CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-116

CORRESPONDENCE

12.20.02 AEV

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-116

Lloyd Incorporated
Attention: Joseph Denhart, Ph.D.
Vice President, Regulatory Affairs
P.O. Box 130
604 West Thomas Ave.
Shenandoah, Iowa 51601-0130

Dear Dr. Denhart:

Please refer to your approved New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyro-Tabs (levothyroxine sodium tablets, USP).

We also refer to your April 22, May 27, and September 25 and 25, 2002, amendments containing stability information, and we refer to our October 24, 2002, approval letter for this application.

We have reviewed your stability data and have established the following expiry dating for the finished drug products:

25 mcg tablets
50, 75, 88 mcg tablets
100, 112, 125, 150, 175, 200, 300 mcg tablets

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

David Orloff
12/20/02 05:47:49 PM

9/25/02 DR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-116

DISCIPLINE REVIEW LETTER

Lloyd Incorporated
Attention: Dr. Joseph W. Denhart
Vice President Regulatory Affairs & Quality Assurance
604 West Tomas Avenue
Shenandoah, Iowa 51601

Dear Dr. Denhart:

Please refer to your August 20, 1999, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyro-Tabs (levothyroxine sodium tablets, USP).

We also refer to your submissions dated October 5 and 30, 2001.

Our review of the Biopharmaceutics section of your application is complete. The Office of Clinical Pharmacology and Biopharmaceutics has reviewed this NDA and finds that the overall "Human Pharmacokinetics" section is acceptable. We have established the dissolution specification for THYRO-TABS as follows:

Table 1: USP 24 Supplement 1	
Medium:	0.01 N HCl containing 0.2% sodium lauryl sulfate
Volume:	500 mL
Apparatus:	2 (paddles)
Speed:	50 RPM
Tolerances:	— Q) of the labeled amount of levothyroxine sodium is dissolved ir —

- Please indicate your acceptance of these specifications in an amendment to your pending NDA or provide information to support a different specification.

- We have made a number of editorial changes to the LEVOTHYROXINE SODIUM TABLETS package insert template labeling since the last version you received. Most of the changes are typographical. Please revise the package insert for your application according to the enclosed draft labeling. In addition to your written response, we would appreciate receiving an electronic copy of the revised labeling in both MSWord and Adobe Acrobat portable document format (*pdf*).

If you wish to receive an electronic copy by email of the template labeling in MSWord format, please contact Steve McCort at 301-827-6415.

Please note that the mailing address for the Division has changed slightly and is as follows:

Center for Drug Evaluation and Research/FDA
Division of Metabolic and Endocrine Drug Products (HFD-510)
Attention: Fishers Document Room 8B-45
5600 Fishers Lane
Rockville, MD 20857

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE

13 Draft Labeling Page(s) Withheld

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

/s/

Enid Galliers
9/25/02 07:16:01 PM

LLOYD
INCORPORATED
(712) 246-4000
P.O. BOX 130 • 604 WEST THOMAS AVE. • SHENANDOAH, IOWA 51601-0130 U.S.A. • FAX (712) 246-5245

27 May 2002

David Orloff, MD, Division Director
Division of Metabolic and Endocrine Drug Products
HDF-150, Department Control Room 14B-19
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Attention: Mr. Steve McCort, Project Manager
Division of Metabolic and Endocrine Drug Products

Subject: NDA 21-116
Amendment Submission No. 19
Revised Labeling for Thyro-Tabs®
(levothyroxine sodium tablets, USP)

Dear Dr. Orloff:

This submission is an amendment to our pending NDA providing the revised labeling for Thyro-Tabs® (levothyroxine sodium tablets, USP) as requested by Mr. Steve McCort on 25 April 2002. The revision consists of incorporating the package insert template edited 4 February 2002 and forwarded to Lloyd, Inc., on 25 April 2002.

Enclosed with this submission are the archival copy and three review copies; one each for the CMC section, Pharmacology Section, and Pharmacokinetic Section. Four complete copies of the amended labeling are provided in the archival copy. We certify that a field copy of this submission has been provided to the Kansas City District office under separate cover.

Correspondence concerning this NDA should be directed to Dr. Joseph W. Denhart, Vice President Regulatory Affairs and Quality Assurance or Stuart Johnson, Vice President Operations at (800) 831-0004 or (712) 246-4000.

Sincerely,

LLOYD, Inc.

