

December 1, 2017

Scott Gottlieb, MD  
Commissioner, Food and Drug Administration

Re: Adding hormone drug products to the “Demonstrably Difficult to Compound” list

Dear Commissioner Gottlieb,

On July 28, 2017, the Food and Drug Administration (FDA) established a new public docket to allow interested parties to “nominate drug products or categories of drug products for inclusion on the Difficult to Compound List, resubmit previous nominations with additional supporting information, or submit comments.” We understand that bio-identical hormones, estradiol, estriol, progesterone, progesterone with estradiol, and testosterone were nominated for inclusion on the list. I am writing on behalf of the Endocrine Society to provide information that may be useful as you consider whether to add these hormone preparations to the list. Founded in 1916, the Society represents physicians and scientists engaged in the treatment and research of endocrine disorders.

While the Endocrine Society does not make recommendations on regulatory decisions related to any specific drug product, our Scientific Statement, [Compounded Bioidentical Hormones in Endocrinology Practice](#), may help inform your decisions. It reviews the pharmacology and physiology of popular compounded hormones including estradiol and estrogens, progesterone and progestins, testosterone, levothyroxine, triiodothyronine, and dehydroepiandrosterone, as well as misconceptions associated with their use. We also have advocated for greater FDA oversight of all hormones regardless of chemical structure or method of manufacture. Our position statement, [Compounded Bioidentical Hormone Therapy](#), outlines potential regulatory changes to achieve this goal.

We appreciate the opportunity to share this information with the FDA. Please contact Stephanie Kutler, Director, Advocacy & Policy at [skutler@endocrine.org](mailto:skutler@endocrine.org) if we can provide any additional information or assistance as the FDA moves forward in this process.

Sincerely,



Lynnette K. Nieman, MD  
President  
Endocrine Society