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(1) osteoporosis as being able to finger a patient who (2) really should be a candidate for a bone forming agent (3) rather than for an anti-resorptive agent.

(4) ACTING CHAIRPERSON MOLITCH: Other (5) comments?

(6) Dr. Orloff.

(7) DR. ORLOFF: If there are no further (8) comments, I'd just like to make a couple of closing (9) remarks.

(10) I want to thank everyone again for (11) participating in this process, the members of the (12) Advisory Committee, the consultants sitting around the (13) table, as well as the consultants who are sitting with (14) the sponsor today.

(15) I also want to recognize and applaud the (16) collegial and successful collaboration that's gone on (17) between the division and the sponsor to date and to (18) say that I hope it continues.

(19) So, again, thank you all and good (20) afternoon.

(21) ACTING CHAIRPERSON MOLITCH: Ms. Reedy.

(22) MS. REEDY: People at the table, if you

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(1) would like us to ship to you again your documents, (2) please put your name on top and indicate so. If you (3) would like us to shred them for you, simply leave them (4) there on your chair.

(5) (Whereupon, at 3:51 p.m., the Advisory (6) Committee meeting was concluded.)

Look-See Concordance Report

UNIQUE WORDS: 3,597
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SINGLE FILE CONCORDANCE

CASE SENSITIVE

NOISE WORD LIST(S): NOISE.NOI

INCLUDES ALL TEXT OCCURRENCES

IGNORES PURE NUMBERS

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NDA/EFFICACY SUPPLEMENT ACTION PACKAGE CHECKLIST

NDA <u>21-318</u> /SE _____	
Drug <u>Forteo (teriparatide) Inj.</u>	Applicant <u>Lilly</u>
RPM <u>151</u>	Phone <u>827-6392</u>
☒ 505(b)(1) ☐ 505(b)(2) Reference listed drug _____	
☐ Fast Track	☐ Rolling Review Review priority: ☒ S ☐ P
Pivotal IND(s) _____	
Application classifications: Chem Class <u>3</u> Other (e.g., orphan, OTC) _____	PDUFA Goal Dates: Primary <u>March 20, 2023</u> Secondary _____

Arrange package in the following order:

Indicate N/A (not applicable),
X (completed), or add a
comment.

GENERAL INFORMATION:

- ♦ User Fee Information: ☒ User Fee Paid
☐ User Fee Waiver (attach waiver notification letter)
☐ User Fee Exemption
- ♦ Action Letter..... ☒ AP ☐ AE ☐ NA
- ♦ Labeling & Labels

FDA revised labeling and reviews.....	<u>4/29/02</u>
Original proposed labeling (package insert, patient package insert)	<u>11/29/00</u>
Other labeling in class (most recent 3) or class labeling.....	<u>None</u>
Has DDMAC reviewed the labeling? <u>Labeling Marketing 4/1/02</u> ☒ Yes (include review) ☐ No	
Immediate container and carton labels	<u>4/29/02 3/15/01</u>
Nomenclature review	<u>+ 12/12/00</u>
- ♦ Application Integrity Policy (AIP) ☐ Applicant is on the AIP. This application ☐ is ☒ is not on the AIP.
 Exception for review (Center Director's memo).....
 OC Clearance for approval.....

- ◆ Status of advertising (if AP action) ☐ Reviewed (for Subpart H – attach review) ☒ Materials requested in AP letter
- ◆ Post-marketing Commitments
 Agency request for Phase 4 Commitments..... 10/24/01 AE Letter
 Copy of Applicant's commitments 5/6/02
- ◆ Was Press Office notified of action (for approval action only)?..... ☒ Yes ☐ No
 Copy of Press Release or Talk Paper In Action Package
- ◆ Patent
 Information [505(b)(1)] 11/16/00
 Patent Certification [505(b)(2)] —
 Copy of notification to patent holder [21 CFR 314.50 (i)(4)] —
- ◆ Exclusivity Summary 9/21/01
- ◆ Debarment Statement 11/21/00
- ◆ Financial Disclosure
 No disclosable information See Med. Review
 Disclosable information – indicate where review is located X
- ◆ Correspondence/Memoranda/Faxes X
- ◆ Minutes of Meetings —
 Date of EOP2 Meeting 10/15/96
 Date of pre NDA Meeting 7/12/00 + 12/15/98
 Date of pre-AP Safety Conference 10/17/01
- ◆ Advisory Committee Meeting Yes
 Date of Meeting 7/27/01
 Questions considered by the committee Page 296
 Minutes or 48-hour alert or pertinent section of transcript Yes
- ◆ Federal Register Notices, DESI documents None

