**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 300 River Place, Suite 5900<br>Detroit, MI 48207<br>(313) 393-8100 Fax:(313)393-8139<br>ORABIMOW.Correspondence@fda.hhs.gov | 9/11/2023-9/15/2023 |
| | FEI NUMBER<br>1819470 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brad B. Woodward, Sr. Vice President Global Patient Safety

| FIRM NAME | STREET ADDRESS |
|---|---|
| Eli Lilly & Company | 893 South Delaware Street |
| CITY, STATE, ZIP CODE, COUNTRY<br>Indianapolis, IN 46285-1782 | TYPE ESTABLISHMENT INSPECTED<br>Commercial Sponsor |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## OBSERVATION 1

An application holder did not ensure healthcare providers (HCPs) who prescribe the drug are specially certified, as required by your approved REMS Element to Assure Safe Use (ETASU) A.

Specifically,

The following healthcare providers (HCPs) were not certified prior to prescribing Zyprexa Relprevv under the REMS program for the Assessment Reporting Period, 31 August 2021 through 30 August 2022:

| Facility Number | Facility Name |
|---|---|
| (b) (4) | |

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Dina A Tallman, Investigator
Jennifer A Kemp, Investigator

X Dina A Tallman
Investigator
Signed By: Dina A. Tallman -S
Date Signed: 09-15-2023
15:33:54

DATE ISSUED
9/15/2023

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
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| 300 River Place, Suite 5900<br>Detroit, MI 48207<br>(313) 393-8100 Fax:(313)393-8139<br>ORABIMOW.Correspondence@fda.hhs.gov | 9/11/2023-9/15/2023<br>FEI NUMBER<br>1819470 |

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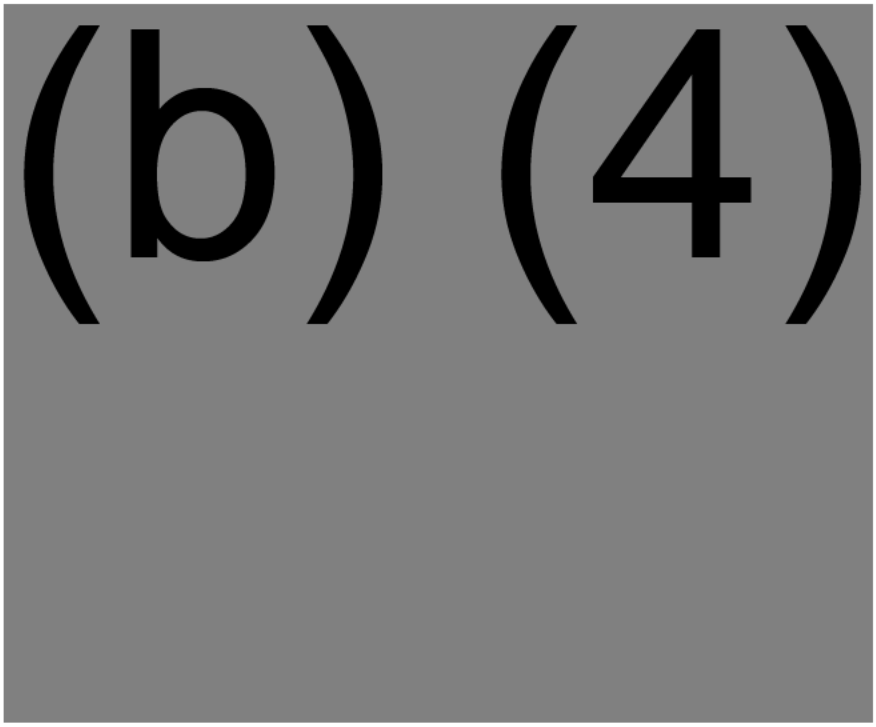
| Brad B. Woodward, Sr. Vice President Global Patient Safety | |
| FIRM NAME<br>Eli Lilly & Company | STREET ADDRESS<br>893 South Delaware Street |
| CITY, STATE, ZIP CODE, COUNTRY<br>Indianapolis, IN 46285-1782 | TYPE ESTABLISHMENT INSPECTED<br>Commercial Sponsor |




**OBSERVATION 2**

An application holder did not ensure pharmacies that dispense the drug are specially certified, as required by your approved REMS Element to Assure Safe Use (ETASU) B.

Specifically,

For the Assessment Reporting Period, 31 August 2021 through 30 August 2022, (b) (4) :

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Dina A Tallman, Investigator<br>Jennifer A Kemp, Investigator | X Dina A Tallman Investigator Signed By: Dina A. Tallman -S Date Signed: 09-15-2023 15:33:54 | 9/15/2023 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
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| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
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| Brad B. Woodward, Sr. Vice President Global Patient Safety | |
| FIRM NAME<br>Eli Lilly & Company | STREET ADDRESS<br>893 South Delaware Street |
| CITY, STATE, ZIP CODE, COUNTRY<br>Indianapolis, IN 46285-1782 | TYPE ESTABLISHMENT INSPECTED<br>Commercial Sponsor |

(A) Was not certified prior to dispensing Zyprexa Relprevv under the REMS program.
(B) Dispensed Zyprexa Relprevv directly to a non-registered patient.

**OBSERVATION 3**

An application holder did not ensure health care settings that dispense the drug are certified, as required by your approved REMS Element to Assure Safe Use (ETASU) C.

Specifically,

The following health care facilities were not certified prior to administering Zyprexa Relprevv under the REMS program for the Assessment Reporting Period, 31 August 2021 through 30 August 2022:

| Facility number | Facility name |
|---|---|
| (b) (4) | |

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Dina A Tallman, Investigator<br>Jennifer A Kemp, Investigator | X Dina A Tallman Investigator Signed By: Dina A. Tallman -S Date Signed: 09-15-2023 15:33:54 | 9/15/2023 |

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| CITY, STATE, ZIP CODE, COUNTRY<br>Indianapolis, IN 46285-1782 | TYPE ESTABLISHMENT INSPECTED<br>Commercial Sponsor |

**OBSERVATION 4**

An application holder did not ensure each patient receiving the drug has evidence or other documentation of safe-use conditions, as required by your approved REMS Element to Assure Safe Use (ETASU) D.

Specifically,

For the Assessment Reporting Period, 31 August 2021 through 30 August 2022, the following pharmacy service providers dispensed Zyprexa Relprevv directly to a patient:

(b) (4)

**OBSERVATION 5**

An application holder did not ensure each patient using the drug required by the REMS be enrolled in a registry, as required by your approved REMS Element to Assure Safe Use (ETASU) F.

Specifically,

For the reporting period beginning Aug 31, 2020 to present, 46 patients received approximately 67 injections of Zyprexa Relprevv prior to enrollment in the REMS program.

X Jennifer A Kemp
Investigator
Signed By: Jennifer A. Kemp -S
Date Signed: 09-15-2023 15:34:29

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Dina A Tallman, Investigator<br>Jennifer A Kemp, Investigator<br>X Dina A Tallman<br>Investigator<br>Signed By: Dina A. Tallman -S<br>Date Signed: 09-15-2023 15:33:54 | 9/15/2023 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."