see United States v. Dotterweich, 320 U.S. 277, 280-81 (1943); United States v. Park, 421 U.S. 658, 670-73 (1975); see also Smith v. California, 361 U.S. 147, 152 (1959) (some penal statutes "dispense with any element of knowledge on the part of the person charged, food and drug legislation being a principal example The usual rationale for such statutes is that the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors — in fact an absolute standard which will not hear the distributor's plea as to the amount of care he has used.").

Moreover, FDA's regulations interpreting sections 201(g)(1) and 201(h), which were adopted after notice and comment rulemaking, and therefore have the force and effect of law, explicitly adopt an objective intent standard. Those regulations, which were originally promulgated in 1952, describe the evidence relevant to determining intent to include:

such [manufacturers' or vendors'] expressions or ... by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such [manufacturers or vendors] or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such [manufacturers or vendors] or their representative, offered and used for a purpose for which it is neither labeled nor advertised ...

21 C.F.R. § 201.128 (1994) (drugs) (emphasis added); see 21 C.F.R. § 801.4 (1994) (parallel provision for devices); see also 17 Fed. Reg. 6818 (July 24, 1952). Thus, under these regulations, evidence of objective intent is not limited to expressions in labeling or advertising, but may be based on the totality of the relevant evidence showing the seller's awareness of how its product is actually used and affects the structure or function of the body, regardless of how the product is labeled or advertised.

The foregoing interpretation of the statutory language is also consistent with FDA's