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VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments to FDA Proposed Rule;
Use of Certain Symbols in Labeling
Docket No. FDA-2013-N-0125

Dear Sir or Madam:

On behalf of the Combination Products Coalition (“CPC”), we welcome the opportunity to comment on FDA’s proposed rule regarding the use of certain symbols in labeling (hereinafter, the “Proposal”). The CPC applauds the Agency’s move toward greater flexibility in labeling. As FDA has recognized, symbols can offer benefits over the written word: they can provide less crowded and more legible product labels, and reduce the chance of labeling errors in globally marketed products where text language will change between countries, but symbols will not.¹ Allowing manufacturers flexibility to use symbols can therefore improve communication with both clinicians and patients.

By way of background, the CPC is a diverse group of drug, biological product, and medical device manufacturers with substantial experience in the combination products area. Our members range in size from small start-ups to multi-billion dollar manufacturers. These companies all share an intense interest in policy issues affecting combination products. Because of our diverse, cross-industry membership, we think the CPC brings a broad and unique perspective to issues affecting combination products.

One of our principal goals is to work with FDA on such issues in order to advance our common mission of providing the best possible health care for patients. In this regard, the CPC has had frequent dialogue with FDA on regulations, guidance documents, and other policy issues that affect combination products and how best to serve patient needs with respect to such products. For example, we have submitted dozens of written comments, policy documents,

¹ See FDA Guidance for Industry: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 2 (Nov. 2004).

proposed guidance documents, and other materials to the agency on these issues for nearly a decade. If you are interested, you can find several of these materials on our website: <http://www.combinationproducts.com/>.

Our comments on the Proposal focus on three issues of particular interest to our members: (1) application of the Proposal to combination products, (2) what it means for a standard to be FDA recognized, and (3) what it means for a symbol glossary to “contemporaneously accompany” an article. We address each issue in turn, below.

I. Application of the Proposal to Combination Products

A combination product is comprised of two or more different regulated components (e.g., drug/device, drug/biological) that are combined into a single entity; co-packaged; or labeled in such a way that the two components must be used together.² Depending on its configuration, a combination may need to meet the requirements on each constituent (e.g., a drug/device combination may be subject to both drug and device regulations), which creates problems if the different constituent regulations conflict.

FDA’s Proposal would amend device (including biological IVD) regulations to allow labeling with symbols that are “contained in a standard that FDA recognizes under its authority under 514(c) of the [Act] and is explained in a symbol glossary that contemporaneously accompanies the [article].”³ However, drug and non-IVD biological regulations continue to require text (except for the prescription symbol “Rx”).⁴ As a result, it is unclear if combination products with drug and non-IVD biological constituents could use symbols that are allowed under the Proposal.

Given that symbols can provide more readable and less error-prone labeling, there is no reason their use should be limited solely to devices. Therefore, the CPC recommends (a) harmonizing drug and non-IVD biological labeling regulations with the Proposal to allow symbols applied to all articles (drugs, biologicals, and devices) or, at minimum, (b) clarifying that combinations products with a device (including biological IVD) constituent can use symbols in accordance with the Proposal.⁵

² 21 C.F.R. 3.2(e).

³ Proposed 21 C.F.R., §§ 660.2, 801.15, 78 Fed. Reg. 23508, 23513-14 (Apr. 19, 2013).

⁴ 21 C.F.R. 201.15; 21 C.F.R. 610, Subpart G.

⁵ The CPC recognizes that procedural issues might prevent FDA from adopting some of the requested changes in the final rule because they were not included in the Proposal. In that case, the CPC recommends extending flexibility in using symbols through enforcement discretion until the drug and non-IVD biological regulations can be updated, and documenting this discretion in the final rule preamble.

II. The Meaning of “A Standard FDA Recognizes”

The CPC recommends that the Agency clarify the meaning of “a standard *FDA* recognizes” (emphasis added), which defines the symbols that could be used under the Proposal. In the past, some CPC members have been told by Agency officials that if a Center adopts a consensus standard it adopts it for all Centers, absent a Center’s statement to the contrary. However, to our membership’s knowledge, this policy has never been documented by FDA.

The CPC is in favor of harmonizing standards Agency-wide whenever possible to reduce conflicting requirements across the Centers that regulate combination products. Also, the CPC always favors transparency in inter-Center coordination so our membership has a clear understanding of FDA expectations; to that end, the CPC has consistently advocated for updating inter-Center agreements to reflect current policies, and clarifying Center coordination in guidance documents and regulations. Therefore, we recommend that the Agency follow a policy that favors Agency-wide adoption of standards, and document its policies in the final rule and/or other enduring materials (e.g., inter-Center agreements, guidance documents).

III. The Meaning of “Contemporaneously Accompanies”

As mentioned above, Proposal states that symbols in labeling must be “explained in a symbol glossary that *contemporaneously accompanies* the [article]” (emphasis added). “Accompanies” in the context of labeling has generally been interpreted broadly to include all varieties of written materials that are connected to a manufacturer’s marketing and sale of a product, even when the materials are not physically with the product.⁶ “Contemporaneous” means that something exists during the same time as something else.⁷ Reading the terms together, the Proposal suggests that a symbol can be used in labeling *provided* a glossary exists at the time it is used. Thus, labeling for an article that includes a reference to a website where the glossary can be found, or a box of multiple units of product that has a single copy of a glossary would satisfy the terms of the rule.

The CPC agrees with the flexibility in this approach, but recommends that the Agency clarify the meaning of the terms to avoid confusion about the terms in the future.

⁶ *E.g., Kordel v. United States*, 335 U.S. 345 (1948).

⁷ Definition of “contemporaneous.” Dictionary.com. *Collins English Dictionary - Complete & Unabridged 10th Edition*. HarperCollins Publishers.
<http://dictionary.reference.com/browse/contemporaneous> (accessed: May 06, 2013).

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We commend the Agency initiative in providing more flexibility in labeling regulation, and appreciate its consideration of these comments. We believe by expanding flexibility and clarifying the rule and aspects of Agency policy that are mentioned herein, the Agency will foster easy-to-read and error-free labeling, which benefits clinicians and patients.

Kindest regards,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson". The signature is written in a cursive style with a large initial "B" and "T".

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition