Combination Products Review Program: Progress and Potential

Commitment	Progress	Next Steps
Issuing more guidance for review of combination products (e.g., our pending draft guidance document on human factors)	• Publication of Draft Guidance "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development" • Publication of Final Guidance "Applying Human Factors and Usability Engineering to Medical Devices	• Finalize Guidance on Human Factors, cGMP, Postapproval Modifications and Final Rule on Postmarket Safety Reporting • Update guidance on classification of medical products • Issue guidance on Pre-RFD process for requesting early feedback on combination products
Enhancing and simplifying data access and sharing for internal staff	• Established process for each medical product center to request and maintain access to databases • Access now granted within 48 hours in most cases (as opposed to several weeks)	• As databases evolve, continue gathering requirements for future enhancements
Facilitating staff in requesting and monitoring inter-center consults	• Leveraged lean tools and concepts to improve intercenter consult request (ICCR) process for combination products review • Currently executing a pilot for the new process using a phased approach across medical product centers	• Pilot completion expected by mid-2017, with final process established and implemented across the Agency. All staff involved with combination products review will be trained on the same process and use the same request form for monitoring submissions and consult requests
Updating and maintaining internal contact directory for experts to review combination products	• Through ICCR pilot, we have begun to clarify roles, establish subject matter experts & identify key points of contact for various disciplines across medical product centers	• Once established internally, we will provide key points of contact in Office of Combination Products and medical product centers for combination product review, and will maintain and update this information
Improving our internal standard operating procedures and policies (SOPPs) for premarket reviews and compliance activities	• Through ICCR pilot, we have initiated a new process for requesting consults for combination products review	• We will draft and implement SOPPs/Staff Manual Guides to improve other areas of review, such as Human Factors labeling