W. Eugene Lloyd, D.V.M., Ph.D.
CEO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
LLOYD, Inc., of Iowa	27 May 2002
TELEPHONE NO. *(Include Area Code)* (712) 246-4000	**FACSIMILE (FAX) Number** *(Include Area Code)* (712) 246-5245
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 604 West Tomas Avenue Shenandoah, Iowa, USA 51601	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE N/A

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* NDA 21-116

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
levothyroxine sodium tablets, USP	Thyro-Tabs ®

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
levothyroxine sodium, USP	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Immediate release tablets	25, 50, 75, 88, 100, 112, 125, 150, 175, 200, 300 mcg	Oral

(PROPOSED) INDICATION(S) FOR USE:

Hypothyroidism, Thyroid Goiter, Thyroid Cancer

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* ☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☒ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug	Holder of Approved Application
N/A	N/A

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: N/A

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA) N/A

REASON FOR SUBMISSION Thyro-Tab Draft Labeling (Amendment Submission #19)

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Labeling *(check one)* ☒ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (k)(3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. Financial Information (21 CFR Part 54)
	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL/AGENT	TYPED NAME AND TITLE	DATE
W E Lloyd	W.E. Lloyd, DVM, PhD, Chairman, CEO	27 May 2002

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
604 West Thomas Avenue, Shenandoah, Iowa 51601	(712) 246-4000

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER, HFD-94
12420 Parklawn Dr., Room 3046
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 356h (4/00)

206 Draft Labeling Page(s) Withheld

5/21/02 ACK'D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-116

Lloyd Incorporated
Attention: W. E. Lloyd, D.V.M., Ph.D.
Chairman, CEO
P.O. Box 130
604 West Thomas Avenue
Shenandoah, Iowa 51601-0130

Dear Dr. Lloyd:

We acknowledge receipt on April 24, 2002, of your April 22, 2002, resubmission to your new drug application (NDA) for Thyro-Tabs (levothyroxine sodium tablets).

This resubmission contains additional chemistry and biopharmaceutics information submitted in response to our June 20, 2000, action letter.

We consider this a complete class 2 response to our action letter. Therefore, the user fee goal date is October 24, 2002.

If you have any questions, call me at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Enid Galliers
5/21/02 08:06:22 PM

11.27.01

LABELING RECOMMENDATIONS FOR NDA 21-116 - THYROTABS

For NDA 21-116 we are requesting a revision of your package insert for THYROTABS to conform with our template labeling for levothyroxine sodium which we have recently revised. We are sending you a copy of the revised template labeling. you submit your revised labeling as a labeling supplement that incoporates the revisions mad in the template labeling. The labeling supplement should include the package insert plus all package labels (include colored copies). In addition send under separate cover as a desk copy the labeling submission to Steve McCort, Project Manager. The desk copy to Mr. McCort should also include a copy of the labeling on a 3.5 diskette. The package insert should be formatted in Microsoft word 7.0 and PDF format. The package labeling should be formatted in PDF format only.

If you have any questions please contact Steve McCort, Project Manager, at 827-6415.

OK TO FAX:

David G. Orloff, M.D.
Division Director, HFD-510

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/s/

Stephen McCort
11/27/01 02:41:30 PM
CSO

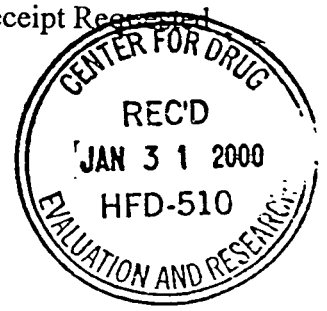
LLOYD
INCORPORATED
(712) 246-4000
P.O. BOX 130 • 604 WEST THOMAS AVE. • SHENANDOAH, IOWA 51601-0130 U.S.A. • FAX (712) 246-5245

ORIGINAL

ORIG AMENDMENT
SU

25 January 2000

Return Receipt Requested



John Jenkins, MD, Acting Division Director
Food and Drug Administration
Division of Metabolic and Endocrine Drug Products, HFD-510
Document Control Room 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

ATTENTION: Steve McCort, Project Manager
Division of Metabolic and Endocrine Drug Products, HFD-510

Subject: **NDA 21-116**
Amendment, Submission No. 4
Thyro-Tabs® (levothyroxine sodium tablets, USP)
(25, 50, 75, 100, 125, 150, 175, 200, and 300 mcg)

Dear Dr. Jenkins:

This submission provides the four month safety update in accordance with the requirements of 21 CFR 314.50(d)(5)(vi)(b).

