

ACCOMPANYING LABELING: Leaflet headed "THE 'NULSAR-6' STORY To You— With an Ulcer problem—Here is wonderful news"; two sheets consisting of a reprint of a portion of an article published in the July 1956 issue of Confidential Magazine and headed "The end of 20,000,000 American bellyaches * * * an amazing new pill that banishes ulcers without drugs or surgery!" and a sheet headed "Nulsar Drug Laboratories, 18444 Sorrento Avenue, Detroit 35, Michigan—Dear Doctor: You have probably seen the enclosed publicity given to the imported tablets that are being taken for ulcers."

CHARGE: The complaint alleged that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the drug *Nulsar* which was misbranded as follows:

502(a)—the labeling of the article, including the designation "Nulsar," the statement "'Nulsar-6' Tablets are most helpful in stomach and duodenum conditions that need a highly absorbent coating over any painful lesions or areas," appearing on the carton, and the statements in the accompanying labeling, were false and misleading since such labeling, when viewed in the setting in which used, represented and suggested that the article was adequate and effective in the treatment of ulcers in humans and in the treatment of stomach and duodenum conditions that need a highly absorbent coating over painful lesions and areas, whereas the article was not adequate and effective in the treatment of such conditions.

The complaint alleged also that if the defendants were forced by an injunction to refrain from using the above-mentioned labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the conditions and purposes for which the article was intended; and that in such case, the article would be misbranded under 502(f) (1) in that its labeling would fail to bear adequate directions for use, because of the omission from the labeling of statements of the conditions and purposes for which the article was intended.

DISPOSITION: On 4-26-57, a temporary restraining order was issued against the defendants. On 5-14-57, the defendants having consented, a decree of permanent injunction was entered enjoining the defendants against using the names, "Nulsar," "Nulsar-6," "Nulsar Drug Laboratories," or "Nulsar Products Company," in any capacity in interstate commerce, and against introducing and delivering for introduction into interstate commerce the article of drug designated as "Nulsar," and against causing the introduction or delivery for introduction into interstate commerce of *Nulsar* or any article of similar composition which—

(1) is accompanied by the above-mentioned accompanying labeling, or any written, printed, or graphic matter substantially to the same effect;

(2) bears or is accompanied by written, printed, or graphic matter which suggests use of the article in the treatment of ulcers, or which contains the false and misleading representations referred to above, or which is otherwise false and misleading; or

(3) does not have labeling that clearly states every disease, condition, symptom, and purpose for which the article is intended to be used and for which it is represented by any means to the public.

5495. Smylax tablets, Smylax tonic, and Ardine tablets. (Inj. No. 313.)

COMPLAINT FOR INJUNCTION FILED: 6-25-57, N. Dist. Ill., against Alexander P. McArthur, t/a Smylax Co. and Ardine Co., Chicago, Ill.