Cortef®, Solu-Cortef® and Solu-Medrol® – New Warnings

- On September 8, 2016, the FDA approved new updates to the *Warnings and Precautions* sections of the Solu-Cortef (hydrocortisone sodium succinate) injection and Cortef (hydrocortisone) tablets drug labels regarding central serous chorioretinopathy, epidural lipomatosis and pheochromocytoma.
- Additionally, the FDA approved a new update to the *Warnings and Precautions* section of the Solu-Medrol (methylprednisolone sodium succinate) injection drug label regarding the risk of hepatotoxicity with high dose administration.
- Refer to the prescribing information for a complete list of labeled indications for Cortef, Solu-Cortef and Solu-Medrol.
- Other warnings and precautions for Solu-Cortef, Cortef and Solu-Medrol are found in the drug labels.
- A few other changes were made to the Solu-Cortef, Cortef and Solu-Medrol drug labels including the addition of leukocytosis to the *Adverse Reactions* section, removal of text regarding impaired mineralocorticoid secretion from the *Precautions* section and addition of non-clinical information regarding impairment of infertility.
    - For Solu-Cortef and Cortef, epidural lipomatosis and central serous chorioretinopathy were also added to the *Adverse Reactions* section.