This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507; 52 Stat. 1050–51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: April 25, 1969.

HERBERT L. LEY, JR.,
Commissioner of Food and Drugs.

[F.R. Doc. 69–5247; Filed, May 1, 1969; 8:46 a.m.]

Dr. LEY. On May 1, 1969, the day this announcement was made public, representatives of the Upjohn Co. came in at my request to discuss the steps to be taken in regard to novobiocin. Upjohn markets this antibiotic as Albamycin. In addition, both Panalba and Albamycin–T, which we had ruled ineffective as fixed combination, contain novobiocin as an ingredient.

At this meeting, we advised the firm that we had stopped certification of new lots and we proposed the following steps with regard to Albamycin:

1. That the company issue a letter to all physicians within 10 days describing the new warning and restrictions on use.
2. Prompt printing of the new labeling.
3. Recall to the user level of all outstanding stocks of novobiocin, both oral and parenteral, with replacement to be made by May 31, 1969, with stocks carrying the new labeling.

With respect to the combinations containing novobiocin, we advised the firm that we had stopped the certification for new lots and we proposed:

1. Decertification of all outstanding stocks of the drugs.
2. Prompt recall to the user level of these outstanding stocks.
3. A report on the status of the combination products in the "Dear Doctor" letter on novobiocin.

We discussed with the Upjohn representatives the company's inability even now to produce or to point to any medical support for their efficacy claims that would satisfy the legal requirements.

I regret to say that the firm, up to now, has taken only one of the steps outlined—it has agreed to the submission of labeling for novobiocin.

We were, therefore, obliged to proceed in other ways to carry out the decisions which I strongly believe are necessary to protect the public health. I submit a copy of the new labeling for the record.

Senator NELSON. It will be printed in the record.

(The document follows:)

NOVOBIOCIN

WARNING

Novobiocin should be used only for those serious infections where other less toxic drugs are ineffective or contraindicated, because of the following:

1. The high frequency of adverse reactions, principally urticaria and maculopapular dermatitis. Hepatic dysfunction and blood dyscrasias have occurred less frefrequently.
2. The rapid and frequent emergence of resistant strains, especially staphylococci.