-- Manufacturing and control operations must be described in written procedures;

-- Appropriate statistical sampling techniques must be followed in quality control testing;

-- A quality control unit must be established with a director who reports to management independent from those responsible for production;

-- All drug products must carry an expiration date on their labels;

-- No penicillin contamination will be permitted in nonpenicillin products; and

-- A new section on sanitation will be added.

FDA 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.