

Received

APR 17 2019

NC Board of Pharmacy



711 East Carefree Hwy., Ste. 207
Phoenix, AZ 85085
844-661-1829

April 11, 2019

Executive Director, Jack Campbell
North Carolina Board of Pharmacy
6015 Farrington Rd., Ste. 201
Chapel Hill, NC 27517

RE: Voluntary Recall of Misbranded Product

Dear Director Campbell:

This letter is written to notify you of a voluntary recall that Atlas Pharmaceuticals completed on two specific lots of compounded drug products. These products were provided to veterinary clinics for their office use from our facility.

The impacted products and their lot information is as follows:

- Metronidazole 50mg Mini Tabs, Lot N-60150, BUD 5/18/2019
- Metronidazole 25mg Mini Tabs, Lot N-60191, BUD 6/18/2019

It was discovered, post production and release, that the labels for these drug products were missing the quantity of tablets purported to be within the bottle. All other required information (product name, dosage, etc.) was present. The quantity of tablets was included in the shipping invoices that were provided to the clinic.

Atlas Quality Assurance immediately quarantined the remaining stock and notified all clinics in receipt of the drug that the labels were missing the quantity of tablets for the bottle they purchased. **The Quality Assurance unit has determined, via risk assessment, that the risk to the end-users was minimal.** At no time were patients at risk as the only missing information from the label was the quantity of tablets in the bottle. Atlas Management notified the FDA and has been working with Ms. Jamie Dion, MPH, Consumer Safety Officer/Acting Recall Coordinator at General Division IV to complete a voluntary recall.

Atlas has been working with the impacted clinics and the FDA through the voluntary recall process and has not received reports of concern or patient impact from any of the clinics in receipt of aforementioned lots. As of 04/10/2019 we have achieved a 98.7% response rate for



711 East Carefree Hwy., Ste. 207
Phoenix, AZ 85085
844-661-1829

Metronidazole 50mg (N-60150) with a 86.3% response marked resolved. As of 04/10/2019 we have achieved a 97.2% response rate for Metronidazole 25mg (N-60191) with a 81.9% response marked resolved.

Atlas personnel and management teams are diligently working to achieve a 100% recovery of drug from clinics. Atlas Management has been providing weekly updates to the FDA on our progress. In addition to conducting a voluntary recall, Atlas Management and Quality Assurance teams have taken immediate steps for discovering the root cause and implementing a robust preventive action plan. Additional mandatory training has been conducted for all personnel regarding the importance of labeling review and reconciliation as emphasized in 21 CFR 211.

If you have any questions regarding this matter, please do not hesitate to contact Nickolaus Banda at 844-661-1829 or nickolaus.banda@atlasdrugs.net.

Sincerely,

A handwritten signature in black ink, appearing to be the initials "NB" or a stylized version of the name "Nickolaus Banda".

Nickolaus Banda, Pharm.D., RPh,
Pharmacist in Charge