

13610 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

commerce at Morris Plains, New Jersey, for delivery to Glendale, New York, and New York, New York; quantities of the drug, Peritrate SA (Sustained Action Pentaerythritol tetranitrate) tablets, which was misbranded, and a new drug for which no approval of a New Drug Application was effective for all the purposes for which it was offered.

There are transmitted herewith a suggested form of criminal information and the following exhibits:

1. Copies of Notices of Hearing.
2. A copy of the approved New Drug Application labeling.
3. A copy of the mailing piece "490T718 October 1965" which included a reprint of "Pentaerythritol Tetranitrate As Adjunct Therapy In the Immediate Postinfarction Period" and "The Use of Coronary Vasodilators In Acute Coronary Occlusion."
4. A copy of the advertisement from the *Journal of the American Medical Association* of January 3, 1966, and February 7, 1966, identified PE-GP-527-4C.
5. A copy of the advertisement from the April 15, 1966, and April 22, 1966, issues of *Medical World News*.
6. The package insert for Peritrate SA.

SECTIONS OF THE ACT INVOLVED

Count I of the Information charges violation of 21 U.S.C. 331(a) in that the defendant caused the introduction into interstate commerce of an article of drug which was misbranded within the meaning of the following sections of 21 U.S.C.:

352(a) in that its labeling, namely, the reprints contained in the mailing pieces contained false and misleading statements and representations concerning the drug;

352(f)(1) in that said labeling failed to bear adequate directions for use, and the drug was not exempt, since the labeling was not substantially the same as the labeling in the approved New Drug Application; and

352(n) in that the defendant failed to include in the advertisement caused to be issued by it with respect to the drug in the January 3, 1966, issue of the *Journal of the American Medical Association*, a true statement of information in brief summary relating to the effectiveness of such drug as required by 21 CFR 1.105(e). Since these charges are set forth at length in the information and were also alleged in the seizure of this drug, they will not be repeated here.

Count II alleges violation of 21 U.S.C. 331(d) in that the drug may not be introduced into interstate commerce in that it was a new drug within the meaning of 21 U.S.C. 321(p) since it was not generally recognized as safe and effective for all of the uses for which it was offered in the labeling and approval of a New Drug Application with respect to such uses was not effective.

Count III alleges that a second shipment of the drug was misbranded within the meaning of 21 U.S.C. 352(n) in that the defendant failed to include in the advertisement caused to be issued in the April 15, 1966, and April 22, 1966 issues of *Medical World News*, a true statement of information in brief summary relating to the effectiveness of such drug as required by 21 CFR 1.105(e).

BACKGROUND INFORMATION

Peritrate SA is a trademark held by the defendant for the drug, pentaerythritol tetranitrate (PETN) in a time release dosage form Warner-Chilcott Laboratories submitted to the Food and Drug Administration, a New Drug Application for Peritrate SA which was approved on November 23, 1959. This permitted the drug to be offered for use in angina pectoris patients.

The mailing piece referred to in this case consisted of reprints of articles in the medical literature concerning experimental use of PETN. The mailing piece was actually addressed and mailed by the firm of Clark-O'Neill, Inc., Fairview, New Jersey. The list of doctors to whom the literature was to be sent was supplied by Warner-Chilcott Laboratories by means of sticker labels which were applied by the firm and it has no record of names. However, Mr. John Owens, Executive Vice-President of Clark-O'Neill informed FDA inspectors that such a mailing usually includes the New York metropolitan area. A total of 91,000 pieces were sent to medical people throughout the country.

The advertisement in the *Journal of the American Medical Association* [JAMA] issue of January 3, 1966 is a five page color ad. The copy of the ad