

Frank A. Nelson, Chicago, Ill., a number of tubes of *Interferin* which were misbranded, and that the defendant subsequently sold a number of the tubes in violation of Section 301 (c).

**PRODUCT:** Unlabeled collapsible tubes containing an amber-colored paste, known as *Interferin*, intended for introduction into the uterine cavity for the purpose of terminating pregnancy.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (1) and (2), the product was in package form and failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), it failed to bear adequate directions for use.

**DISPOSITION:** August 14, 1946. A plea of guilty having been entered, the court imposed a fine of \$1,000.

**1957. Misbranding of Chinaroid Rectal Balm. U. S. v. The Knox Co. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 16543. Sample No. 39536-F.)**

**INFORMATION FILED:** October 29, 1945, Western District of New York, against the Knox Co., a corporation, Buffalo, N. Y.

**ALLEGED SHIPMENT:** On or about October 9, 1943, from the State of New York into the State of California.

**PRODUCT:** This product was an ointment in a collapsible tube with a key attachment. The directions called for a "one-quarter turn" of the key. At the start, one-quarter turn would cause an application of ointment containing 0.444 gram of stramonium. As the tube rolled up, the amount would increase until, at the maximum, the one-quarter turn would cause an application of ointment containing 5.056 grams of stramonium.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the labeling of the drug was misleading since it failed to reveal the material fact that the use of the article in accordance with the following directions on the label might have resulted in an overdosage of stramonium, and that an overdosage of stramonium may be dangerous: "Use Twice Daily Attach key to bottom of tube and turn slightly until salve reaches end of applicator and exudes. Insert applicator gently into rectum and turn key, attached to tube, one-quarter turn. This provides the proper dose of Chinaroid. If bleeding exists apply Chinaroid with finger instead of inserting applicator. Repeat morning and night as needed to relieve rectal discomfort. If satisfactory relief is not obtained after using for 2 weeks consult a physician."

Further misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since the directions would provide for the administration of an amount of ointment varying from 0.444 gram to 5.056 grams, which might have resulted in a dangerous overdosage of stramonium; and, Section 502 (f) (2), the label failed to bear adequate warnings against unsafe dosage, or methods or duration of administration or application, since it failed to warn that the dosage should be decreased if blurring of the vision or dryness of the throat should develop, and it failed to warn that if those conditions persisted after decreasing the dosage, use of the article should be discontinued. The labeling failed also to warn against use of the drug in those pathological conditions where its use might have been dangerous to health, since it failed to warn that the article should not be used in case of bleeding, which warning is necessary in the case of drugs intended for introduction into the rectum.

**DISPOSITION:** January 28, 1946. A plea of nolo contendere having been entered on behalf of the defendant, a fine of \$500 was imposed.

**1958. Misbranding of Improved Special Tablets. U. S. v. 34 Bottles of Improved Special Tablets. Default decree of condemnation and destruction. (F. D. C. No. 20277. Sample No. 57040-H.)**

**LABEL FILED:** June 20, 1946, District of Massachusetts.

**ALLEGED SHIPMENT:** On or about April 30, 1946, by M. A. Williams, Inc., from Woonsocket, R. I.

**PRODUCT:** 34 bottles, each containing 24 *Improved Special Tablets*, at Boston, Mass.

**LABEL, IN PART:** "Improved Special 24 Tablets."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state why the article was to be used.