

States, for deposit to the special account “Salaries and Expenses, Certification, Inspection and Other Services, Food and Drug Administration.”

[39 FR 11750, Mar. 29, 1974, as amended at 42 FR 27227, May 27, 1977; 48 FR 788, Jan. 7, 1983; 60 FR 56516, Nov. 9, 1995]

**Subpart G—Records**

**§ 429.60 Records of distribution.**

(a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting certification, and showing each such shipment and delivery into, or from any place in, any State or Territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Secretary, the person to whom a certificate is issued, at all reasonable hours within 2 years after disposal of all the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

**PART 430—ANTIBIOTIC DRUGS;  
GENERAL**

**Subpart A—General Provisions**

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**Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962**

430.10 Certification or release of antibiotic drugs affected by the drug amendments of 1962.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 357, 371; 42 U.S.C. 216, 241, 262.

**Subpart A—General Provisions**

**§ 430.3 Definitions applicable to all certifiable antibiotic drugs.**

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this chapter covering the certification of antibiotic and antibiotic-containing drugs.

(b) The term *Commissioner* means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purpose of the regulations for the certification of antibiotic and antibiotic-containing drugs.

(c) The term *act* means the Federal Food, Drug, and Cosmetic Act and amendments thereto. (52 Stat. 1040 *et seq.*; 21 U.S.C. 301–392).

(d) The term *U.S.P.* means the official Pharmacopeia of the United States, including supplements thereto. The term *N.F.* means the official National Formulary, including supplements thereto.

(e) The term *batch* means a specific homogeneous quantity of a drug.

(f) The term *batch mark* means an identifying mark or other identifying device assigned to a batch by the manufacturer or packer thereof.

(g) The term *manufacture* does not include the use of a drug as an ingredient in compounding any prescription issued by a practitioner licensed by law to administer such drug.

[39 FR 18925, May 30, 1974]

**§ 430.4 Definitions of antibiotic substances.**

(a) The following are definitions of antibiotic substances:

(1) *Penicillin*. Each of the several antibiotic substances (e.g., penicillin F, penicillin G, penicillin X) produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum*, and each of