PRODUCT: 42 gross of rubber *prophylactics* at Houston, Tex. Examination of samples showed that 4 percent were defective in that they contained holes.

LABEL, IN PART: "Apris Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "Prophylactics" were false and misleading as applied to an article containing holes.

DISPOSITION: January 31, 1947. Default decree of condemnation and destruction.

2326. Adulteration and misbranding of prophylactics. U. S. v. 311 Gross * * *. (F. D. C. No. 24628. Sample No. 30329–K.)

LIBEL FILED: May 11, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about April 5, 1948, by the Rexall Drug Co., from St. Louis, Mo.

PRODUCT: 311 gross of rubber *prophylactics* at Vernon, Calif. Examination of samples showed that 2.4 percent were defective in that they contained holes.

LABEL, IN PART: "Roger (O.K.) Prophylactic Manufactured by Roger Rubber Products Inc., Los Angeles, Calif."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: June 15, 1948. Default decree of condemnation and destruction.

2327. Adulteration and misbranding of prophylactics. U. S. v. 144½ Gross * * *. (F. D. C. No. 23801. Sample No. 24704–K.)

LIBEL FILED: October 9, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about September 9 and 17, 1947, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo.

PRODUCT: 144½ gross of rubber *prophylactics* at Minneapolis, Minn. Examination of samples showed that 9 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Tested * * * An Aid in Preventing Venereal Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: April 21, 1948. Default decree of destruction.

2328. Adulteration and misbranding of prophylactics. U. S. v. 120 Gross * * *. (F. D. C. No. 19810. Sample No. 51406–H.)

LIBEL FILED: May 1, 1946, District of Minnesota.

ALLEGED SHIPMENT: On or about January 22 and March 15, 1946, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo.

PRODUCT: 120 gross of *prophylactics* at Minneapolis, Minn. Examination of samples showed that 3.7 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Tested on New, Modern Equipment for Your Protection * * * An Aid in Preventing Venereal Diseases" were false and misleading as applied to an article containing holes.

DISPOSITION: The Dean Rubber Manufacturing Co., claimant, filed an answer denying that the product was adulterated or misbranded, and on September 13, 1946, it filed a motion for an order requiring the Food and Drug Administration to deliver a portion of the official sample, remaining untested, to enable the claimant to make an adequate test thereof. After consideration of the arguments and briefs of counsel with respect to the motion, the court handed down, on March 11, 1947, the following decision in denial of the motion:

NORDBYE, *District Judge:* "This is a libel proceeding commenced by an information. The claimant brings this motion for an order requiring the Federal Security Agency of the Food and Drug Administration at Minneapolis, Minnesota, to deliver on payment therefor a sufficient number of prophylactics from the official sample remaining untested to enable the claimant to make an adequate test thereof, or, in the alternative, in the event such part of the official sample is not furnished that the proceeding be dismissed with prejudice.

"Involved in this proceeding are 120 gross of rubber prophylactics. The Food and Drug Administration took an official sample of one and one-half gross prior to the seizure on May 3, 1946. On August 9, 1946, the claimant requested in writing that four dozen of prophylactics out of the official sample of one and one-half gross be turned over to it for analysis, and offered to pay for the same. The request of the claimant has been denied. The reason assigned is that the entire official sample taken by the Government has been used in testing and analysis and no part of the sample which was taken remains. Claimant bases its right to a part of the official sample for analysis under Section 372 (b), 21 U. S. C. A., which reads as follows:

> Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

"Under Section 371, 21 U. S. C. A., the Administrator is specifically given authority to promulgate regulations for the efficient enforcement of the Act and pursuant to this authority the Administrator has promulgated regulations under the sampling provisions of the Act. These regulations provide that, when a sample is collected for analysis, examination, and tests under the Act, it shall be designated as an official sample, and it is then provided

> (b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the Act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless
> * * *
> (2) the costs of twice the quantity so estimated exceeds $10; * * *
> (c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the Act, or otherwise subject to the prohibitions of the Act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the Act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, * * *.

"The Government objects to the motion on the grounds that (1) the statute referred to and the regulations promulgated thereunder refer only to 'a food, drug, or cosmetic' and that a rubber prophylactic must be considered to be a 'device' under the Act, United States v. 43½ Gross Rubber Prophylactics, 65 F. Supp. 534, 535, aff'd March 4, 1947, Circuit Court of Appeals, Eighth Circuit, and therefore is not covered by the Act referred to, and that (2) under Section b (2) of the regulations above quoted, it was not necessary for the Department to collect a quantity in excess of that estimated to be sufficient for analysis by the Government.