CLINICAL INFORMATION:

Indicate N/A (not applicable),
 X (completed), or add a
 comment.

10/17/01

- ◆ Summary memoranda (e.g., Office Director's memo, Division Director's memo, Group Leader's memo) 4/24/02 + 10/1/01
- ◆ Clinical review(s) and memoranda 9/10/01 + 9/14/01

Continued ⇨

- ◆ Safety Update review(s) 4/24/02
- ◆ Pediatric Information
 - ☐ Waiver/partial waiver (Indicate location of rationale for waiver) ☐ Deferred Pediatric Page..... 5/2/02
 - ☐ Pediatric Exclusivity requested? ☐ Denied ☐ Granted ☐ Not Applicable
- ◆ Statistical review(s) and memoranda 6/12/01
- ◆ Biopharmaceutical review(s) and memoranda..... 6/30/01
- ◆ Abuse Liability review(s) None
 Recommendation for scheduling —
- ◆ Microbiology (efficacy) review(s) and memoranda 6/23/01
- ◆ DSI Audits 7/13/01
☒ Clinical studies ☐ bioequivalence studies

CMC INFORMATION:

Indicate N/A (not applicable),
X (completed), or add a
comment.

- ◆ CMC review(s) and memoranda 4/17/02
- ◆ Statistics review(s) and memoranda regarding dissolution and/or stability NA
- ◆ DMF review(s) 4/30/02
- ◆ Environmental Assessment review/FONSI/Categorical exemption 9/21/02
- ◆ Micro (validation of sterilization) review(s) and memoranda 6/23/01
- ◆ Facilities Inspection (include EES report)
 Date completed ☒ Acceptable ☐ Not Acceptable
- ◆ Methods Validation ☐ Completed ☒ Not Completed

PRECLINICAL PHARM/TOX INFORMATION:

Indicate N/A (not applicable),
X (completed), or add a
comment.

- ◆ Pharm/Tox review(s) and memoranda 9/7/01
- ◆ Memo from DSI regarding GLP inspection (if any) None

- ◆ Statistical review(s) of carcinogenicity studies 5/14/01
- ◆ CAC/ECAC report 7/5/01 & 11/5/01

APPEARS THIS WAY
ON ORIGINAL

DUPLICATE

Lilly

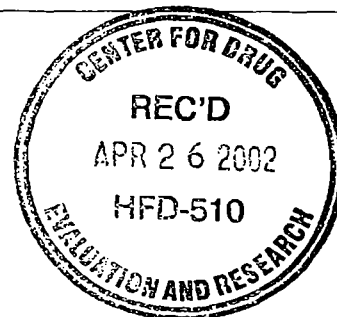
www.lilly.com

Lilly Research Laboratories
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285 U.S.A.

Phone 317 276 2000

April 25, 2002

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine
Drug Products, HFD-510
Attn: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857-1706



Re: NDA 21-318, LY333334 [rDNA (teriparatide injection)]

Reference is made to the submission (November 29, 2000) of an original New Drug Application (NDA) for FORTEO™ for the indication of the treatment of osteoporosis in postmenopausal women and in men.

In follow-up to the meeting with FDA on November 28, 2001, we are hereby providing you physician education materials for your information. Under separate cover, we are also submitting this information to DDMAC for their review.

Please call me at (317) 277-4418 if you require any additional information or if there are any questions. Alternatively, you may contact Dr. Gregory G. Enas, Ph.D., Director, U.S. Regulatory Affairs, at (317) 276-4038.

