



August 24, 2018

Dianne Post, Attorney, Chapter Secretary
Central Phoenix
Inez Casiano NOW
Chapter #0140
P.O. Box 32336
Phoenix, AZ 85064

Dear Ms. Post,

Thank you for sharing the National Organization for Women's (NOW) concerns regarding the need for funding to improve and advance women's health. Our Office of Women's Health (OWH) has worked with NOW over the years to provide women's health information to the public. As a result, your recent letter to Commissioner Gottlieb was referred to my office for a response.

As you may know, the Food and Drug Administration (FDA) is responsible for protecting the public health by assuring that human and veterinary drugs, as well as vaccines, other biological products, and medical devices intended for human use are safe and effective. Additionally, we advance the public health by helping to speed product innovations. To clarify the role of FDA, we are not like the National Institutes of Health "one of the largest medical research bodies in the U.S." Our Congressionally defined regulatory mandate and budget focus on the science of developing new tools, standards, and approaches to assess the safety and efficacy, quality, and performance of FDA-regulated products. The basic research for these is presented to FDA in product applications which come from individual companies for us to evaluate for their potential benefits and risks.

My office, the FDA Office of Women's Health (OWH), was established in 1994. We are committed to advancing the health of women. We serve as the principal advisor to the Commissioner and other key Agency officials on scientific, ethical, and policy issues relating to women's health and coordinate efforts to establish and advance a women's health agenda for the Agency. Our office works to promote the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and the completion of sex/gender analysis. We continuously provide consumers with important information about safety and other pertinent issues pertaining to FDA products. In summary, FDA dedicates multiple activities and resources to supporting the health of women. Additional information can be found at <https://www.fda.gov/aboutfda/centersoffices/oc/officeofwomenshealth>.

I hope this information has been clarifying. And please know that as science evolves to provide more safe and effective product options for patients, FDA will move them through our regulatory process as quickly as possible to reach the patients who need them with accurate information for healthcare providers.

Sincerely,

Marsha B. Henderson
Associate Commissioner for
Women's Health

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