

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

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Addition of URLs to Electronic Product Labeling

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

Contains Nonbinding Recommendations

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.

21 CFR 1010.3 - Identification.



[Code of Federal Regulations - Title 21: Food and Drugs](#)

TITLE 21 - FOOD AND DRUGS

CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER J - RADIOLOGICAL HEALTH

PART 1010 - PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

subpart a - GENERAL PROVISIONS

1010.3 - Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be 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 standard. Except for foreign equivalent abbreviations as authorized in paragraph (a)(1) of this section all such labels or tags shall be in the English language.

(1) The full name and address of the manufacturer of the product; abbreviations such as Co., Inc., or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Director, Center for Devices and Radiological Health with sufficient information to identify the manufacturer of the product.

(2) The place and month and year of manufacture: (i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health with the key to such code.

(ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows: Manufactured: (Insert Month and Year of Manufacture.) (b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Center for Devices and Radiological Health a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

[40 FR 32257, July 31, 1975, as amended at 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988]

Read more: <http://cfr.vlex.com/vid/1010-3-identification-19716314#ixzz11hEpEp5X>