Sincerely,

ELI LILLY AND COMPANY

Sunita Zalani

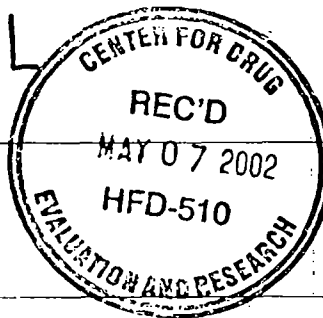
Sunita Zalani, Ph.D.
Regulatory Research Scientist
U.S. Regulatory Affairs

cc: Desk copies:
Mr. Randy Hedin
Dr. Bruce Stadel
Dr. Bruce Schneider

Answers That Matter.

ORIGINAL

www.lilly.com



Lilly

Lilly Research Laboratories
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285 U.S.A.

Phone 317 276 2000

May 6, 2002

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine
Drug Products, HFD-510
Attn: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857-1706



Re: NDA 21-318, Forteo™, LY333334, Teriparatide (rDNA origin) Injection

Reference is made to the submission (November 29, 2000) of an original New Drug Application (NDA) for FORTEO™ for the indication of

Based on a request from Dr. Bruce Stadel and Mr. Randy Hedin on May 3 we are hereby providing a document that outlines Lilly's Phase 4 commitments. We are also listing Lilly's other commitments for Forteo.

Please call me at (317) 277-4418 if you require any additional information or if there are any questions. Alternatively, you may contact Dr. Gregory G. Enas, Ph.D., Director, U.S. Regulatory Affairs, at (317) 276-4038.

Sincerely,

ELI LILLY AND COMPANY

Sunita Zalani

Sunita Zalani, Ph.D.
Regulatory Research Scientist
U.S. Regulatory Affairs

cc: Desk copies:
Dr. Eric Colman
Mr. Randy Hedin
Dr. Bruce Schneider
Dr. Bruce Stadel

TYPE OF SUBMISSION
(check one) ☐ ORIGINAL ☐ REVISION

2002-05-06

Answers That Matter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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

FOR FDA USE ONLY

APPLICATION NUMBER
21-318

APPLICANT INFORMATION

NAME OF APPLICANT Eli Lilly and Company	DATE OF SUBMISSION May 6, 2002
TELEPHONE NO. (Include Area Code) 317-276-2000	FACSIMILE (FAX) Number (Include Area Code) 317-276-1652
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): Lilly Corporate Center Indianapolis, IN 46285	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) NDA 21-318		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name) teriparatide injection	PROPRIETARY NAME (trade name) IF ANY FORTEO	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)	CODE NAME (If any) LY333334	
DOSAGE FORM: teriparatide injection	STRENGTHS: 3 ml cartridge (20 microgram dose)	ROUTE OF ADMINISTRATION: subcutaneous injection

(PROPOSED) INDICATION(S) FOR USE:

Treatment of

APPLICATION INFORMATION

APPLICATION TYPE (check one) ☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)	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	
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	
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ PRIOR APPROVAL (PA)	
REASON FOR SUBMISSION Phase 4 Commitments	
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.

IND /
DMF

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

Number of Pages
Redacted 11



Confidential,
Commercial Information

FDA APPROVES TERIPARATIDE TO TREAT OSTEOPOROSIS

FDA has approved teriparatide for the treatment of osteoporosis in postmenopausal women who are at high risk for having a fracture. The drug is also approved to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture.

Patients with osteoporosis suffer from progressive thinning of bones and are at an increased risk of spine, wrist, and hip fractures. Teriparatide is the first approved agent for the treatment of osteoporosis that stimulates new bone formation. Teriparatide is administered by injection once a day in the thigh or abdomen. The recommended dose is 20 mcg per day.

Teriparatide is a portion of human parathyroid hormone (PTH), which is the primary regulator of calcium and phosphate metabolism in bones. Daily injections of teriparatide stimulate new bone formation leading to increased bone mineral density.

