

the monographs closely correspond to the approved labeling. In addition, as a result of the Court's interpretation of the phrase "substantially the same" as used in the former regulation (21 C.F.R. 1.105) the agency has changed the regulations under which the labeling violation would be brought. This, of course, is also applicable in the case of the mailing piece, the use of which was claimed to violate the labeling regulations.

Thus, the institution of the criminal action requested would not serve any useful purpose in obtaining a judicial interpretation of the present labeling regulations or as to what constitutes labeling.

Any prosecutions based upon the advertisement of Salutensin in the medical publication for November, 1965, must be predicated upon the regulation which was in force at that time. This prosecution would necessarily involve certain contentions relative to the meaning of the statute and regulations with reference to practices which are not distinctly set out therein. Inasmuch as the agency is in the process of issuing new regulations which will clearly and in detail inform those subject thereto concerning what information is expected to be included and what conduct is prohibited, it is our opinion that the agency's interpretation of the statute can be best advanced by defending any judicial challenge to the issuance of the regulation, or if none is forthcoming, by bringing either a civil seizure or a criminal prosecution based on acts occurring after the regulations have become effective.

The institution of previous criminal proceedings has made known to the industry that this Department intends to make use of criminal sanctions for enforcement of the labeling and advertising provisions of the statute whenever it is necessary to do so to prevent the use of improper promotional materials. Industry publications contain accounts of instances in which drug manufacturers have, after consultation with agency representatives, circularized the medical profession calling attention to improper advertisements or mailing pieces and correcting any misstatements therein.

Representatives of the subject company have stated that it has made an effort to comply with the regulations and intends to do so in the future. They have protested that a misunderstanding as to what practices constituted a violation was possible under the regulations then in force and that Bristol-Myers' violation was occasioned by such a mistake.

Accordingly, we do not believe that the suggested criminal prosecution is required to obtain judicial determination as to legal contentions of the agency or as a necessary aid to enforcement of the Act and regulations. Therefore, prosecution is declined.

While we stand ready to use any of the enforcement procedures prescribed by the statute to insure that prescription advertising fits the requirements of the statute and the regulations, candor requires us to observe that in those instances where we have secured criminal convictions for this type of violation, the penalties imposed by the Courts have not been such as to provide effective deterrents. On the other hand, the technique recently employed by the Commissioner of Food and Drugs, about which we have read in the trade media, appears to provide more assurance of future compliance on the part of those Companies subject to the regulations. It seems obvious that an ethical pharmaceutical company will regard the so-called Dear Doctor letter as a more opprobrious experience than any other available enforcement measure, particularly since it has not been the Commissioner's practice to recommend for prosecution the responsible individuals of the offending corporations. We urge that the Commissioner of Food and Drugs continue to utilize this technique which he has stated has proved very effective, while resorting to civil or criminal litigation only in respect to those recalcitrant offenders, if any there be, as to whom other measures have proved ineffective. If the Government can show that prosecution is resorted to only in such circumstances, the Courts may well adopt a different attitude in imposing sentence.

We are closing our file on this matter.

Sincerely,

WILL WILSON,
Assistant Attorney General,
Criminal Division.

By HAROLD P. SHAPIRO,
Chief, Administrative Regulations Section.