-- The relationship between the management of quality control and the management of production operations;

-- The use of expiration dates on drug labels;

-- Detailed requirements for plant sanitation.

The Food and Drug Administration is also giving priority attention to the development of separate GMP regulations for specific processes such as the production of large volume parenterals, tablets or capsules, medicinal gases, and radiopharmaceuticals.

Specific GMP regulations are also being drafted for manufacturers of bulk drugs and for repackers and relabelers.

Compliance Profiles

We have initiated a new system of firm compliance profiles under which we will be better able to determine the current regulatory status of any firm which manufactures medical products, or the regulatory status of and problems with any particular product that firm manufactures in support of the Government-wide Quality Assurance Program. By September 1, 1975, we shall have such profiles on every formulator of prescription drugs and on every manufacturer which has had contracts with any Federal procurement agency for any drugs. We shall complete the profiles library on all other manufacturers as soon as possible.