

United States Department of Agriculture,

OFFICE OF THE SECRETARY.

NOTICE OF JUDGMENT NO. 1194.

(Given pursuant to section 4 of the Food and Drugs Act.)

ALLEGED MISBRANDING OF PEROXIDE CREAM.

At the December term of the Circuit Court of the United States for the Eastern District of New York the United States Attorney for said district, acting upon a report of the Secretary of Agriculture, filed information in said court against the American Druggists Syndicate, a corporation, New York, N. Y., alleging shipment by it, in violation of the Food and Drugs Act, on or about February 12, 1909, from the State of New York into the District of Columbia, of a product labeled "Peroxide Cream" which was misbranded. The product was labeled: (On circular) "A. D. S. Toilet Dainties." "A. D. S. Peroxide Cream." "It is a pure skin cerate, in which a harmless and efficient whitening agent has been successfully incorporated."

Analysis by the Bureau of Chemistry of a sample of said product showed the following results: Fatty acids, 29.317 per cent; moisture, 40.327 per cent; glycerine, 30.156 per cent; gum, 0.416; ash, 0.7417; boric acid, small amounts, and indication of a very small quantity of peroxide. Misbranding was alleged in the information in two counts; in the first count because the label bore statements, designs, and devices regarding such article and the ingredients and substances contained therein, which were false and misleading in that the words "Peroxide Cream" represented the peroxide as an important ingredient, and was intended to lead the purchaser to believe that peroxide was an important ingredient of such article, when in fact said article contained only an indication of a very small quantity of some peroxide, which said quantity was insignificant. Misbranding was alleged in the second count for the reason that the circular accompanying the article "A. D. S. Toilet Dainties" bore statements, designs, and devices regarding the article and the ingredients and substances contained therein, which were false and misleading in that the statement "Is a pure skin cerate" was false and misleading in that it represented the article to contain wax, when in fact the article contained no wax, and was not therefore a cerate.

On January 13, 1911, the American Druggists Syndicate appeared and filed a general demurrer to the information. On April 11, 1911, the case coming on for hearing on said demurrer, the court after hearing argument of counsel and being fully advised in the premises, rendered the following opinion sustaining said demurrer, and dismissing the information:

VEEDER, J. The defendant has demurred to both counts of a criminal information charging it with misbranding a drug in violation of the act of June 30, 1906, C. 3915, par. 2, 34 Stat. 768, known as the Food and Drugs Act. Section two of the act prohibits "the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia of any article of food or drugs which is adulterated or misbranded within the meaning of this act", and provides that any person who shall ship or deliver for shipment, as therein described, any such article so adulterated or misbranded, shall be guilty of a misdemeanor. The offense of misbranding is defined in section 6 as follows:

"That the term 'misbranded', as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the packages or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this act an article shall also be deemed to be misbranded:

In the case of drugs:

First, if it be an imitation of or offered for sale under the name of another article.

Second, if the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

The remainder of the section deals in similar detail with the case of foods.

The first count of the information alleges that the defendant shipped from the State of New York to the District of Columbia a certain article and drug, which was a mixture of substances for external use, upon which there was a label reading: "A. D. S. Peroxide Cream. Cleansing, Soothing and Healing to the Skin, Antiseptic, Cooling and Refreshing." Elsewhere upon the carton, and upon the package or jar enclosed therein, were immaterial variations of this statement of the properties and purposes of the preparation. It is charged that this was a misbranding within the meaning of the act, "in that the label then and there bore statements, designs and devices regarding the said article and the ingredients and the substances contained therein, which were false and misleading, in that the words 'Peroxide Cream' represent that peroxide is an important ingredient, and tend to lead the purchaser to believe that peroxide is an important ingredient of the article, whereas, in truth and in fact, the article then and there contained only an indication of a very small quantity of same peroxide which said quantity is insignificant."

The scope of the general terms of the definition of misbranding in section 8, "any statement, design or device regarding such article, or the ingredients or

substances contained therein which shall be false or misleading in any particular", must be ascertained by construing them in connection with the subject matter and other provisions of the act. It includes, in the first place, not only statements concerning the ingredients or substances contained in the article, but certain other statements "regarding such articles." What such statements are appears, in the case of drugs, in the paragraph immediately following the definition of misbranding; for instance, drugs in imitation of or offered for sale under the name of another article. The only possible ground for doubting this construction arises from the manner in which the general definition of the term misbranding is followed, in the case of drugs, by specifications which purport to be additions. The remainder of section 8, dealing with the case of food, is perfectly clear. The first three paragraphs specify the particulars other than statements regarding the ingredients or substances contained therein which shall be deemed misbranding, and then follows the general provision covering any statement "regarding the ingredients or the substances contained therein which shall be false or misleading in any particular." Having regard to the fact, however, that the general definition of the term misbranded is expressly applicable to both food and drugs, it does not appear that the difference in phraseology and form of arrangement of the specific provisions for the two articles affects their substantial equality in scope. It is clear that the section does not apply to any statement regarding a drug which does not have reference to the ingredients or substances contained therein, or to any of the particulars specified in the section in the case of drugs. The same process of reasoning discloses the scope of the phrase "false or misleading in any particular." If there is any appreciable difference in the import of the words false and misleading, the scope of the latter term is to be found in the specific provisions of this section in the case of drugs; for instance, where the label fails to state, as required, the quantity or proportion of alcohol contained therein. No statement regarding a drug can therefore be false or misleading in any particular, within the meaning of the act, unless it relates to some one or more of the various particulars expressly enjoined or prohibited by the act.

