Guidance for Industry and FDA Staff

Acceptable Media for Electronic Product User Manuals

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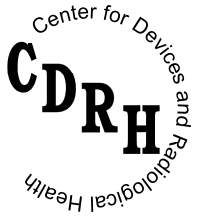

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Electronic Products Branch
Division of Mammography, Quality, and Radiation Programs
Office of Communication, Education, and Radiation Programs

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm205782.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (#1710) to identify the guidance you are requesting.

Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to allow manufacturers to provide user manuals accompanying electronic products in either paper or electronic form. This is done to recognize that electronic media are now being widely used to provide instruction, while at the same time reducing paper consumption, increasing accessibility and providing rapid means for editing and updating content.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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 guidances means that something is suggested or recommended, but not required.

2. User Manuals

The Code of Federal Regulations (CFR) Title 21 Part 1002.3 states in part: "The Director… of the Center for Devices and Radiological Health… may require a manufacturer of a radiation emitting electronic product to provide to the ultimate purchaser…performance data and other technical data related to safety of the product…" These data are typically contained in user manuals that accompany electronic products and historically the media for these manuals has been printed paper. Specific performance standards in 21 CFR Parts 1020.20(c)(4)(i), 1020.30 (h), 1020.40 (c)(9), 1030.10(c)(4), 1040.10(h), 1040.20(e), and 1050.10(f)(2) also contain requirements for providing instructions to users of electronic products. For example, 21 CFR 1020.30(h) and

1040.10(h) specify information manufacturers must provide to users of diagnostic x-ray and laser products respectively.

With the availability of electronic information storage and display technology, many commercial product manuals are being provided electronically. Electronic documentation saves storage space, reduces paper consumption, increases accessibility, and provides rapid means for editing and updating of content.

For these reasons, the Center for Devices and Radiological Health (CDRH) will allow manufacturers to provide the required user information in a commonly used electronic format (*e.g.* Adobe Acrobat or Rich Text Format). Manufacturers may provide the required information as a web site download, on a compact disc (CD) or on other storage media in common use (*e.g.* USB external drive), so long as it is made available directly to the purchaser of the product. If the product purchaser is unable to access the electronic version provided, the manufacturer must make the required documentation available in hard copy (*e. g*. printed paper) at no additional cost. The manuals in whatever form provided should be in the English language.

3. Impact on Required Reports

Radiation safety reports (including user manuals) required by 21 CFR 1002.10 through 1002.13 may be submitted to FDA in one of the following ways:

1) Electronically using FDA's eSubmitter software which can be downloaded at no cost from http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm. Documents prepared using eSubmitter may be sent directly to CDRH via FDA's Electronic Submissions Gateway (ESG).

2) On CD using FDA's eSubmitter software. Documents prepared using eSubmitter may be loaded on a CD and mailed to CDRH for processing, or

3) In hard copy, paper documentation may be mailed to the address shown at http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/RecordsandReporting/ucm118122.htm.

Note: FDA will not accept electronic versions of user manuals unless the required radiation safety report is also submitted electronically.