In regard to the count based on the advertisement in *Modern Medicine*, September, 1965, we would ask you to reconsider your decision not to prosecute with the following considerations.

We have previously written you our views as to the legal necessity for including in the brief summary, information from the package insert titled there "warnings" and "precautions". [United States v. Wyeth Laboratories, F.D.C. 52673 Your ref: FMV:JNK:mfs. 21-62-326 22A-48-20] The law requires that every ad for a prescription drug shall present in brief summary form "such other information * * * relating to side effects, contraindications, and effectiveness as shall be prescribed in regulations."

The regulations require that this summary shall fairly show the effectiveness of the drug in the conditions for which it is recommended, * * * together with those side effects and contraindications that are pertinent with respect to the uses suggested in the advertisement and any other use or uses for which the dosage form advertised is commonly prescribed. When the drug is an approved new drug this information shall be the information from the approved new drug application.

Here, the information omitted, though headed precautions in the approved labeling, was information relating to side effects and contraindications. It warned against use of the drug by persons with anorexia, insomnia, vasomotor instability and other conditions. This was to tell the physician that such persons might experience serious side effects—so serious that the drug should be avoided. While the drug may not be completely contraindicated for all persons with these symptoms, it is contraindicated in some, and in others, side effects are to be expected.

So literally this information was related and pertinent to side effects and contraindications in the medical sense.

Far more important, however, is the fact that Congress used "side effects" and "contraindications" in 502(n) to cover the relevant hazards—whether so denominated in the labeling so-called precautions or warnings.

The legislative history on this point clearly shows that Congress intended the physician to be fully informed by those ads, since they recognized that the majority of doctors learn about drugs from such promotions. This has been discussed in greater detail in our previous letter. For example, the provision, that ads could be exempted from all of the requirements of informing the physician, if they included a statement that full information could be obtained on request, was rejected on the floor of the House. Cong. Rec. House 87th. Cong., 2d Sess., September 27, 1962, pp. 19928-9. The information to be supplied would be the full disclosure inserts which were required even then to include "precautions". The sponsor of this amendment, Representative Blatnik, specifically stated that "There is ample evidence to demonstrate that because of time limitations physicians rely on drug advertisements a great deal in deciding which they should prescribe for their patients. It is incumbent upon us to assure that no false or misleading information is inadvertently relied upon.", p. 19922, and then, "I want to see this bill so drawn as to make sure that doctors get all available information * * *" [in the advertisement itself], p. 19923. To leave a doctor with the impression that no special consideration or care need be given to a patient with anorexia, etc. is certainly misleading.

President Kennedy's proposed amendment on advertising to the Senate Bill was offered on the ground that "Such advertisements should be required to make fair disclosure to physicians of the information (good or bad) needed to permit them to do a better job of selecting drugs for use in their practice". Letter from President Kennedy to Senator Eastland, August 4, 1962, reported Cong. Rec. Senate, August 6, 1962, p. 14682. This would, in our opinion, include precautions.

We think that a reading of the Legislative History on this matter leaves no doubt that the information lacking in this ad was of the sort that Congress intended be presented to the physician.

If we may be of any further assistance, please do not hesitate to call upon us.

Sincerely yours,

WILLIAM W. GOODRICH,
Assistant General Counsel,
Food and Drug Division.