The 1962 drug amendments to the FD&C Act introduced the concept that drugs should be produced in accordance with GMPs. The drug industry and FDA jointly developed the GMPs after a careful review of the methods followed in producing drugs. By following the jointly developed guidelines, it is presumed that the marketing of adulterated drugs will be minimized and that if marketed, they could be readily recalled.

The Secretary of Health, Education, and Welfare (HEW) issued regulations (21 CFR 133) for determining whether drugs have been manufactured, processed, packed, or held in accordance with GMPs. Some examples of GMPs are:

--Prepare and maintain for at least 2 years a separate batch-production control record for each batch of drugs produced. The record should include an accurate reproduction of the appropriate formula and a description of each step in the manufacturing, processing, packaging, labeling and controlling of the batch, including dates and specific identification of each batch of components used.

--Establish laboratory controls that include adequate specifications and test procedures to insure that components, drug preparations in the course of processing, and finished products conform to appropriate standards of identity, strength, quality, and purity.

--Maintain, for at least 2 years, complete records of the distribution of each batch of drug in a manner that will facilitate its recall if necessary.

The regulations also include GMPs covering such areas as buildings, equipment, personnel, components, production and control procedures, product containers, packaging and labeling, and complaint files. Appendix II contains more details on GMPs.

To prevent adulterated drugs from reaching the consumer, FDA can initiate one or more of the following legal actions through the Department of Justice.

--Prosecute an individual who violates provisions of of the FD&C Act.