

Special Investigations Unit updates: recent FDA warnings

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The Special Investigations Unit (SIU) is tasked to conduct investigations involving allegations of fraud, waste and abuse, to work with our providers to resolve billing practice issues in order to reduce or eliminate future payment issues, and, where appropriate, to recover overpayments.

As part of our role to help safeguard our members and provide relevant information to providers, we are relaying the following recent Food and Drug Administration (FDA) Warning Letters:

Estring - On June 19, 2018, the Food and Drug Administration issued a letter of warning to Pfizer for "false or misleading" promotional materials related to ESTRING® (estradiol vaginal ring). According to the FDA the posted "... video is especially concerning from a public health perspective because it fails to include any risk information about Estring, which is a drug that bears a boxed warning due to several serious, life-threatening risks, including endometrial cancer, breast cancer, and cardiovascular disorders, as well as numerous contraindications and warnings. The video thus creates a misleading impression about the safety and efficacy of Estring".

Xtampza – On February 9, 2018, the Food and Drug Administration issued a letter of warning to Collegium Pharmaceuticals for publicly providing false or misleading representations regarding Xtampza (oxycodone) ER because it "fails to adequately communicate information about the serious risks associated with Xtampza ER use".

Further details regarding these Warning Letters from the FDA can be obtained at:
Estring:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM612143.pdf>

Xtampza:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM597584.pdf>

URL: <https://providernews.anthem.com/connecticut/article/special-investigations-unit-updates-recent-fda-warnings>

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