

FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2731-2750

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 3, 1950.*

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**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAIL-
URE TO BEAR ADEQUATE DIRECTIONS OR WARNING
STATEMENTS**

2731. Misbranding of Nanette Hormone Cream. U. S. v. Nix Cosmetics Co., Inc.
Plea of nolo contendere. Fine, \$800. (F. D. C. No. 23603. Sample Nos.
50260-H, 61334-H to 61336-H, incl.)

INFORMATION FILED: May 20, 1949, Western District of Tennessee, against the
Nix Cosmetics Co., Inc., Memphis, Tenn.

ALLEGED SHIPMENT: Between the approximate dates of April 30, 1946, and
March 21, 1947, from the State of Tennessee into the States of Alabama and
Pennsylvania.

LABEL, IN PART: "Nanette Hormone Cream * * * Distributed By—Nan-
ette Company Memphis 1, Tenn."

*For failure to bear a label containing an accurate statement of the quantity of the contents, No. 2732;
failure to bear a label containing the name and place of business of the manufacturer, packer, or distribu-
tor, No. 2733; cosmetic, subject to the drug provisions of the Act, No. 2731.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Hormone Cream" and the label statement "Each 2 Oz. Contains 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)" were false and misleading since the name and the statement represented and suggested that the article contained a hormone and that it would exert a beneficial hormone-like, or beneficial estrogenic, effect upon the body when used as directed. The article did not contain a hormone and would produce no beneficial hormone-like, or beneficial estrogenic, effect upon the body when used as directed.

Further misbranding, Section 502 (f) (1), the directions for use in the labeling "Apply gently $\frac{1}{2}$ heaping teaspoonful at bedtime. Leave on overnight" were inadequate since they failed to indicate the conditions in which the article was to be used, the body area to which the article was to be applied, and the duration of its use.

DISPOSITION: May 20, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$800.

2732. Misbranding of Coxey-Lax. U. S. v. 24 Bottles * * *. (F. D. C. No. 26620. Sample No. 14188-K.)

LIBEL FILED: March 2, 1949, Northern District of Indiana.

ALLEGED SHIPMENT: On or about December 3, 1948, by Jacob S. Coxey, Sr., from Massillon, Ohio.

PRODUCT: 24 bottles of *Coxey-Lax* at Tremont, Ind. Examination showed that the product consisted essentially of epsom salt, sugar, water, and extracts of plant drugs.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective in the treatment of the diseases and conditions stated and implied: "An Efficient Quick Tone-Up A Valuable Tone-Up * * * An efficient Tone-Up used in cleansing the liver, kidneys, bladder, blood streams, intestines and bowels; aiding in expelling gallstones, and poisonous matter from the body; and to correct constipation, nervousness, headaches, fatigues, and many of the common ailments; immediate relief from Acute indigestion, * * * After Bowels become regulated * * * A Priceless Possession Good Health; has been My Reward; From Using (Daily) Coxey-Lax For years I have traveled through the various parts of the country and many people have asked: How do you keep so young and spry? My reply has been, Coxey-Lax is responsible for it All; the continuous daily use of it (for twenty-five years), having aided digestion thru churning of food, cleansing and expelling poisonous matter from my intestines, liver, kidneys, bladder, body, and purifying my blood; has kept me feeling young, strong and active; never getting tired; only requiring five to eight hours sleep out of twenty-four * * * A tip: By taking Coxey-Lax once a day, it will keep a doctor away, and save \$2 trip and hospital bill."

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (2), it was essentially a laxative and its labeling failed to warn that frequent or continued use of the article may result in dependence upon laxatives to move the bowels, and its labeling failed also to warn that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis.

DISPOSITION: May 11, 1949. Default decree of condemnation and destruction.