



Wanda Filer, MD, MBA, FAAFP
Board Chair
American Academy of Family Physicians
1133 Connecticut Ave, N.W.
Washington, DC 20036

Dear Dr. Filer,

Thank you for your letter addressed to Dr. Scott Gottlieb, Commissioner, Food and Drug Administration (FDA, or the Agency) and Seema Verma, Administrator Centers for Medicare and Medicaid (CMS) on behalf of the American Academy of Family Physicians. Your letter was referred to the Center for Drug Evaluation and Research (CDER) for response. AAFP is requesting that FDA and CMS endorse and implement policies and coverage decisions that allow adolescents, regardless of age, to be included in the over-the-counter (OTC) oral contraceptives studies required by the FDA.

CDER oversees prescription and nonprescription (OTC) drug labeling and ensures that the benefits outweigh the risks. Please refer to the following link for more information on how the FDA regulates Nonprescription Products:

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm093452.htm>. Drug Trials Snapshots provide consumers with information about who participated in clinical trials that supported the FDA approval of new drugs. Please refer to these links for more information on Drug Trial Snapshots: <https://www.fda.gov/Drugs/InformationOnDrugs/ucm412998.htm> and <https://www.fda.gov/Drugs/NewsEvents/ucm424178.htm>.

We understand that including adolescents in such studies would help determine whether OTC access is appropriate for this population. For development programs for drug products that are proposed for a switch from prescription to nonprescription status, FDA often requires consumer behavior studies (e.g., label comprehension studies, self-selection studies, or actual use studies) to demonstrate that consumers can understand how to use a drug safely and effectively in the nonprescription setting, without the help of a healthcare professional. These studies are expected to include subject populations that are representative of the population that is likely to use the drug in the nonprescription setting. Because prescription oral contraceptives are used by adolescents, and it is likely that there would be interest in use of nonprescription oral contraceptives by adolescents, FDA expects that a development program for a potential nonprescription oral contraceptive would include adolescents in its consumer behavior studies.



I appreciate the American Academy of Family Physicians' continued vigilance in assuring the health of our communities and equipping the workforce that serves them.

Sincerely,

Dr. Janet Woodcock
CDER Center Director