

13614 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

others as to the medical conclusions to be drawn from the facts are not required.

The last quotation, the omission of which the agency argues creates a criminal offense, does not appear to be related to the use of the drug advertised but seems to refer to a general medical procedure recommended in the use of all thyroid products by elderly patients. Such an omission again seems to be only a failure to set forth an opinion or conclusion of one medical researcher and is not necessary to complete a factual statement about the drug advertised.

There is apparently some basis for questioning the failure of the ad to disclose the chemical identity of some of the components of Prolid with those of the drugs with which the ad undertook to make some comparisons, although we also understand there may be some difference of opinion as to whether there is complete identity, as reflected by the statement of the Company. But assuming the Agency's contention in this regard is supportable, we do not understand you would contend for prosecution on this factor alone.

Accordingly, it is our view that the matter is not one which justifies the bringing of a criminal action. Even if the agency contentions are technically correct, a fact as to which there appears to be at least an arguable basis for a different view, they involve technical refinement of the nuances which flow from the statements used as in our judgment to preclude a successful prosecution. We strongly feel that this is not the kind of a matter in which to undertake criminal action.

Accordingly, prosecution is declined.

Sincerely,

FRED M. VINSON, Jr.,
Assistant Attorney General,
Criminal Division.
By HAROLD P. SHAPIRO,
Chief, Administrative Regulations Section.

DECEMBER 5, 1966.

The Honorable ATTORNEY GENERAL,
Department of Justice,
Washington, D.C.

Attention Harold P. Shapiro, Chief, Administrative Regulations Section.
Re Wyeth Laboratories, Inc., F.D.C. No. 52677, Federal Food, Drug, and Cosmetic Act. Your reference: FMV:JWK:ik, 21-62-326.

DEAR MR. ATTORNEY GENERAL: This is in reply to your letter of October 5, 1966. We enclose a revised form of Information which charges the violative shipment of Serax capsules on July 21, 1965 [in lieu of June 17, 1965], as well as on April 25, 1966.

At your request, the evidence of the July 21, 1965 shipment has been obtained in order to avoid charging a shipment which occurred before the advertisement's publication dates of June 28 and July 5, 1965.

The July 21, 1965 shipment charged in Count I of the revised form of Information involves the introduction into interstate commerce by Wyeth Laboratories, Inc., at Paoli, Pennsylvania, on July 21, 1965, via the Pennsylvania Railroad, of 1248 100-capsule bottles of 15 mg. Serax capsules for delivery to Wyeth Laboratories, Division of American Home Products Corporation, Baltimore, Maryland.

The April 25, 1966 shipment charged in Count II involves the introduction into interstate commerce by Wyeth Laboratories, Inc., at Paoli, Pennsylvania, on April 25, 1966, via Needham's Motor Service, Inc., of 180 500-capsule bottles of 10 mg. Serax capsules, for delivery to Wyeth Laboratories, Division of American Home Products Corporation, Secaucus, New Jersey.

The violative shipments were made pursuant to Wyeth Finished Stock Transfer Orders No. 51481 and 12226, as confirmed by signed statements made by the respective branch managers at the branches where the lots were received after their shipment in interstate commerce.

We have noted your request concerning copies of the advertisements which appeared in the April 25, 1966 issue of the Journal of the American Medical Association, the April 18, 1966 issue of Medical Economics, and in the March 1966 issue of the American Journal of Psychiatry. Because those advertisements do not photocopy well, one set of the actual advertisements has been obtained for your use and is hereby transmitted together with photocopies of the advertisements.