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Washington, D.C., May 7, 1968.

To: Senate Subcommittee on Antitrust and Monopoly (attention Mr. Gordon).
From: American Law Division.
Subject: Does Food and Drug Administration have authority over oral statements of drug manufacturer's representatives who contact physicians directly.

No specific authority is conferred on the Food and Drug Administration to deal with the matter in question. The Food and Drug Act deals, in pertinent part, with labels and labeling. A drug shall be deemed to be misbranded in several situations set forth in the law. See 21 U.S.C. § 352. We have located three court decisions involving prosecutions under the Food and Drug Act for oral representations which apparently were misstatements respecting the product to which they relate. None of these, however, were concerned with statements to physicians. In *U.S.* v. *Hohensee,* 243 F. 2d 367 (1957) the evidence was sufficient to sustain the conviction of the defendant who subsequent to shipment of harmlessly labeled food products in interstate commerce to pre-arranged towns, went to such towns to give lectures and distribute literature promoting the use of such products to promote health. The case of *Nature Food Centres, Inc.* v. *U.S.* 310 F 2d 67 held that defendants selling drugs identified on attached labels as dietary supplements could not meet branding requirements of Federal Food, Drug, and Cosmetic Act through sale of "lecture notes" concerning the drugs where some of the drugs were destined for sale at stores where notes were not available and, even at halls where lectures were delivered and drugs were available, notes were obtainable only upon payment of additional price In *U.S.* v. *Article of Drug, etc.* 362 F. 2d 923 the court held that the evidence supported the finding that the drug company claimant adopted as its own representation a radio broadcaster's claim that vitamins were efficacious for prevention and treatment of human disease, and that claimant intended its products to be used for general purposes recommended by broadcaster, as asserted by the government which charged misbranding in that claimant's catalogs failed to contain adequate directions for use.

These three cases involving oral statements would appear to have but limited application, if any, to the quetsion presented. It seems to us that there is no clearly defined authority for the exercise of control by the Food and Drug Administration over oral statements of manufacturer's representatives to physicians in all situations.

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(Whereupon, at 10:35 a.m., the subcommittee recessed to reconvene at 9:30 a.m., Wednesday, September 18, 1968.)