Clifton Health Department
Recall Notification

Food/Drug/Pet Recall: Ukoniq

ISSUE: The FDA is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. The FDA determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, the FDA is alerting patients and health care professionals that FDA is re-evaluating this risk against the benefits of Ukoniq for its approved uses.

The FDA is continuing to evaluate the results from the clinical trial called UNITY. The FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq. The FDA has also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while the FDA continues to review the UNITY findings. The FDA will communicate our final conclusions and recommendations when the FDA has completed the review or has more information to share.

For more information about this alert, click on the red button **"Read Alert"** below.

BACKGROUND: Ukoniq is a prescription medicine approved to treat adults with marginal zone lymphoma (MZL) when the disease has returned or it did not respond to prior treatment with at least one specific type of medicine. Ukoniq is also approved to treat adults with follicular lymphoma (FL) when the disease has returned or it did not respond to at least three prior treatments.

RECOMMENDATIONS:

- **Health care professionals** should review patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.

Patients should talk to your health care professionals about the risks and benefits of Ukoniq or any concerns you may have, including about possible alternative treatments.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.

[02/03/2022?-?Drug Safety Communication?- FDA]