From: Michelle Dunston
Sent: 09 February 2023 19:11

To: Acorda PV

**Subject:** CON\_ACO\_174027\_2022 and CON\_ACO\_174228\_2022

**Attachments:** 0308\_001.pdf; 0309\_001.pdf

Follow Up Flag: Follow up Flag Status: Flagged

Categories: Triage

Dear all,

I am attaching 2 letters that were received on 09-Feb-23.

Thanks,

Michelle Dunston PV Assistant



Michelle Dunston
PV Assistant

## michelle.dunston@primevigilance.com

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FEB 09 2023

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## RECEIVED

Reference #: ACO\_174027\_2022

Jan 6, 2023

FEB **0 9** 2023

Lynn Kretlow 2344 ALTA VISTA DR WAUKEGAN, IL WAUKEGAN

Dear Ms. Kretlow.

This letter is in reference to a report that we received from, either you, your healthcare professional or Specialty Pharmacy, about an event (s) that you experienced while using an Acorda product **Ampyra and Dalfampridine**.

To better understand your adverse event(s), please provide the name, address, and telephone number of your prescribing physician. This will give Acorda permission to obtain additional information. Please answer the questions below, as it would be helpful to Acorda if you would provide an update regarding your event (s).

Please be aware Acorda is required by law to submit this information to the Food and Drug Administration (FDA). However, Acorda will ensure your information is handled in a manner that is compliant with the medical privacy rule, which is commonly known as the Health Insurance Portability and Accessibility Act (HIPAA). Acorda will submit your information without any personal identifiers (i.e., name, address, phone number) to the FDA.

Thank you in advance for your assistance.

Sincerely

Drug Safety and Pharmacovigilance

I'm sorry the back side is a mess!, I was in a hurry.



Reference #: ACO\_174027\_2022

Are you currently taking <b>Dalfampridine?</b> $060622$
Are you currently taking Dalfampridine?  [] Yes [X] No, Stop Date: MM / DD / YYYY
If no, provide reason for discontinuation: <u>T+dudn+ work</u> well.
Please provide lot number and expiration date located on the bottle of Dalfampridine.
Lot Number: 154384817627 Expiration Date: 66/69/2023  RX  MM/DD/YYYY
Please provide manufacturer: Sun Pharma
Are you currently taking Ampyra?
Yes No, Stop Date: MM / DD / YYYY
If no, provide reason for discontinuation:
Please provide lot number and expiration date located on the bottle of Ampyra.
Lot Number: 154384864466 Expiration Date: 04/04/2003 12/19/2013
It was reported that generic did not work as well.
When did this occur? Date: / / since I started taking  When did this occur? Date: / / taking  MM/DD/YYYY it a few years or 8.
Please further clarify that generic did not work as well.
When I went from taking Ampyra to Delfamprise
Please further clarify that generic did not work as well.  When I went from taking Ampyra to Delfamprise  I noticed a change to worse I thought  Thank you in advance for your assistance in providing Acorda with this information. A postage paid envelope is enclosed for your convenience. Alternately, you may fax this information to us at 914-606-9548.  That it had to be switched because that it had to be switched because
of insurance when I mentioned This
V4.0 (19Sep2017)
said she could over ride it Delfampriding

## RECEI VED



FEB 09 2023

Patient's Printed Name:

Lynn Kreflow

Patient/Guardian Signature: Jum Bucklow Date: 01/04/2023

Please provide your physician or other healthcare provider information to obtain additional details about your adverse event(s).

Physician's Name:

Dr. Susan Rubin

2180 Pfingsten RL., Suite 2000

Chenvicu, FL 60026

Physician's Telephone:

Patient's Printed Name:

Patient/Guardian Signature:

Dr. Susan Rubin

2180 Pfingsten RL., Suite 2000

Chenvicu, FL 60026

B47-570-2570 Fax:

Patient/Guardian Signature:

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Date: Ol/O4/2023