It appears upon the face of the information that the preparation in question contained some peroxide. There was no statement on the label as to the quantity or proportion, nor does the act require any such statement in the case of peroxide. Certainly, then, the label was not false. In *re Wilson*, 168 Fed. Rep. 566; *United States vs. Boeckmann*, 176 Fed. Rep., 382. But the information alleges that the label is "false and misleading, in that the words 'Peroxide Cream' represent that peroxide is an important ingredient, and tend to lead the purchaser to believe that peroxide is an important ingredient of the article, whereas, in truth and in fact, the article then and there contained only an indication of a very small quantity of same peroxide, which said quantity is insignificant." It is asserted (and it is a fair inference) that the label tends to lead purchasers to believe that peroxide is present to such an extent that the antiseptic and healing qualities of peroxide may be obtained from its use; and it is argued that such is not the fact, and therefore the label is misleading. In other words the Government contends that the statement on the label with reference to the remedial effect of the article is a misbranding within the meaning of the act because the article is in fact ineffectual for the purpose indicated. Assuming that the information is sufficient as a pleading to raise such an issue, this contention is based upon an entire misconception of the scope and purpose of the act. The purpose was to protect the public against deception in the purchase of drugs and food by punishing adulteration and misbranding as therein defined. If the label on a drug is not false or misleading in any of the particulars enjoined or prohibited by section 8, no offense is committed under

that section. By no possible construction can the terms of the act be extended to such a boundless field of inquiry as that involved in the accuracy of the remedial effects claimed for a drug. Such an inquiry could be pursued only through the opinions of contending experts and the experience of those who had used the article, and a conclusive determination could seldom, if ever, be reached. At all events, it is sufficient to say that the act discloses no purpose to hold manufacturers and vendors of preparations like the one in issue here to criminal responsibility for misstatements as to their curative or remedial effects. *United States vs. Johnson*, 177 Fed. Rep. 313.

The second count of the information alleges that there was enclosed with the article a circular entitled "A. D. S. Toilet Dainties," containing the following words under the heading "A. D. S. Peroxide Cream": "It is a pure skin cerate, in which a harmless and efficient whitening agent has been successfully incorporated"; and asserts that this was a misbranding "in that the circular accompanying the article bore statements, designs and devices regarding the said article, and the ingredients and substances contained therein, which were false and misleading, in that the statement 'is a pure skin cerate' is false and misleading in that it represents the article to contain, wax, whereas, in truth and in fact, the said article did not then and there contain wax, and was not then and there a cerate". In other words, the information shows that the alleged false and misleading statement constituting misbranding appeared, not upon the label of the article itself, or upon the package in which the article was contained, but upon a separate circular (the title of which indicates that it advertised other articles) which was enclosed with the article in the enveloping package.

The terms brand and label as used in this connection are perfectly clear and definite; they indicate a statement, design or device affixed to an article. Confusion can only arise from the failure to employ uniform phraseology throughout the different paragraphs of section 8 to express the same idea. In the second numbered paragraph relating to food the phraseology is "if the package fail to bear a statement on the label"; in the fourth numbered paragraph relating to food the phraseology is, "if the package containing it or its label shall bear any statement". Doubtless these variations in expression were employed in view of the fact that such articles are commonly sold either in bottles, jars or cans, in which case the statement, design or device would ordinarily appear on a printed label attached thereto, or in an enveloping carton or package, when the statement would ordinarily be printed on the package. But the clearest provision in the section (the third numbered paragraph relating to food) omits the word label altogether: "If in package form, and the contents are stated in terms of weight or measure they are not plainly and correctly stated on the outside of the package". The plain sense of the language in question is that it embraces any statement, design or device regarding the article, which appears on the outside of the package in which the drug is offered for sale, whether such statement be printed upon or otherwise affixed to the package itself or impressed upon a separate label which is then affixed to the package. An advertising circular enclosed with an article inside the carton in which it is offered for sale, does not induce the sale or deceive the intending purchaser, and is not within the purview of the act.

The demurrer is sustained.

W. M. HAYS,
Acting Secretary of Agriculture.

WASHINGTON, D. C., November 4, 1911.