

On March 22 and April 29, 1940, the United States attorneys for the Eastern District of Michigan and the District of Nebraska filed libels against 74 cartons of Bromo-Citra at Detroit, Mich., and 22 cartons of the product at Kenesaw, Nebr., alleging that the article had been shipped in interstate commerce on or about January 15 and February 14, 1940, by the Drexel Co. from Elgin, Ill.; and charging that it was misbranded.

The product in both shipments was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency prescribed, recommended, or suggested in the labeling; and in that the labeling failed to reveal facts material with respect to consequences which might result from the use of the article under the conditions of use prescribed in the labeling. Misbranding was alleged with respect to both shipments for the reason that the name "Bromo-Citra" was false and misleading since it indicated that the article was derived from the ingredient sodium bromide; whereas the principal ingredient was acetanilid. Misbranding was alleged with respect to both shipments for the further reason that the representation in the labeling that the average net weight was 100 grams was false and misleading since the net weight of sample vials taken from the shipments showed an average of 6.73 grams and 7.12 grams, respectively.

The shipment of January 15, 1940, to Detroit, Mich., was alleged to be misbranded further in that the representation in the labeling that each ounce contained 16 grains of sodium bromide, was false and misleading since each ounce contained more than represented, namely, not less than 18.36 grains of sodium bromide.

The shipment of February 14, 1940, to Kenesaw, Nebr., was alleged to be misbranded further in that its labeling bore representations that it was to be used as a relief for the discomfort due to simple headache, neuralgia, overindulgence, i. e., too much food, drink, or smoking; that the dose consisted of the contents of the vial in $\frac{1}{2}$ glass of water, that not more than 3 doses should be taken within a period of 24 hours, which were false and misleading since they created the impression that the article constituted an appropriate treatment in such conditions; whereas it was not a safe and appropriate remedy but was a dangerous drug.

On May 14 and June 28, 1940, no claimant having appeared, judgment of condemnation were entered and the product was ordered destroyed.

142. Misbranding of Koenig's Nervine. U. S. v. 45 Bottles of Koenig's Nervine. Default decree of condemnation and destruction. (F. D. C. No. 1529. Sample No. 89142-D.)

This product contained sodium, potassium, and ammonium bromides, extracts of plant material (including valerian), glycerin, alcohol, and benzoic acid. It would be dangerous to health when used as directed, prescribed, recommended, or suggested in its labeling. The labeling was further objectionable since it created the impression that the article was an appropriate treatment for the conditions for which it was recommended and because of failure to reveal the consequences which might result from its use.

On February 29, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 45 bottles of Koenig's Nervine at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about February 15, 1940, by the Koenig Medicine Co. from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that its labeling bore representations that it was indicated as a sedative in common nervousness, sleeplessness, restlessness, nervous irritability, functional nervous disturbances, and headache due to common nervousness, and bore directions that the dose for an adult was $\frac{1}{2}$ to $\frac{3}{4}$ tablespoonful in $\frac{1}{2}$ glass of water 3 times a day, that it should preferably be taken after the noonday and evening meals and at bedtime, that the dose for children 12 to 18 years old was one-half the adult dose, that $\frac{1}{2}$ to $\frac{3}{4}$ tablespoonful should be taken in $\frac{1}{2}$ glass of water after the evening meal for sleeplessness due to nervousness and that the dose should be repeated before retiring if needed; that some individuals are more easily affected by the sedative action of the product and the dose should be regulated accordingly; that if sleepiness occurs during the day the dose should be reduced; that for the conditions indicated it should not be necessary to use the product continuously for long periods and that in cases of persistent nervousness a physician should be consulted; that the product had been used for 50 years and contained no opiates; that some persons are peculiarly susceptible to bromides and on those persons their use might produce a rash; that if such rash appeared the use of the product should be discontinued until the rash disappeared, when its use might be resumed in smaller doses and gradually increased to the point of tolerance; that a very large percentage of nervous disorders are due to a strained, overworked, and irritable condition of

the nervous system; that the product would give relief in those cases by its sedative action which would accomplish a quieting and soothing influence and take the strain and tension from the overtaxed nerves and help them function calmly—which representations were false and misleading in that they created the impression that the article constituted an appropriate treatment for use as a sedative in common nervousness, sleeplessness, restlessness, nervous irritability, functional nervous disturbances, and headache due to common nervousness; whereas it did not constitute an appropriate treatment for such conditions but was a dangerous drug. It was alleged to be misbranded further in that its labeling failed to reveal the fact, material in the light of the representations made, that the use of the article in accordance with the directions might lead to mental derangement, skin eruptions, and other serious effects. It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

On May 27, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

143. Misbranding of Capsules Ka-No-Mor. U. S. v. 144 Packages of Capsules Ka-No-Mor. Default decree of condemnation and destruction. (F. D. C. No. 1941. Sample No. 14238-E.)

This product contained acetanilid, caffeine, and aspirin; and it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling. It was misbranded further for the reasons indicated below.

On May 9, 1940, the United States attorney for the District of Delaware filed a libel against 144 packages of Ka-No-Mor at Wilmington, Del., alleging that the article had been shipped in interstate commerce on or about April 23, 1940, by A. G. Luebert, P. D., from Coatesville, Pa.; and charging that it was misbranded.

It was alleged to be misbranded in that the labeling bore representations that it would give quick relief from pains and aches, headache, neuralgia, colds, fever, toothache, neuritis, and rheumatic pains; would relieve pain and discomfort of simple headaches and neuralgias, head colds, muscular pains and aches; and that it did not contain opiates or narcotics in any form, that one capsule should be taken with a half glass of water and repeated in 20 minutes if necessary, then one every 3 hours as required; that for simple headaches one capsule should be taken with a glass of water and if not relieved within 1 hour, that the dose should be repeated; that when pain is severe, one capsule could be taken every 3 hours until relief is obtained; that for simple neuralgia, such as nerve pains of the head, face, back or limbs, 1 capsule should be taken with a glass of water; repeated in 1 hour if necessary and continued every 3 or 4 hours as required; that it would relieve toothache and was splendid for the relief of pain after extraction of teeth and would relieve the ache after sensitive teeth had been filled; that common colds would usually respond more quickly if one capsule were taken every 3 hours; that it would tend to reduce fever and that it could be taken regularly every 4 hours if required when pain is severe and continual, which representations were false and misleading in that they created the impression that the article constituted an appropriate treatment for these conditions; whereas it was not such a safe and appropriate remedy but was a dangerous drug and also because the label failed to reveal the fact, material in the light of the representations above referred to, that the use of the article in accordance with directions might cause serious blood disturbances, anemia, collapse, or dependence on the drug.

It was alleged to be misbranded further in that its label failed to bear adequate directions for use and adequate warnings for the protection of users.

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

On June 10, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

144. Misbranding of Renton's Hydrocin Tablets. U. S. v. 10 Bottles, 14 Bottles, and 2 Bottles of Renton's Hydrocin Tablets. Default decrees of condemnation and destruction. (F. D. C. Nos. 138, 139. Sample Nos. 41545-D, 59567-D.)

This product contained cinchophen. Its labeling bore representations regarding its use as an analgesic and antipyretic, recommending a dose of 1 to 2 tablets as directed by the physician and that it should be used solely under a