Guidance for Industry and Food and Drug Administration Staff

Addition of URLs to Electronic Product Labeling

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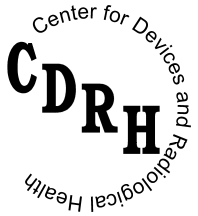

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Communications, Education, and Radiation Programs
Division of Mammography Quality and Radiation Programs
Electronic Products Branch

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, Room 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to www.regulations.gov. 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.

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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 is issuing this guidance document to recommend that manufacturers include their Uniform Resource Locator (URL) on their electronic product labels in addition to the requirements under 21 CFR 1010.3(a)(1) and (2) that manufacturers include their full name and address and place, month and year of manufacture on their electronic product identification tags or labels. FDA's decision to encourage the addition of URLs on electronic products is a result of the recognition that URLs are now widely used in product identification. In addition, using a manufacturer's website address enables the manufacturer to provide the manufacturer's location and details that would not typically be included in a product tag or label, and allows the manufacturer to promptly update its address information whenever there is a change.

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. Identification Labels

Manufacturers of electronic products are required to include their full name and address and place, month and year of manufacture on their product's identification tag or label (21 CFR 1010.3(a)(1) and (2)). CDRH recommends that, when feasible, the manufacturer add its URL to

its electronic product tag or label, in addition to the identification information required under 21 CFR 1010.3(a)(1) and (2). CDRH does not, however, recommend inclusion of the URL in instances where a manufacturer is unable to place its URL, in addition to the required full name and address and place, month and year of manufacture, on its current product label in a manner that is legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable performance standard.

When a manufacturer adds its URL to a product tag or label, the URL should point directly to:

1. A web page where the manufacturer's full name and current physical address are posted, or

2. A web page which displays an easily identifiable link (*e.g.* "Contact Us") that connects to a web page where the manufacturer's full name and current physical address are posted.

In addition, the manufacturer's physical address should be kept current on the manufacturer's website by updating any change to its physical address no later than 15 days following a change.

Under certain circumstances, FDA may determine that information about an electronic product on a firm's website is "labeling" within the meaning of section 201(m) of the Federal Food, Drug, and Cosmetic Act. The presence of the URL on the product label is one factor the Agency may consider in making such a determination.