



July 23, 2020

Dear Ms. Griffen:

Thank you for your letter regarding medical countermeasures, such as vaccines and treatments, being developed for the coronavirus disease 2019 (COVID-19). I appreciate your alliance's interest in ensuring that vaccines and treatment options for pregnant women and lactating women are available, as well as including ethnic and socioeconomic diverse populations in clinical studies to evaluate the safe and effective use of these products.

The Food and Drug Administration's (FDA or the Agency) mission is to protect and promote the health of the American public. FDA has engaged in partnerships across public and private sectors to perform data collection and research that will be imperative to the development of preventive and therapeutic medical products to combat the COVID-19 pandemic. As part of this effort, FDA has taken steps to encourage the development of candidate vaccines for COVID-19 for pregnant women and lactating women.

Clinical Trials

FDA is committed to encouraging the participation of a diverse group of individuals in research used to support marketing applications for regulated medical products. Our Diverse Women in Clinical Trials Initiative, developed in collaboration with the National Institutes of Health (NIH), conducts outreach to share best practices and increase, in clinical trials, the participation of women of different ages, races, ethnic backgrounds, disabilities, and health conditions. I encourage you to visit our [web page](#) to learn more about the initiative's activities, as well as to review other resources such as [pregnancy registries that are studying how COVID-19 may affect a pregnant woman and her newborn](#).

Over the past few decades, FDA's policy initiatives have focused on promoting enrollment practices that will lead to clinical trials better reflecting the population most likely to use the product if it is approved, primarily through broadening the eligibility criteria for the trials. Despite these efforts, challenges to participation in clinical trials remain, and certain groups continue to be underrepresented in many clinical trials. In June 2019, FDA issued a draft guidance for industry entitled "[Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices, and Trial Designs](#)." When finalized, this will represent FDA's current thinking on this issue. This guidance recommends approaches that sponsors of clinical trials can take to broaden their eligibility criteria, when scientifically and clinically appropriate, and to increase their enrollment of underrepresented populations in their clinical trials.

With specific regard to COVID-19, FDA is working with vaccine developers to facilitate inclusion of a diverse population in all phases of development. FDA is strongly encouraging the enrollment of

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populations most disproportionately affected by the disease, specifically racial and ethnic minorities, and is recommending that sponsors incorporate strategies to help ensure that a diverse population is included in their current and future COVID-19 clinical trials.

Vaccines

With respect to vaccines, FDA supports inclusion of pregnant women in clinical studies of vaccines against emerging infectious diseases, including vaccines to prevent COVID-19. Studying such vaccines in pregnant women is important to obtain data pertaining to the safety and effectiveness of use during pregnancy, including data on the safety outcomes in infants. The Agency is engaging with vaccine manufacturers in planning for the inclusion of pregnant women in prelicensure clinical trials with COVID-19 vaccine candidates. Clinical trials in pregnant women may proceed provided that adequate nonclinical studies, including reproductive and developmental toxicity studies in animal models, are conducted and safety and immunogenicity data for the vaccine are available from early phase 1 and 2 clinical studies conducted in nonpregnant individuals. In this regard, FDA's guidance for industry entitled "[Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications](#)" sets forth recommendations for assessing the developmental toxicity potential of preventive vaccines for infectious diseases for females of childbearing potential and for pregnant women. In addition, in 2015, to facilitate prelicensure studies in pregnant women, FDA convened its [Vaccines and Related Biological Products Advisory Committee](#) to solicit the input of independent, external experts on the evaluation of investigational vaccines intended for use during pregnancy to prevent diseases in infants. The committee's input on evaluating safety outcomes in pregnant women and infants is broadly relevant to the evaluation of preventive vaccines used during pregnancy, whether the vaccine is intended to protect the mother and/or infant.

Task Force on Research Specific to Pregnant Women and Lactating Women

The [21st Century Cures Act](#) created the Task Force on Research Specific to Pregnant Women and Lactating Women ([PRGLAC](#)). This task force has been imperative in facilitating communication among stakeholders, which has helped support the development of safe and effective therapies and advance women's health. FDA, along with several federal experts and non-federal experts and representatives, are PRGLAC members. FDA's dedication to safe and effective therapies has ensured the continued advancement of research to identify medical issues and conditions specific to pregnant women and lactating women. In the task force's [first report released in 2018](#), the task force's recommendations addressed the inclusion of pregnant women and lactating women in clinical research agendas, increases in research both for therapeutic products already in use by pregnant women and lactating women and for the discovery and development of new therapeutic products for these populations. At the most recent PRGLAC meeting on February 3, 2020, FDA participants played key roles in exploring the best ways to implement many of the 15 recommendations that were submitted to the Secretary of Health and Human Services in September 2018.

Communications and COVID-19

During the COVID-19 pandemic, FDA has increased its amplification of clinical trial diversity messages and provided tailored COVID-19 communications to racial and ethnic minority stakeholders. FDA also held a listening session with diverse stakeholders both to learn more about the gaps and needs of racial

and ethnic minority communities and to share information on FDA's COVID-19 activities. In addition, the Agency has increased its outreach to consumers by disseminating COVID-19 health education materials in multiple languages. For example, FDA's COVID-19 web pages, including frequently asked questions, are available in Spanish. The Agency has also created a COVID-19 multilingual resources web page that features a growing collection of educational materials in Spanish, simplified Chinese, Korean, Vietnamese, Tagalog, and other languages. To further enhance outreach and dissemination, FDA launched a COVID-19 bilingual (English/Spanish) Social Media Toolkit that features consumer-friendly messages and culturally appropriate graphics.

Other FDA Resources

You may be interested in reviewing additional resources from FDA, which include:

- A draft guidance for industry entitled "[Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials](#)," which lays out further recommendations on how and why to include pregnant women in drug development research.
- A draft guidance for industry entitled "[Postapproval Pregnancy Safety Studies](#)," which provides sponsors and investigators with recommendations on how to design investigations to assess the outcomes of pregnancies in women exposed to drugs and biological products regulated by FDA (i.e., pregnancy safety studies).
- A draft guidance for industry entitled "[Clinical Lactation Studies: Considerations for Study Design](#)," which provides recommendations for sponsors conducting clinical lactation studies to assess the presence of drugs in breastmilk and their safety in breastfeeding infants.
- A guidance for industry entitled "[COVID-19: Developing Drugs and Biological Products for Treatment or Prevention Guidance for Industry](#)," which includes information to guide drug development for pregnant women and lactating women. As described in this guidance, FDA encourages the enrollment of pregnant women and lactating women in phase 3 clinical trials, when appropriate, and emphasizes the need to generate clinical trial data to inform the use of drugs in these populations.
- A final guidance for industry entitled "[Development and Licensure of Vaccines to Prevent COVID-19](#)," which specifically addresses the inclusion of, in prelicensure clinical trials, pregnant women and women of childbearing age who are not actively avoiding pregnancy.
- A final guidance for industry and FDA staff entitled "[Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#)," which provides a policy to help expand the availability and capability of non-invasive fetal and maternal monitoring devices to facilitate patient monitoring while reducing patient and health care provider contact and potential exposure to COVID-19 during this pandemic.

FDA is steadfast in its dedication to protect the health of minority populations by working to correct health disparities and advance health equity. We share your commitment to ensuring that women in high-risk populations are protected through research, both during this pandemic and at all times. Thank you for contacting FDA, and please feel free to contact me again if you have additional concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Hahn".

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs