Cefzil® (cefprozil), Ceftin® (cefuroxime) – Indication Removal

- On November 22, 2016, the FDA announced the removal of the indication for secondary bacterial infection of acute bronchitis (SBIAB) from the Cefzil (cefprozil) and Ceftin (cefuroxime axetil) drug labels.
    - SBIAB was removed from the *Indications and Usage* and *Dosage and Administration* section of the Cefzil drug label.
    - SBIAB was removed from the Indications and Usage, Dosage and Administration, Adverse Reactions and Clinical Studies sections of the Ceftin drug label.
- Per the FDA, the revisions are necessary to furnish information needed for the safe use of these drugs, as the FDA no longer grants the indication of SBIAB.
- Cefzil is also indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of certain microorganisms for the following conditions: pharyngitis/tonsillitis, otitis media, acute sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated skin and skin-structure infections.
- Ceftin is also indicated for the treatment of the following infections due to susceptible bacteria: pharyngitis/tonsillitis, acute bacterial otitis media, acute bacterial maxillary sinusitis, acute bacterial exacerbation of chronic bronchitis, uncomplicated skin and skin-structure infections, uncomplicated urinary tract infections, uncomplicated gonorrhea, early lyme disease, and impetigo.