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Marion F. Gruber, PhD is the Director of the Office of Vaccines Research and Review (OVRR) in the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration. In this position, she directs the review, monitoring, and evaluation of investigational new drug applications and biologic license applications encompassing vaccines and related biological products as well as research pertaining to the development, manufacturing and testing of vaccines.

From 2009 - 2011 Dr. Gruber served as OVRR Deputy Director and from 2005 – 2009 as OVRR Associate Director for Policy. In these positions she has gained extensive experience in developing policies and programs affecting the regulation of vaccines. Dr. Gruber has served on numerous agency and interagency working groups and committees and has represented the OVRR on national and international task forces to foster communications and collaborations related to the safety, quality and efficacy of vaccines.

Dr. Gruber has over 20 years of experience in the regulatory review and approval of preventive vaccines and related biologics. She has generated guidance for industry documents critical to the development of preventive vaccines and has contributed to rule making affecting the regulation of vaccines. She has represented OVRR in numerous FDA wide initiatives, as well as national and international meetings.