It is our understanding that liver function studies will continue to be periodically carried out in all of the patients who are on long term study with this drug as discussed with your representatives Dr. F. Joseph Murray and Dr. McMaster personally on March 31, 1960. It is also our understanding that immediate report will be made to the administration of all abnormalities developing in liver function tests in patients on long term study as they relate to this drug. We further understand that precautionary remarks regarding the advisability of periodic liver function tests will be made in the proposed brochure.

In accord with the provisions of section 130.10 of the regulations and with the understanding that all of the conditions agreed to and listed above will be met, the application is now conditionally effective. It will be effective when you submit specimens of final printed labeling, incorporating the changes agreed to above, and when all of the other agreed to conditions are fully met. If the new drug is marketed prior to the submission to the New Drug Branch of specimens of such labeling, or without meeting all of the above stated conditions, the application will be considered not effective.

We recommend that you give consideration to the provisions of section 502(c) of the Act by designing the printed labeling to bear information required by the Act prominently and conspicuously as compared to other words, statements, designs, and devices; and to those of section 301(1) which prohibits the use in the labeling or in any advertising of any representation or suggestion that an application with respect to the drug is effective under section 505, or that the drug complies with the provisions of this section.

Paragraph (9) of the new drug application form is regarded as a commitment on your part that all representations in this application regarding the components, composition, manufacturing methods, facilities, controls, and labeling apply to the drug produced until an effective supplement provides for a change or the article is no longer a new drug.

Section 505(e) of the Act provides for the suspension of the effectiveness of the application if further experience and tests with the article show it to be unsafe for use or if it is found that the application contains any untrue statement of a material fact. The application may contain an untrue statement of a material fact by reason of any labeling or advertising in which you prescribe, recommend or suggest conditions of use of the drug differing from the conditions of use provided for in the application (see regulation 130.30 and paragraphs (6) and (9) of the new drug application form).

The effectiveness of this application does not extend to the drug labeled with another distributor's name, or repacked or relabeled by another person, unless covered by an effective original or supplemental application.

The effectiveness of this application under section 505 in no way relieves you of the responsibility for complying with all other provisions of the Act.

Please submit five copies of the final printed labels and other labeling and three finished market packages of the drug when available.

Sincerely yours,

FRANK J. TALBOT, M.D.,
Medical Officer, New Drug Branch,
Bureau of Medicine.

U.S. DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
Washington, D.C., May 12, 1960.

The WM. S. MERRELL CO.,
Lockland Station, Cincinnati, Ohio.
(Attention of Dr. F. Jos. Murray.)

GENTLEMEN: We acknowledge the receipt on April 25, 1960, of your communication dated April 22, 1960, enclosing printed labeling pursuant to your new drug application for "M.E.R.-29 (Triparanol Capsules)."

We have completed our study of this application which became conditionally effective on April 19, 1960, and in accord with the provisions of regulation 130.10 under the Federal Food, Drug, and Cosmetic Act it is effective. Our letter of April 19, 1960, detailed the conditions relating to the effectiveness of this application.

Sincerely yours,

FRANK J. TALBOT, M.D.,
Medical Officer, New Drug Branch,
Bureau of Medicine.