No new clinical studies have been conducted by LLOYD, Inc., during the last four months. A review of the literature pertaining to safety of levothyroxine sodium has been conducted covering the period from 19 August to 31 December 1999 to fulfill the safety update requirement.

Correspondence concerning this NDA should be directed to Dr. Joseph W. Denhart, Vice-President Regulatory Affairs and Quality Assurance, LLOYD, Inc., 604 W. Thomas Avenue, P.O. Box 130, Shenandoah, Iowa 51601-0130. He or I can be contacted by telephone at (712) 246-4000, or by facsimile at (712) 246-5245.

Seen my 5/22/2000
rec'd
LS
5/26/2000

REVIEWS COMPLETED

OSD ACTION:
☐ LETTER ☐ M.A.I. ☐ MEMO

OSD INITIALS DATE

Respectfully,

LLOYD, Inc.

W. E. Lloyd by Ronald D. Ketchum

W. E. Lloyd, DVM, PhD
CEO

WEL/JWD:sc

LLOYD
INCORPORATED
(712) 246-4000
P.O. BOX 130 • 604 WEST THOMAS AVE. • SHENANDOAH, IOWA 51601-0130 U.S.A. • FAX (712) 246-5245

14 October 1999

Ronald W. Steigerwalt, PhD
Pharmacology Team Leader
Food and Drug Administration
Division of Metabolic and
Endocrine Drug Products, HFD-510
Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 21-116, 08 October 1999
Request for information

Dear Dr. Steigerwalt:

This letter is in regard to the 08 October 1999 fax from Steve McCort, Project Leader, requesting information concerning "Recommendation for submission of preclinical data to support Levothyroxine products for replacement therapy."

Please refer to volume 6 of 31 of our NDA submission on page 18 Section 5.1.3. Nonclinical Toxicology Studies. We noted that, "No formal nonclinical toxicology studies were identified in the literature search." As noted on page 7 of this volume under Section 5.1.1. Introduction, a search of relevant English language articles from 1966 to 1999 of MEDLINE and EMBASE databases was done. The results of the search including printed abstracts were provided in Appendix 5.1.7.1. The search strategy including terms used in the search was presented in Appendix 5.1.7.2.

The search for nonclinical toxicology articles was repeated after receiving the fax. The search did not provide any nonclinical toxicology articles. Please let us know if you believe we have used an incorrect search strategy.

Since we did not find any pertinent articles in the literature search we have not made any reference to specific animal data in our labeling.

Thank you for your consultation in this regard. Please call Dr. Joseph W. Denhart at 712-246-4000 or fax us at 712-246-5245 as to how we should proceed in this matter.

Sincerely,

LLOYD, Inc.

W.E. Lloyd, DVM, PhD
CEO

cc:
Archival NDA 21-116
HFD-510/Div. Files
HFD-510/S.McCort
HFD-510/Reviewers and Team Leaders
DISTRICT OFFICE

Drafted by: ddk/August 23, 1999
Initialed by:E.Galliers 8.23.99
final:DK 8.24.99
filename: 21116AC

ACKNOWLEDGEMENT (AC)

MC Cert

AUG 24 1999

NDA 21-116

Lloyd, Inc. of Iowa
Attention: W.E. Lloyd, DVM, Ph.D.
Chairman, CEO
604 West Thomas
Shenandoah, Iowa, USA 51601-0130

Dear Dr. Lloyd:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Thryo-Tabs® (levothyroxine sodium tablets) 25, 50, 75, 100, 125, 150, 175, 200, and 300 mcg
Therapeutic Classification:	Standard (S)
Date of Application:	August 19, 1999
Date of Receipt:	August 20, 1999
Our Reference Number:	NDA 21-116

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 19, 1999, in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be June 20, 2000, and the secondary user fee goal date will be August 20, 2000.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within 120 days of receipt of your pediatric drug development plan, we will notify you of the pediatric studies that are required under section 21 CFR 314.55.

If you believe that this drug qualifies for a waiver of the study of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We

will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov.cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. If you do not submit a Proposed Pediatric Study Request within 120 days from the date of this letter, we will presume that you are not interested in obtaining pediatric exclusivity and will notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

151 /or

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research