Drugs approved to treat osteoporosis must be shown to preserve or increase bone density and maintain bone quality. The effects of teriparatide on bone mineral density and fractures were studied in 1,637 postmenopausal women with osteoporosis who were treated for a median time of 19-months and 437 men with primary or hypogonadal osteoporosis who were treated for ten months. Patients treated with 20 mcg of teriparatide per day, along with calcium and vitamin D supplementation, had statistically significant increases in bone mineral density (BMD) at the spine and hip when compared to patients taking only calcium and vitamin D supplementation. Clinical trials also demonstrated that teriparatide reduced the risk of vertebral and non-vertebral fractures in

postmenopausal women. The effects of teriparatide on fracture risk have not been studied in men.

In animal studies with teriparatide, there was an increase in the number of rats developing osteosarcoma, a rare but serious cancer of the bone. In the human studies, no osteosarcomas were reported, but the possibility that humans treated with teriparatide may face an increased risk of developing this cancer cannot be ruled out. This safety issue is highlighted in a black box warning in the drug's label for health professionals and explained in a brochure, called a Medication Guide, for patients. To help ensure that patients are aware of important information about teriparatide, the Medication Guide will be distributed by the pharmacist each time the drug is dispensed. Because people with growing bones (i.e., children and adolescents) and people with Paget's disease of the bone have a higher risk for developing osteosarcoma, it is important that they not be treated with teriparatide.

Most side effects reported in association with teriparatide in clinical trials were mild and included nausea, dizziness, and leg cramps. During the clinical trials, early discontinuation due to adverse events occurred in 5.6% of patients assigned to placebo and 7.1% of patients taking teriparatide.

Persons with hypercalcemia, women who are pregnant or nursing, or persons who have ever been diagnosed with bone cancer or other cancers that have spread to the bones, should not use teriparatide. Because the effects of long-term treatment with teriparatide are not known at this time, therapy for more than 2 years is not recommended.

Teriparatide is manufactured by Eli Lilly and Company of Indianapolis, Ind., and will be marketed under the trade name Forteo.

**APPEARS THIS WAY
ON ORIGINAL**

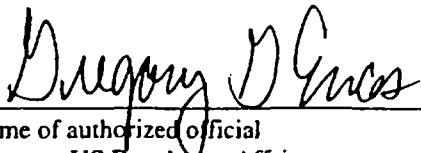
ITEM 13: PATENT INFORMATION

NDA 21-318

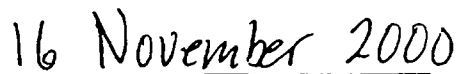
FORTÉO™

(teriparatide)

The undersigned declares that there are no patents covering the product which is the subject of the present NDA for which approval is being sought.



Name of authorized official
Director, US Regulatory Affairs



Date

ITEM 14: PATENT CERTIFICATION

NDA 21-318

FORTÉO™ (teriparatide)

Eli Lilly and Company (Lilly) claims a three (3) year period of exclusivity for the use of FORTÉO™ (teriparatide injection 20 µg) in the treatment of _____, as provided by 21 C.F.R. 314.108(b)(5).

Clinical trials conducted which are essential to approval of this NDA are identified as follows:

Pivotal Placebo Controlled Studies

B3D-MC-GHAC: Effects of LY333334 in the Treatment of Postmenopausal Women with Osteoporosis

B3D-MC-GHAJ: Effects of LY333334 in the Treatment of Men with Osteoporosis

Supporting Studies

B3D-MC-GHAA: Safety and Pharmacological Effects of LY333334 on Biochemical Markers of Bone Metabolism in Healthy, Postmenopausal Women

B3D-MC-GHBJ: Interim Report: Extended Follow-up of Patients in LY333334 Trials

As required by 21 C.F.R. 314.50(j)(4), Lilly certifies that to the best of Lilly's knowledge:

1. each of the above clinical investigations included in this supplemental application meets the definition of "new clinical investigation" as set forth in 21 C.F.R. 314.108(a);

the above clinical investigations are "essential to approval" of this supplemental application. Lilly, through its employees and others, electronically searched the scientific literature (as of October 12, 2000) via: