local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) *Responsible persons.* Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) *Compliance with Federal, State, and local law.* Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Approved by the Office of Management and Budget under control number 0910–0251)

[55 FR 38023, Sept. 14, 1990, as amended at 64 FR 67763, Dec. 3, 1999]

PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

Sec.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 371; 42 U.S.C. 262.

SOURCE: 58 FR 47958, Sept. 13, 1993, unless otherwise noted.

§ 206.1 Scope.

This part applies to all solid oral dosage form human drug products, including prescription drug products, over-the-counter drug products, biological drug products, and homeopathic drug products, unless otherwise exempted under § 206.7.

§ 206.3 Definitions.

The following definitions apply to this part:

The act means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

Debossed means imprinted with a mark below the dosage form surface.

Drug product means a finished dosage form, e.g., a tablet or capsule that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Embossed means imprinted with a mark raised above the dosage form surface.

Engraved means imprinted with a code that is cut into the dosage form surface after it has been completed.