

## HB316 INTRODUCED



1 HB316  
2 96QTMPM-1  
3 By Representatives Butler, Harrison, Gidley, Robertson,  
4 Wadsworth, Whorton, Wood (D), Yarbrough, Mooney, Bolton,  
5 Fincher, Fidler, Stadthagen, Lamb  
6 RFD: Health  
7 First Read: 20-Feb-25



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SYNOPSIS:

Under existing law, the term "drug" is defined for purposes of preventing the possession, sale, or manufacture of adulterated or misbranded drugs.

This bill would include within the meaning of the term "drug" all foods that contain a vaccine or vaccine material.

This bill would specify that foods containing vaccine material are misbranded if not packaged according to certain requirements.

This bill would also make nonsubstantive, technical revisions to update the existing code language to current style.

A BILL  
TO BE ENTITLED  
AN ACT

Relating to drugs; to amend Sections 20-1-20 and 20-1-25, Code of Alabama 1975, to add foods that contain vaccines or vaccine material to the definition of the term "drug"; to define the term "vaccine or vaccine material"; to



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29 provide certain labeling requirements for food containing  
30 vaccine material; and to make nonsubstantive, technical  
31 revisions to update the existing code language to current  
32 style.

33 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

34 Section 1. Sections 20-1-20 and 20-1-25, Code of  
35 Alabama 1975, are amended to read as follows:

36 "§20-1-20

37 When used in this chapter, the following ~~words and~~  
38 ~~phrases shall~~ terms have the following meanings, respectively,  
39 unless the context clearly indicates otherwise:

40 (1) ARTICLE. When referring to food or drugs, ~~such~~ the  
41 term is used in the broad and comprehensive sense and has  
42 reference to the food product or the drug product in question.

43 (2) BABY FOOD. A food ~~which~~ that purports to be or is  
44 represented for special dietary use as a food for babies by  
45 reason of its special formulation or its particular  
46 suitability for children under two years of age.

47 (3) BOARD. The State Board of Agriculture and  
48 Industries.

49 (4) CLASS A FOODS. Baby food, infant formula, and  
50 potentially hazardous food.

51 (5) COMMISSIONER. The Commissioner of Agriculture and  
52 Industries.

53 (6) DEALER. A manufacturer, wholesaler, retailer,  
54 jobber, and similar establishments, mobile or permanent,  
55 engaged in the sale of food for consumption on premises.

56 (7) DEPARTMENT. The Department of Agriculture and



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57 Industries.

58 (8) DRUG. All medicines and preparations recognized in  
59 the United States pharmacopoeia or national formulary for  
60 internal or external use and any substance or mixture of  
61 substances to be used for the cure, mitigation, or prevention  
62 of disease in ~~man~~ humans or domestic animals. The term  
63 includes food that contains a vaccine or vaccine material.

64 (9) FOOD. All articles of food, drink, confectionery,  
65 or condiment, whether simple, mixed, or compound, used or  
66 intended for use by ~~man~~ humans or domestic animals.

67 (10) FOOD SALES ESTABLISHMENT. Retail and wholesale  
68 stores and places of business, and similar establishments,  
69 mobile or permanent, engaged in the sale of food primarily for  
70 consumption off the premises.

71 (11) INFANT FORMULA. A food which purports to be or is  
72 represented for special dietary use solely as a food for  
73 infants by reason of its simulation of human milk or its  
74 suitability as a complete or partial substitute for human  
75 milk.

76 (12) LABEL. A display of written, printed, or graphic  
77 matter upon the immediate container of any article.

78 (13) MISBRANDED. ~~Such term shall apply to all drugs or~~  
79 ~~foods or articles which enter into the composition of food,~~  
80 ~~the~~ The package or label of ~~which~~ any drug, food, article, or  
81 ingredient or substance that enters into the composition of an  
82 article shall bear or contain that bears or contains any  
83 statement, design, or device regarding ~~such~~ the article or ~~the~~  
84 ingredients or substances contained therein ~~which shall be~~



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85 that is false or misleading in any ~~particular~~ way, including  
86 ~~and to any food or drug product which is falsely branded~~ as to  
87 the state, territory, or country in which it is manufactured  
88 or produced.

89 (14) OPEN-DATE STATEMENT. The terms "Sell By"; "Freeze  
90 By"; "Sell or Freeze By"; "Not to be Sold After"; "Best if  
91 Used By"; "Expiration"; or other terms as defined by ~~rules or~~  
92 ~~regulations~~ rule; or a date without additional words shall be  
93 considered an open-date statement.

94 (15) OUT-OF-DATE. Any article with a label containing  
95 an open-date statement with a date affixed thereto ~~which~~ that  
96 has passed.

