



# COMPLIANCE POLICY GUIDE

## CHAPTER -1

### SUB CHAPTER -140

Sec. 140.100 Regulatory Policy on the Disposition of Publications that  
Constitute Labeling (CPG 7153. 13)

#### INTRODUCTION:

This compliance guidance document revises existing CPG 7153.13, Seizure of Books that Constitute Misleading Labeling. It is being updated and re-titled to clarify FDA's policy concerning the disposition of publications and other printed materials that are labeling and that cause a regulated product to be in violation of the Federal Food, Drug, and Cosmetic Act, as amended (the Act). It will be included in the next printing of the Compliance Policy Guides (CPG) Manual. It is intended for FDA personnel and will be added to the electronic version of the CPG manual available on the Internet.

This guidance document represents the agency's current thinking on the disposition of printed materials that constitute labeling that renders a product violative. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

#### BACKGROUND:

##### Labeling in General:

Printed material that promotes or is used to promote the use of a product generally is labeling within the meaning of Section 201(m) of the Act. This material may, in

some cases, include scientific journal articles, reference publications, and books. To meet the definition of labeling, material must either be affixed to or “accompany” a product. The term accompany has been interpreted by the courts to mean that material need not physically accompany the product to be labeling. The Supreme Court has explained that a product is “accompanied” by written, printed, or graphic material when the material supplements or explains the product; no physical attachment one to the other is necessary. It is the textual relationship between the product and the written material that is significant. The courts have also considered whether the material and the product are part of an “integrated distribution program” where, for example, the material and the product originate from the same source or the material is designed to promote the eventual distribution and sale of the product. Thus, printed material that is textually related to a product or is part of an integrated distribution program for the product “accompanies” the product and is, therefore, labeling for the product under Section 201 (m) of the Act.

Different types of materials can “accompany” a product. For example, materials may consist of information generated by or on behalf of the manufacturer, packer or distributor. This information may take the form of printed sheets bearing the name of a particular product, stating its intended uses and directions for use, and naming the manufacturer, packer, or distributor. Such materials may also be in the form of a book or similar reference publication that might include scientific information about one, or several, products, or maybe reprints or copies of articles in scientific journals that may report on a new use of a product or class of products.

Information also may be prepared and printed by an independent publishing company or professional society, unrelated to the manufacturer, packer, or distributor of a product. These independently prepared materials maybe available routinely in bookstores or libraries, where they would not be labeling. A manufacturer, distributor, wholesaler, or retailer may also use such independently produced materials to promote a product – for example, by distributing, displaying, or referencing them with a product – so as to make the materials, when so used, labeling for the product.

It should be noted that there are two sets of circumstances, as provided by Section

403B and Sections 551-557 of the Act, in which materials that accompany a product may not be considered labeling.

### Dietary Supplements:

The Dietary Supplement Health and Education Act of 1994 (DSHEA), which applies only to products for human use, added Section 403B to the Act. Section 403B(a) exempts certain publications when used in connection with the sale a dietary supplement to consumers from the definition of labeling, under Section 201 (m) of the Act. Section 403B(a) provides that such a publication -- which may include an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and that was prepared by its author or the editors of the publication -- is not labeling provided it is printed in its entirety and meets each of the following five criteria:

- (1) It may not be false and misleading;
- (2) it may not promote a particular manufacturer or brand of a dietary supplement;
- (3) it must be displayed or presented, or displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
- (4) if displayed in an establishment, it must be physically separate from the dietary supplements; and
- (5) it may not have appended to it any information by sticker or any other method.

Under Section 403 B(a), therefore, a retail store that sells dietary supplements may, in connection with those sales, use publications that meet these five conditions without the publications becoming labeling for those dietary supplements. For example, the publications may be made available in a reference section of the store.

Section 403B(a) implies that publications that fail to meet any one of these five criteria *are* labeling. However, Section 403B(b) provides that Section 403B(a) “shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.” Section 403B(b) means that books or other

publications that are offered for sale by a retailer or wholesaler of dietary supplements do not become labeling for those dietary supplements simply because they fail to meet one or more of the criteria of Section 403 B(a). Books or other publications for sale by a retailer or wholesaler of dietary supplements become labeling for a product in the wholesaler's warehouse or the retailer's store only if the wholesaler or retailer uses them to promote the sale of the product.

In general, under Section 201 (m) of the Act, for a dietary supplement wholesaler, a publication written and published by a party who is independent of the manufacturer or distributor of a product (a "third party") does not become labeling if the wholesaler does not promote the publication and the product together. In general, a dietary supplement retailer does not use a book or other publication that is written and published by a third party to promote a product when the publication is displayed with other books and publications and these books and publications are physically separate from the product, and there is no joint display of the publication and the product. Third party books and other publications so used would not become labeling in the retail store even if they are false or misleading, they reference a particular manufacturer or brand of dietary supplements, or they do not present a balanced view of the scientific information on a dietary supplement.

