# Design Considerations for Devices Intended for Home Use

# Guidance for Industry and Food and Drug Administration Staff

**Document issued on November 24, 2014.**

**This document supersedes "Design Considerations for Devices Intended for Home Use" issued August 5, 2014.**

**This document provides clarification about the use of standards applicable to supply mains (section VII-E-1) and electromagnetic compatibility (section VII-E-6).**

For questions about this document regarding CDRH-regulated devices, contact Mary Brady at 301-796-6089 or by e-mail at mary.brady@fda.hhs.gov; or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-7800.



**U.S. Department of Health and Human Services**
**Food and Drug Administration**

**Center for Devices and Radiological Health**

**Center for Biologics Evaluation and Research**

# Preface

## Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number FDA-2012-D-1161. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

### CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1750 to identify the guidance you are requesting.

### CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD, 20993, or by calling 1-800-835-4709 or240-402-7800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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*Contains Nonbinding Recommendations*

# Design Considerations for Devices Intended for Home Use

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## I. Introduction

This guidance is intended to assist manufacturers in designing and developing home use devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Devices used in the home or other non-clinical environments are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This guidance identifies several factors that manufacturers of home use devices should consider, especially during device design and development, and provides recommendations for minimizing these unique risks.

Throughout this guidance the term "you" refers to manufacturers as defined in 21 CFR 820.3(o). For convenience the definition is restated here: Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

For additional information or questions about the FDA-recognized standards referenced in this guidance document, please contact CDRH's Standards Program.[1]

[1] Web site addresses for all hyperlinked material in this guidance document can be found in Appendix 1: List of References.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

# II. Background

For a variety of reasons, use of devices outside professional healthcare facilities is on the rise. First, the United States population is aging, and the elderly are more likely to live with chronic diseases that require daily medical care at home. Second, due to medical advancements, many individuals with chronic diseases are living longer but are dependent on home medical care. Finally, an increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the home health care market. Integral to the home health care market are home use devices. Although home use devices provide significant benefits to patients and families, including quality of life improvements and cost savings, they are also associated with unique risks. These risks result from interactions among the user, the use environment, and the device, and can greatly affect user and patient safety.

Due to the increasing prevalence of home use devices, minimizing the risks they posed can greatly improve the public health. With this in mind, FDA developed the following considerations that can help manufacturers reduce or minimize common risks posed by home use devices. These risks are best addressed at the design stage. Failure to adequately consider potentially hazardous situations during the design of home use devices may result in inappropriate use, use error, or incompatibilities between the use environment, the user, and the device. This could cause the device to malfunction, possibly contributing to death or serious injury.

When developing a new home use device, you should take the considerations in this guidance document into account and, to the extent possible, reduce or minimize risk to acceptable levels through device design (sometimes referred to as “designing risk out of the device”). For any premarket submission to FDA, you should ensure that the device is suitable for home use and provide in the submission data that demonstrate how you considered and addressed the relevant hazards and risks, such as the ones mentioned in this guidance document. This can help FDA determine whether applicable safety and effectiveness requirements have been met.

Following the recommendations in this guidance can help you develop a device that is best suited to the home use environment, which should decrease the occurrence of adverse events by minimizing the risks to patient and user safety.

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