ADMINISTRATION

Total control of quality is a plant-wide activity and represents the aggregate responsibility of all segments of a company. The responsibility for auditing the control system and for evaluating product quality is that of a specific group referred to in this statement as Quality Control. A basic principle in the control of quality is that a production group should not have sole responsibility for final approval of products for distribution. The head of Quality Control should have the authority to release satisfactory lots of products, to reject unsuitable lots, and to recommend the recall from distribution of any lots subsequently found to be unsuitable. He should be responsible to a level of management which enables him to exercise independent judgment. His responsibilities and authority should be clearly defined by management.

BASIC CONSIDERATIONS IN A TOTAL QUALITY CONTROL SYSTEM

A system for the total control of quality should be designed to provide proper personnel, product design, specifications and procedures, facilities and equipment, materials, and records. Provision should be made for the audit, evaluation, maintenance, and revision of the system. The failure of any component is cause for review of the reliability of the system.

I. *Personnel:* Individuals involved in the research, development, engineering, production, and control of any medicinal and related product markedly influence its ultimate quality. These people should be competent in their respective fields of endeavor by reason of academic training, experience, or on-the-job training. Total control of quality can be achieved consistently only through quality-mindedness in each employee and an understanding among all personnel of the part their performance contributes toward product quality.

II. *Product Design:* The quality of a product must be built into it during research, clinical evaluation, development, and engineering. The formulation, the method of manufacture, the tests, the choice of materials, and the packaging and labeling should impart to the product or describe the desired quality characteristics. Effective quality control calls for a continuing quality evaluation and improvement program.

III. *Specifications and Procedures:* Specifications should state clearly the desired characteristics and acceptable tolerances for all raw materials, intermediates, packaging supplies, labeling, and finished packaged products. Procedures should clearly state the necessary steps to evaluate sources, to obtain, receive, test, and accept purchased materials; to produce, store, test, and handle intermediates and products; to provide for checks and audits and such other functions that are necessary to assure products of the desired quality. Specifications and procedures should be recorded and dated to clearly designate the period of their use.

IV. *Facilities and Equipment:* Facilities, buildings, and equipment for manufacturing, testing, and storage should be of such design, size, and construction as to assure the desired quality characteristics of each product. Construction of facilities and equipment should take into account such considerations as ease of cleaning and maintenance and proper location in relation to surroundings in order to help avoid contamination or mix-ups.

V. Materials: Materials used in the manufacture of a product including raw materials, intermediates, packaging supplies, and labeling should be of a level of quality to assure that the final product meets specifications. The method of evaluation of quality characteristics in a material, including identification, sampling, testing, stability, and use in a particular manufacturing operation, should be predicated on the product's intended use and should be sufficient to assure conformance to specifications.

VI. Records: The key element by which administrative control of each lot of product is maintained is the control numbering system and related documentation. This is a system of identifying each product lot and includes marking of each distributed package of the manufactured lot so that the manufacturer can establish the history of the package and its contents, the source of each ingredient, the records of tests made on ingredients as well as on the final product, and the identity of the individual responsible for each of the steps in