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Subject: In Accordance with 18 VSA 4637 (c)
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To whom it may concern:

This notice is being submitted in accordance with 18 VSA § 4637(c) with regards to ORTIKOS (budesonide) extended release capsules (“ORTIKOS”), which Ferring launched on July 20, 2020.

Ferring is supplementing its initial notice provided on July 22, 2020. pursuant to 18 VSA § 4637(b). Ferring’s marketing plan for ORTIKOS is directed to healthcare professionals only. Several marketing materials have been developed for hard copy distribution, as well as digital assets to promote the product. Hard copy materials include one-page leave behinds, paper coupons, pharmacy tear pads, as well as a core visual aid for Ferring GI sales representative use only, never to be left with HCPs. Other assets include digital banner advertisements, brand website, electronic coupon/integration and denial conversion. A small quantity of ORTIKOS 9 mg samples are also available for HCPs to gain real-world clinical experience with ORTIKOS. Ferring is not providing its pricing plans as such information is not public. Ferring estimates~800 patients may be prescribed ORTIKOS. ORTIKOS did not receive breakthrough therapy or priority review designations from the FDA prior to approval. Ferring acquired the rights to market ORTIKOS on October 4, 2019, but is not providing the price, as such information is not public.

Regards,

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