# Addressing Issues Relating to Combination Products: Human Factors

Posted on March 24, 2016 by FDA Voice

By: Jill Hartzler Warner, J.D., and Thinh Nguyen

Combination products represent an important and growing category of therapeutic and diagnostic products under the FDA's regulatory authority. These products, which combine a drug, device, and/or biological product (referred to as "constituent parts") with one another, do not fit into traditional categories for medical products.

Jill Hartzler Warner, J.D., FDA's Associate Commissioner for Special Medical Programs.

Combination products come in three basic configurations: their constituent parts may be physically or chemically combined; they may be co-packaged; or they may be separately distributed with specific labeling that provides instructions for their combined use.

The different constituent parts of a combination product can add complexity to the final product. For example, when a medical device is part of the combination product, issues that relate to how the product is used can be as important as the product itself.

Human factors engineering, and the closely related field of usability engineering, both study how people interact with technology, to understand how the design of user interfaces for technology affects the quality, experience, and outcomes of that interaction. The questions addressed by human factors studies overlap with those addressed by "medication error" assessments, another area of user-product interaction evaluation commonly applied to drugs. The understanding gained from these evaluations can be applied to the design and review of the user interfaces for FDA-regulated products to assure their safety and effectiveness.

Because the design of a combination product can have a significant impact on whether a given product is safe and effective for its intended use, human factors evaluations are a central consideration for FDA when it assesses combination products, particularly those that include certain devices.

Thinh Nguyen, FDA's Director, Office of Combination Products

In February 2016, FDA published draft guidance for industry and FDA staff titled "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." This draft guidance builds on principles articulated in earlier guidances that discuss human factors and medication error considerations for medical devices and drugs. When final, it will represent FDA's thinking on when and how combination product manufacturers should perform human factors evaluations for investigational or marketing applications.

The draft guidance provides examples of combination products that include devices and describes recommendations for how to approach human factors studies for them, focusing on key challenges for developers such as:

- The timing and sequencing of human factors studies in relation to overall development and study of a combination product;
- How human factors studies compare with and relate to other types of clinical studies;
- When changes to a combination product call for new human factors studies to be performed;
- The role of simulated-use versus actual-use human factors studies; and
- What information should be provided to the FDA, and when, to ensure timely feedback for a human factors study.

During the comment period on the draft guidance, FDA is seeking input on the overall guidance, as well as requesting that stakeholders submit examples of combination products in their comments and address whether they believe human factors studies are needed for them. The Agency is also seeking input on what challenges and development risks may arise if such studies are conducted before, in parallel to, or after major clinical studies for combination products. Input from stakeholders will help inform FDA's final guidance in this important area. The comment period for this draft guidance closes on May 3, 2016.

Watch for more to come from FDA this year to further enhance transparency and predictability of combination products regulation. We are developing additional guidance for combination products, including current good manufacturing practices and a final rule on postmarket safety reporting. We also welcome your feedback regarding topics related to combination products that you would like us to address.

***Jill Hartzler Warner, J.D., is FDA's Associate Commissioner for Special Medical Programs***

***Thinh Nguyen is FDA's Director, Office of Combination Products***