"It is the Government's position that, when Congress enacted Section 372 (b), 21 U. S. C. A., and used the terms 'food, drug, or cosmetic,' it did so deliberately, and under Section 321, 21 U. S. C. A., the term 'drug' is specifically defined as 'articles intended for use in the * * * prevention of disease in man * * * but does not include devices or their components, parts, or accessories.' The Government reasons that the omission of 'devices' from Section 372 (b), 21 U. S. C. A., was not an oversight but was done deliberately because 'devices' are generally bulky and expensive, and that it would not be practical to obtain samples of 'devices' in quantities which would be adequate for the inspection of both parties. Claimant, however, urges that the term 'drug' as used in Section 372 (b) includes the term 'device' and that the Food and Drug Department has heretofore construed the term 'drug' as including rubber prophylactics.

"Under the circumstances herein, however, I do not find it necessary to pass on the first objection to claimant's motion because, under the regulations promulgated by the Administrator, the motion must be denied. So far as the record herein indicates, the sample of one and one-half gross was the estimated quantity necessary for analysis by the Government. The showing is that this entire quantity was in fact used for this purpose and is no longer in existence in that by reason of the tests and analysis made by the Government, the entire sample was necessarily destroyed. Under the regulations, it was incumbent upon 'an officer or employee of the Department' to collect 'twice the quantity estimated by him to be sufficient for analysis' unless 'the cost of twice the quantity so estimated exceeds $10.' In response to the motion herein, the Government has filed an affidavit from which it appears that the one and one-half gross taken by the Government as a sample for the purpose of analysis cost $7.05. Twice the cost of the official sample totals $14.10, which, of course, is in excess of the $10 limitation provided in Section (b) 2 hereinbefore recited.

"The Department was under no obligation to permit the claimant to examine any part of the sample which it needed for its own analysis. When a sample is obtained, the Department has no means of knowing whether any claimant will request an examination of the official sample or not. Undoubtedly that fact prompted the Administrator to provide that, where the cost of twice the quantity estimated to be sufficient for analysis exceeds $10, no obligation rests on the officer or employee of the Department to collect twice the quantity. True, the claimant has to make advance payment of the cost of the part of the official sample requested by it for analysis, but the item of initial outlay by the Department is a matter of importance because the Department has no means of knowing whether any demand for inspection will be made by claimant, and therefore has no means of knowing whether any part of the expense in purchasing a sample will be defrayed by the claimant. It appears from the showing herein that, under the regulations, by reason of the cost of the quantity estimated to be sufficient for analysis, it was not necessary for the Government to purchase twice the quantity, and it further appearing that the entire sample has been used for making such analysis and is no longer in existence, it must follow that, if for no other reason, the motion must be denied. It may be pointed out in passing that, by reason of the stipulation entered into between the parties under date of June 10, 1946, and an order of Court made thereon, both the libelant and the claimant were authorized to withdraw representative samples of the property and merchandise seized, not to exceed two gross each, for the purpose of examination, testing and analysis. While the samples thus withdrawn do not constitute a part of the official sample, the claimant must content itself under the circumstances herein with such sample for the purpose of examination, testing and analysis.

"The motion of the claimant is therefore denied. An exception is reserved to the Claimant."

On April 17, 1948, the claimant having withdrawn its answer and consented to the entry of a decree, judgment was entered ordering that the product be destroyed.

2329. Adulteration and misbranding of prophylactics. U. S. v. 38 Gross * * *. (F. D. C. No. 24637. Sample No. 18962–K.)

LIBEL FILED: May 14, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 9, 1948, by the Latex Distributing Co., from Chicago, Ill.

PRODUCT: 38 gross of rubber *prophylactics* at Cincinnati, Ohio. Examination of samples showed that 3.4 percent were defective in that they contained holes.

LABEL, IN PART: "Tetratex Prophylactic Mfd. By L. E. Shunk Latex Prod. Inc. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic," "Prophylactics," and "Germ Proof" were false and misleading as applied to an article containing holes.

DISPOSITION: June 18, 1948. Default decree of condemnation and destruction.