WITNESSES

The principal witnesses in this case will be the Government inspectors who collected the samples; Government chemists who examined the Artane Elixir sample; cooperating physicians who subscribe to the *Journal of the American Medical Association* or the *Archives of Internal Medicine;* and medical officers of the Food and Drug Administration's Bureau of Medicine who can testify as to the approved new-drug applications, approved labeling, and the serious nature of the alleged medical journal advertising misbrandings.

It is requested that, if the information is amended, we will be provided with a copy thereof. Upon request, this office shall render such further assistance as may be possible.

Sincerely yours,

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

NOVEMBER 6, 1968.

Re American Cyanamid Co., Inc., FDC 53050. Your ref. FMV:JWK:jbg: 21-51-518.

Hon. FRED M. VINSON, Jr.,
Assistant Attorney General,
Department of Justice,
Washington, D.C.

DEAR MR. VINSON: Thank you for your letter of October 30, 1968, enclosing a copy of the United States Attorney's letter of July 1, 1968, declining prosecution in this case.

The reasons given for declining prosecution are that the case is old, that the law and regulations are vague, and that the Company's failure to include side effect and contraindication information in its advertisements did not appear to have sufficiently grave medical seriousness to persuade a jury that criminal action had occurred.

It is true that the case is old. We sent it to your office in November 1966. We contacted the United States Attorney urging him to file the case, sent a physician to New York to explain the medical significance of the advertising failures, and supplied a memorandum to him pointing out the medical failures.

The law is not vague. The regulations are clear enough to cover what happened here.

The regulations required the Company to include in all advertisements a brief summary relating to side effects, contraindication and effectiveness and to achieve a fair balance in presenting information related to effectiveness and side effects and contraindications. Quite pertinent here is 21 CFR 1.105(f), which requires that any advertisement for a new drug approved prior to October 10, 1962, "shall present information from [the approved new drug] labeling concerning those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and for any other use or uses for which the dosage form advertised is commonly prescribed."

It is clear to us that the advertisements here involved failed to comply with regulation 1.105 (a) and (f)(2). The details of the inadequacies are set out in the information we sent you and in the memorandum we supplied to the United States Attorney.

The warning ideas that were omitted from the advertisements were required in the labeling as a condition of the approval of the drugs for marketing through the new drug procedures. That they present information which the physician must have in mind for safe patient care cannot be successfully disputed.

The Company had no reason to be in doubt as to what information was required in the advertisements. It had only to go to its approved labeling and fairly summarize that information in the advertisements. The best that can be said for Lederle is that in its summarizations it made a choice of what information it thought the physician needed. But that choice was not available to it. The regulations, which have the force of law, required a summary of the approved prescribing information in the package insert labeling.

To say that "moon face", "buffalo hump", "acne" and some of the other distressing side effects of corticosteroids are unimportant because they merely