identifies such products by inspecting the firm's facilities and by testing the finished products.

Section 704 of the FD&C Act provides FDA inspectors authority to visually inspect the manufacturing practices, methods, facilities, and conditions under which products are manufactured, processed, or packed. For prescription drugs (but not for drugs which may be purchased without prescription), FDA's authority also extends to a review of production control, quality control, formula, and shipping records, as well as complaint files. These records are used by FDA in the course of its inspections. They are used also to identify and locate products suspected or known to be violative.

Production control records show the step-by-step manufacturing process for each product and can be of great value to inspectors trying to isolate a product containing raw materials suspected or known to be violative or produced under a defective manufacturing process. Quality control records are used to determine whether a firm is maintaining appropriate safeguards for such things as product purity, potency, and stability in its manufacturing process.

The formula is the recipe for the product. It is a complete list of ingredients and the weight or measurements for each ingredient, together with the specifications for combining the ingredients and the conditions and procedures for manufacturing the product. Access to the formula provides FDA inspectors with information to identify the specific ingredients and processes which are supposed to be used and to identify any ingredients or processes which might cause a violative product.

Shipping records enable FDA to determine the specific shipping destinations and indicate whether FDA has regulatory jurisdiction, which extends only to products received or shipped in interstate commerce. Complaint files can give FDA leads on potentially harmful products.

FDA has two methods--seizures and recalls--available for removing products suspected or known to be violative from the market. Seizures are authorized under section 304 of the FD&C Act but require a civil court action and are