hexanitrate, and *tablets of caffeine and ergot alkaloids* were being held for sale at the Corner Drug Store, after shipment in interstate commerce, the defendant caused one bottle of *methyltestosterone tablets* to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician; and the defendant caused various quantities of the other drugs to be repacked and dispensed without a physician's prescription, which acts of the defendant resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *methyltestosterone tablets* failed to bear adequate directions for use. (The bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing the drug without a physician's prescription, however, caused the exemption to expire.)

Further misbranding, Section 502 (b) (1), the repackaged *tablets of caffeine and ergot alkaloids* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *tablets of phenobarbital and mannitol hexanitrate* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labeling of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *ergot and apiol capsules* and the *tablets of caffeine and ergot alkaloids* failed to bear labels containing the common or usual name of each active ingredient of the drugs; Section 502 (f) (1), all of the repackaged drugs failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the repackaged *ergot and apiol capsules* and *tablets of caffeine and ergot alkaloids* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: November 19, 1952. A plea of nolo contendere having been entered, the court fined the defendant $600.

3884. Adulteration and misbranding of dextro-amphetamine sulfate tablets and amphetamine sulfate tablets and misbranding of Femo pills, Super Femo pills, Femo perles, and ergot and apiol capsules. U. S. v. Saul M. Lipton (Kumfort Drug Products Co.). Plea of guilty. Fine, $1,200. (F. D. C. No. 33723. Sample Nos. 3111–L, 3121–L, 7176–L, 7181–L to 7184–L, incl., 20953–L, 20988–L.)

INFORMATION FILED: October 1, 1952, Northern District of Ohio, against Saul M. Lipton, trading as the Kumfort Drug Products Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about July 14 and August 3, 1950, and January 29, February 3, April 9, and May 12 and 21, 1951, from the State of Ohio into the District of Columbia and the States of Texas and Pennsylvania, of a number

of unlabeled bottles of *dextro-amphetamine sulfate tablets* (represented as 4.62-milligram and 5-milligram strength) and *amphetamine sulfate tablets* (represented as 10-milligram strength), a number of bottles of *ergot and apiol capsules*, and a number of boxes of *Femo pills*, *Super Femo pills*, and *Femo perles*.

LABEL, IN PART: "Marlene Dee Femo Pills [or "Super Femo Pills" or "Femo Perles"] * * * Manufactured for Marlene Laboratories Cleveland, Ohio," and "Ergot and Apiol Capsules."

NATURE OF CHARGE: *Dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets*. Adulteration, Section 501 (d) (2), tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate had been substituted for *dextro-amphetamine sulfate tablets*, and tablets containing not more than 6.3 milligrams of amphetamine sulfate had been substituted for 10-milligram *tablets of amphetamine sulfate*. Misbranding, Sections 502 (b) (1) and (2), the tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f), the labeling of the tablets failed to bear (1) adequate directions for use and (2) such adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users. Further misbranding, Section 502 (e) (2), the *dextro-amphetamine sulfate tablets* (4.62 and 5 milligrams) were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient contained in the tablets; and, Section 502 (i) (3), the *dextro-amphetamine sulfate tablets* (4.62 and 5 milligrams) consisted of tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate and were offered for sale under the name of another drug, namely, *dextro-amphetamine sulfate tablets*.

Ergot and apiol capsules. Misbranding, Section 502 (b) (1), the capsules failed to bear a label containing the name and place of business of the manufacturer, packer or distributor; Section 502 (e) (2), the capsules were not designated in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual names of each active ingredient; and, Section 502 (f) (1), the labeling of the capsules failed to bear adequate directions for use.

Femo pills, Super Femo pills, and Femo Perles. Misbranding, Section 502 (a), the label statement "Containing * * * Emmenogogues," displayed upon the boxes containing the articles, was false and misleading since it represented and suggested that the articles were effective as an emmenagogue, whereas the articles were not effective as an emmenagogue. Further misbranding, Section 502 (e) (2), the *Femo perles* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual name of each active ingredient.

DISPOSITION: October 31, 1952. A plea of guilty having been entered, the court imposed a fine of $1,200.