#### Drugs, Biologics, and Medical Devices for Human Use:

The Food and Drug Administration Modernization Act of 1997 added to the Act Sections 551-557, which permit manufacturers of drugs, biologics, and devices for human use to disseminate certain written information concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling. To do so, the manufacturer must comply with certain statutory requirements. For example, the information to be disseminated must meet certain requirements:

- (1) It must be about a human drug or device that is lawfully marketed;
- (2) it must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication and not be false or misleading; and
- (3) it must not pose a significant risk to the public health.

Additionally, 60 days prior to dissemination, the manufacturer must submit to

FDA a copy of the information to be disseminated along with any clinical trial information and reports of clinical experience relating to the safety or effectiveness of the new use. The manufacturer must also satisfy one of three alternative requirements:

- (1) It must submit to FDA a supplemental application for the new use; or
- (2) certify that it will submit a supplemental application within 6 months (if the studies have been completed) or within 36 months (if the manufacturer submits to FDA an acceptable protocol and schedule for conducting the studies); or
- (3) it must demonstrate to FDA that it is exempt from the requirement for a supplemental application because it is economically prohibitive or unethical to conduct the studies.

Under Section 557, the dissemination of information relating to a new use in accordance with section 551 of the Act will not be considered labeling or evidence of intended use for the drug or device. The dissemination of information that does not comply with sections. 551-557 will be considered labeling and evidence of intended use for the drug or device.\*

#### FDA's Past Practice and Current Law:

For many years, the agency has recommended the seizure not only of violative products but also of the labeling that causes the products to be violative. Courts have condemned and ordered the destruction of labeling that was seized with a violative product. In such cases, some claimants have challenged the court's authority under the Act to seize, condemn, and destroy labeling, arguing that these actions are contrary to the free speech protections of the First Amendment. The courts have generally rejected these challenges.

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\*The constitutionality and scope of Sections 551-557 are under examination in Washington Legal Foundation v. Henney, C.A. No. 94-1306 (D. D.C.).

In 1976, the Supreme Court extended certain free speech protections of the First Amendment to “commercial speech.” Commercial speech may consist of proposing or promoting a commercial transaction by, among other things, extolling the benefit of a particular product. Labeling, which may include a book, reference publication, or a reprint or copy of a scientific journal article, may nonetheless be regulated if it causes a product to be in violation of the Act.

Since 1982, however, the agency has not, as a matter of policy, recommended the seizure of such labeling when it is in the form of books. Instead, the agency has recommended the seizure of the violative product only. To do so, the agency would collect an official sample of the book as evidence that the product is violative. Prior to initiating such legal action, the agency generally provides the opportunity for voluntary compliance action, such as relabeling, that would bring the product into compliance with the Act.

#### POLICY:

In instances where labeling, other than books, reference publications, and reprints or copies of scientific journal articles, renders a product violative, and the labeling is closely associated with the product in question (e.g., brand name, generic drug name, proximity at point of sale), the agency will consider available remedies under the law and continue to recommend seizure of both the product and the labeling. In this context, the disposition of any labeling subject to the jurisdiction of the court will be ultimately determined by the court.

Where books, reference publications, or reprints or copies of scientific journal articles are considered labeling or otherwise evidence of the intended use of a product (and not exempted under DSHEA or FDAMA, as explained above), and the agency believes that the use of this printed material causes a product to be in violation of the Act, the agency will inform the manufacturer, distributor, wholesaler, or retailer and seek to bring the product into compliance.

In situations of voluntary compliance activity, the agency should focus on bringing products into compliance. The disposition of the labeling, including books, reference publications, or reprints or copies of scientific journal articles,

that causes a product to be in violation of the Act is the option of the manufacturer, distributor, wholesaler, or retailer, as long as that disposition does not cause a further violation of the Act. The agency should point out that a number of options maybe available for using such books, reference publications, and reprints or copies of scientific journal articles in ways that do not cause a product to be in violation of the Act. For example, it maybe that materials can be donated to, for instance, libraries, or sold independently of the product, provided that the recipient of the material does not use it to promote the product. Under such circumstances, it generally is not necessary to inventory the supply of such materials on hand.

If the manufacturer, distributor, wholesaler, or retailer indicates that it plans voluntarily to recall books, reference publications, or reprints or copies of scientific journal articles, the agency should follow the standard recall procedures. (See Regulatory Procedures Manual, Chapter 7, Subchapter: Recalls, Section: Firm-initiated Recalls and Investigations Operations Manual, Chapter 8, Subchapter 800, Parts 815-816 and Subchapter 820, Parts 821-823.)

If the product is not brought into compliance through voluntary compliance activities, the agency may consider taking appropriate regulatory action, including filing a complaint for forfeiture against the product, an injunction to halt the misuse of the printed material, or other remedies. As a matter of policy, the agency will not recommend the seizure nor will it seek, encourage, or suggest the destruction of books, reference publications, or reprints or copies of scientific journal articles that may serve as labeling for the product.

When the agency investigates situations in which books, reference publications, or reprints or copies of scientific journal articles cause a product to be in violation of the Act, agency personnel should mark only those items collected as official samples. Furthermore, if agency investigators collect a book or other publication as an official sample as evidence that the product is violative, they should follow procedures for payment for the sample. (See Investigations Operations Manual, Chapter 4, Subchapter 410, Part 416.)

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