Data Requirements

1. DRUGS.—For convenience, advertisements for drugs (including vaccines and biologicals) may be separated into four categories, as follows:

(a) *New Drugs or New Claims for Drugs Which Have Not Previously Been Advertised in AMA Publications.* A new drug is here defined as any pharmaceutical product which has not been advertised previously in AMA scientific journals. Example of a new claim: use of an established antimalarial drug, such as chloroquine phosphate, in rheumatoid arthritis. In all such cases, the Office of Advertising Evaluation will require supportive scientific evidence for review. It is suggested that clinical and laboratory data on new drugs be submitted to the Office of Advertising Evaluation at the time a New Drug Application is filed with the Food and Drug Administration. This will make it possible, in many cases, to obtain product and advertising clearance prior to the introduction of the drug. However, the Association will not grant final clearance of advertising until notified that the New Drug Application has been approved by the FDA.

(b) *Drugs Which Represent an Additional Brand of a Product That is Already Eligible.* The advertisement alone may be submitted. Supportive data are not required.

(c) *Drugs Which Represent a Modification of an Eligible Product.* Example: Some modification of a previously eligible drug, such as a new salt or ester. All pertinent clinical and laboratory data should be submitted to the Office of Advertising Evaluation.

(d) *Mixtures of Drugs.* Clinical and laboratory data should be submitted for review by the Office of Advertising Evaluation. Clearance depends primarily on showing justification for the rationality of the combination.

2. APPARATUS, INSTRUMENTS, AND DEVICES.—The Office of Advertising Evaluation determines the eligibility of products and the suitability of claims for medical equipment intended for preventive, diagnostic, or therapeutic purposes. Advertisements for products which have not been advertised previously in AMA scientific journals, and new claims for eligible devices should be accompanied by complete scientific and technical data concerning the product's safety, operation, and usefulness. The data should include the results of clinical and