

4-5 RECEIPT FOR SAMPLES - FDA 484

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER 850 Third Avenue Brooklyn, NY 11232 718-340-7000	
2. NAME AND TITLE OF INDIVIDUAL Richard A. Frost, General Manager		3. DATE 12-4-06	4. SAMPLE NUMBER 25563
5. FIRM NAME Quality Wholesale Drug Co.		6. FIRM'S DEA NUMBER AB3632918	
7. NUMBER AND STREET 3146 Front Street		8. CITY AND STATE (Include Zip Code) Brooklyn, NY 11232	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification) The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form. (NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.) One Box of 25 - 1 cc ampoules, Dilaudid HCl (hydromorphone) 2 mg/cc, lot # 0103213 manufactured by Knoll Pharmaceutical Co., Orange NJ.			
10. SAMPLES WERE <input type="checkbox"/> PROVIDED AT NO CHARGE <input checked="" type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> CASH <input type="checkbox"/> BILLED <input type="checkbox"/> VOUCHER <input type="checkbox"/> CREDIT CARD \$15.00	
12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) <i>Richard A. Frost</i>			
13. COLLECTOR'S NAME (Print or Type) Sylvia H. Rogers		14. COLLECTOR'S TITLE (Print or Type) Investigator	
15. COLLECTOR'S SIGNATURE <i>Sylvia H. Rogers</i>			

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Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

(1) ****

(2) ****

(3) ****

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form FDA 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."
