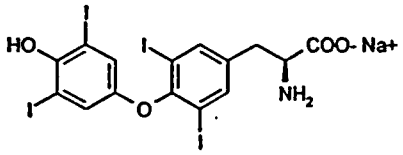
DOSAGE FORM: Oral tablet
STRENGTHS: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg

ROUTE OF ADMINISTRATION: Oral

Rx/OTC: _X_ Rx __ OTC

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

Levothyroxine sodium
O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-*L*-tyrosine monosodium salt



$C_{15}H_{10}I_4NNaO_4$ 798.86 g/mol

SUPPORTING DOCUMENTS: Letters of authorization allowing reference to the following Drug Master Files (DMF's): ——— levothyroxine sodium, USP):

RELATED DOCUMENTS (if applicable):

Type/Number	Subject	Holder	Status	Review Date
DMF			Adequate	4-15-96
DMF			Adequate	6-29-94
DMF			Adequate	12-01-97
DMF			Adequate	7-24-94
DMF			Adequate	6-27-95
DMF			Adequate	9-03-98
DMF			Adequate	2-14-95
DMF	Levothyroxine sodium, USP		Adequate	4-29-99

CONSULTS: Trade name Consult (OPDRA)

REMARKS: Vintage Pharmaceuticals, Inc. (Charlotte, NC) is submitting NDA 21-137 in accordance with the Federal Register Notice of August 14th, 1997 (Volume 62, Number 157), in which drug products containing levothyroxine sodium were re-classified as new drugs, and were subject to formal NDA application and FDA review. The application is classified as a New Drug Application (21 CFR § 314.50), and is classified as Type 505(b)(2). Previously, this drug product has been submitted to the FDA as IND 51,923. Vintage Pharmaceuticals, Inc. has been marketing levothyroxine sodium tablets in various strengths (25 through 300 mcg) as a non-approved drug for several years. Pursuant to the Federal Register Notice, Vintage reformulated the drug product, in order to attain a higher degree of stability without the inclusion of a manufacturing overage. The drug substance (levothyroxine sodium, USP) is manufactured and supplied by CMC information contained in DMF The drug product consists

21-137 contains several deficiencies, concerning chemistry, manufacturing and controls information, which are addressed in the Draft Letter of Information Requests which were FAXed to the sponsor on 1-18-00. Letters of Authorization are provided, allowing reference to DMF (Active Pharmaceutical Ingredient),

are not included; these letters should be provided. An EER (acceptable) for the manufacturing and testing facilities is attached (dated 1-19-00).

APPEARS THIS WAY
ON ORIGINAL

CONCLUSIONS & RECOMMENDATIONS: This application is deficient, regarding chemistry, manufacturing and controls information. See Draft Letter of information requests that has been transmitted to the sponsor (1-18-00). The applicant has provided a response to the requests for information (amendment dated 2-09-00); however, there is not adequate time for the chemist to review these responses at this time and include the new information in Chemistry Review No. 1. The review of the IR responses will be contained in Chemistry Review No. 2.

cc:
Org. NDA 21-137
HFD-510/ Division File
HFD-820/Chemist/D Lewis/DGWu
HFD-510/S. McCort

/S/ 2-11-00
David B. Lewis, Ph.D.
Review Chemist

R/D Init by: /S/ 2-11-00
Filename: NDA 21-137 Chemistry Review # 1.doc

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CHEMISTRY REVIEW

Chemistry Assessment Section

Application: NDA 21137/000 Priority: 5S Org Code: 510
Stamp: 03-MAY-1999 Regulatory Due: 18-JUN-2002 Action Goal: District Goal: 25-JAN-2001
Applicant: VINTAGE PHARMS
3241 WOODPARK BLVD
CHARLOTTE, NC 28206
Brand Name: LEVOLET(LEVOTHYROXINE SODIUM)25/30 MCG T
Established Name:
Generic Name: LEVOTHYROXINE SODIUM
Dosage Form: TAB (TABLET)
Strength: 25 - 300 MICROGRAMS

FDA Contacts:			
S. MCCORT	(HFD-510)	301-827-6415	, Project Manager
D. LEWIS	(HFD-510)	301-827-6420	, Review Chemist
D. WU	(HFD-510)	301-827-6375	, Team Leader

Overall Recommendation:

ACCEPTABLE on 10-APR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062
ACCEPTABLE on 26-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062
ACCEPTABLE on 17-DEC-2001 by J. D AMBROGIO (HFD-324) 301-827-0062
WITHHOLD on 13-FEB-2001 by S. FERGUSON (HFD-324) 301-827-0062
ACCEPTABLE on 19-JAN-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: DMF No:
AADA No:

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 03-JUN-1999
Decision: ACCEPTABLE
Reason: BASED ON PROFILE
Responsibilities: DRUG SUBSTANCE MANUFACTURER

Establishment: DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-SEP-1999
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Responsibilities: DRUG SUBSTANCE OTHER TESTER

Establishment: 1038197 DMF No:
VINTAGE PHARMACEUTICALS INC AADA No:
3241 WOODPARK BLVD
CHARLOTTE, NC 28206

Profile: TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 10-APR-2002
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Responsibilities: FINISHED DOSAGE MANUFACTURER

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: NDA 21137/000
Stamp: 03-MAY-1999 Regulatory Due: 10-MAR-2000
Applicant: VINTAGE PHARMS
3241 WOODPARK BLVD
CHARLOTTE, NC 28206

Priority: 5S Org Code: 510
Action Goal: District Goal: 10-JAN-2000
Brand Name: LEVOLET(LEVOTHYROXINE SODIUM)25/30 MCG T
Established Name:
Generic Name: LEVOTHYROXINE SODIUM
Dosage Form: TAB (TABLET)
Strength: 25 - 300 MICROGRAMS

FDA Contacts:

S. MCCORT	(HFD-510)	301-827-6415	, Project Manager
D. LEWIS	(HFD-510)	301-827-6420	, Review Chemist
D. WU	(HFD-510)	301-827-6375	, Team Leader

Overall Recommendation:

ACCEPTABLE on 19-JAN-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment:
DMF No: —
AADA No:

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 03-JUN-1999
Decision: ACCEPTABLE
Reason: BASED ON PROFILE
Responsibilities:

Establishment:
DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-SEP-1999
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Responsibilities: —

Establishment: 1038197
VINTAGE PHARMACEUTICALS INC
3241 WOODPARK BLVD
CHARLOTTE, NC 28206
DMF No:
AADA No:

Profile: TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 19-JAN-2000
Responsibilities: FINISHED DOSAGE MANUFACTURER

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

APPEARS THIS WAY
ON ORIGINAL