Allergan – Recall of Taytulla® (norethindrone acetate/ethinyl estradiol and ferrous fumarate)

- On May 29, 2018, Allergan announced a voluntary, consumer-level recall of one lot of Taytulla (norethindrone acetate/ethinyl estradiol and ferrous fumarate) capsules because of a report stating that a physician's sample pack had four placebo capsules that were placed out of order.
    - Specifically, the first four days of therapy had four non-hormonal placebo capsules instead of four active capsules.
- The recalled product was distributed nationwide to healthcare providers:

Product Description	NDC #	Lot # (expiration date)
Taytulla softgel capsules 1 mg/20 mcg, 6 X 28 sample	0023-5862-31, 0023-5862-28, 0023-5862-29	5620706 (May 2019)

- Taytulla is indicated for use by females of reproductive age to prevent pregnancy.
- As a result of the packaging error, oral contraceptive capsules that are taken out of sequence may place the user at risk for contraceptive failure and unintended pregnancy. The reversing of the order may not be apparent to either new users or previous users of the product, increasing the likelihood of taking the capsules out of order. If patients have concerns regarding the possibility of an unintended pregnancy they should consult their physician.
- The Taytulla pill pack is a 28 count blister card that has 24 active pink softgel capsules with "WC" printed on the outer shell in white to be taken for 24 days, followed by 4 maroon softgel capsules also imprinted with "WC" on one side to be taken for the next four days.
- Allergan is notifying customers by recall letter and is arranging for return of all recalled product. Patients who have the sample pack product with the associated lot number should notify their physician to arrange a return.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.
- Contact Allergan at **1-800-678-1605** for any questions regarding this recall.