97 (16) PERSON. An individual, partnership, corporation,  
98 ~~or~~ association, or any combination thereof.

99 (17) POTENTIALLY HAZARDOUS FOOD. A food that is natural  
100 or synthetic and that requires temperature control because it  
101 is in a form capable of supporting rapid and progressive  
102 growth of infectious or toxigenic microorganisms, or ~~the~~  
103 growth and toxin production of Clostridium botulinum, or ~~the~~  
104 growth of Salmonella Enteritidis. The term does not include  
105 foods ~~which~~ that have a pH level 1 of 4.6 or below; ~~or~~ a  
106 water activity (a sub w) of 0.85 or less; or ~~or~~ a  
107 hermetically sealed containers processed to achieve and  
108 maintain commercial sterility under unrefrigerated conditions.  
109 The foregoing notwithstanding, the board may by rule adopt the  
110 definition for "Potentially Hazardous Food" set out in  
111 subparagraph 1-201.10 (B) (61), Food Code, 1999 Recommendations  
112 of the United States Public Health Service, Food and Drug



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113 Administration, National Technical Information Service  
114 Publication, PB99-115929.

115 (18) STANDARD OF PURITY OR QUALITY. The standards of  
116 purity for food products ~~promulgated~~ adopted by the State  
117 Board of Agriculture and Industries and by statutes of this  
118 state.

119 (19) VACCINE or VACCINE MATERIAL. A substance intended  
120 for use in humans to stimulate the production of antibodies  
121 and provide immunity against a disease that is prepared from  
122 the causative agent of the disease, its products, or a  
123 synthetic substitute; treated to act as an antigen without  
124 inducing the disease; and that is authorized or approved by  
125 the United States Food and Drug Administration."

126 "§20-1-25

127 An article of food shall be deemed misbranded in all of  
128 the following cases:

129 (1) If it is offered for sale under the name of another  
130 article~~+~~.

131 (2) If it is labeled or branded so as to deceive or  
132 mislead the purchaser, or purports to be a foreign product  
133 when ~~not so~~ it is not or if the contents of the package as  
134 originally put up ~~shall~~ have been removed in whole or in part  
135 and other contents ~~shall~~ have been placed in ~~such~~ the  
136 package~~+~~.

137 (3) If, in package form, the name of the article  
138 together with the quantity of the contents in terms of weight,  
139 measure, or numerical count and the name and principal address  
140 of the manufacturer or other person responsible for placing



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141 the article on the market are not plainly and conspicuously  
142 marked on the outside of the package~~†~~.

143 (4) If, in package form, the package is not filled with  
144 the food it purports to contain within the limits of tolerance  
145 fixed by the State Board of Agriculture and Industries,  
146 irrespective of whether the quantity of the contents is  
147 plainly and conspicuously marked on the outside of the package  
148 in terms of weight, measure, or numerical count~~†~~.

149 (5) If the package containing it or its label~~shall~~  
150 ~~bear~~ bears any statement, design, or device regarding the  
151 ingredients or the substances contained therein,~~which~~ and the  
152 statement, design, or device~~shall be~~ is false or misleading  
153 in any particular~~†~~.

154 (6) If, in bulk, it is colored so as to deceive or  
155 mislead the purchaser~~†~~.

156 (7) If it is offered for sale under false  
157 representations~~†~~.

158 (8) If it is an imitation of another article and is not  
159 marked with the word "imitation," followed, without  
160 intervening descriptive matter, by a list of the ingredients  
161 contained therein~~†~~.

162 (9) If it is a compound for which no standard of purity  
163 or quality has been established, and it is not labeled with  
164 the word "compound" followed, without intervening descriptive  
165 matter, by a list of the ingredients; provided, that in the  
166 case of a compound~~which~~ that may be now or from time to time  
167 ~~hereafter~~ known as an article of food under its own  
168 distinctive name and which is not an imitation of or offered



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169 for sale under the name of another article, ~~it~~. It shall not  
170 be deemed to be misbranded if the name of the article is  
171 accompanied on the same label or brand with a statement of the  
172 place where ~~such~~ the article was manufactured or produced; ~~or~~.

173 (10) If the package, label, or brand fails to give the  
174 ingredients or substances by their common names.

175 (11) If it contains a vaccine or vaccine material and  
176 the package, label, or brand fails to bear, in a font of  
177 uniform size and prominence, the words "Contains Vaccine or  
178 Vaccine Material" and does not specify that the article of  
179 food is classified as drug under this chapter."

180 Section 2. This act shall become effective on October  
181 1, 2025.