February 2, 2022

The Honorable Buddy Carter
United States House of Representatives
Washington, DC 20515

Dear Representative Carter:

Thank you for your letter of December 14, 2021, cosigned by 21 of your colleagues regarding patient access to compounded hormone therapies also known as "bioidentical hormone replacement therapy" (cBHRT).

Compounded bioidentical hormone replacement therapies are used at times instead of FDA-approved drug products for hormone replacement therapy. Some compounders market cBHRT products as superior to FDA-approved drugs by making assertions that they are more natural, safer, or better for patients than FDA-approved drug products. However, cBHRT products are not FDA-approved, which means these products have not undergone an FDA assessment of safety, effectiveness, or quality prior to marketing.

To help inform the public and the Food and Drug Administration's (FDA or the Agency) policies regarding cBHRT, the Agency entered into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM) to convene an ad hoc committee to conduct a study on the clinical utility of cBHRT drug products. The committee also reviewed which populations may benefit from the use of these preparations and considered whether the available evidence supports their use to treat patients. The committee issued its report, "The Clinical Utility of Compounded Bioidentical Hormone Therapy," on July 1, 2020.[1]

Reports published by NASEM aim to provide independent, objective expert advice. With regard to cBHRT, NASEM held six open session meetings for the Committee on Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy. According to NASEM, these meetings provided an opportunity for the committee to gather data and contextual information from relevant BHRT compounders and BHRT medical professionals.

The NASEM report discusses some of the uncertainties of the potential benefits and safety risks associated with the use of these compounded products. FDA believes the results of NASEM's research provide important information that will increase public understanding regarding cBHRT products. When developing Agency policies, FDA intends to consider the information in the NASEM report, along with information and comments received from members of the public, while taking into account patient access concerns.

[1] https://www.nationalacademies.org/our-work/clinical-utility-of-treating-patients-with-compounded-bioidentical-hormone-replacement-therapy

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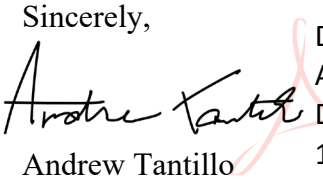
Thank you again for contacting us regarding this matter. If you have any questions, please let us know.

Sincerely,



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Andrew Tantillo
Acting Associate Commissioner for Legislative Affairs

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