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# 21 U.S. Code § 352

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## Misbranded drugs and devices

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A drug or device shall be deemed to be misbranded—

### **(a) False or misleading label**

(1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 for such drug or device, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or device under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42. The requirements set forth in section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

(2)

(A) For purposes of this paragraph, <sup>[1]</sup> the term “health care economic information” means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug or device. Such analysis may be comparative to the use of another drug or device, to another health care intervention, or to no intervention.

(B) Such term does not include any analysis that relates only to an indication that is not approved under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 for such drug or device.

### **(b) Package form; contents of label**

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

### **(c) Prominence of information on label**

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and

understood by the ordinary individual under customary conditions of purchase and use.

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