6715. Rubber prophylactics. (Inj. No. 407.)

COMPLAINT FOR INJUNCTION FILED: 7–3–61, W. Dist. Mo., against M & M Rubber Co., Inc., and Neil F. Murry, Jr., Kansas City, Mo.

CHARGE: The complaint alleged that the defendants were engaged in the business of receiving bulk shipments of rubber prophylactics, made in Puerto Rico and Japan, and thereafter testing, packaging, labeling, selling and distributing the articles in interstate commerce; and that when introduced into interstate commerce, by the defendants, the articles were adulterated under 501(c) in that their quality fell below that which they purported and were represented to possess in that they contained holes, and were misbranded under 502(a) in that the labeling contained false and misleading representations that the articles were effective in the prevention of disease.

It was alleged further that the adulterated and misbranded condition of the articles resulted from, among other things, the defendants' failure to test all lots of the articles for the presence of holes; the use of insufficient electric current and insufficient electrolyte solution in the operation of the electronic testing machine used for the detection of holes in the articles; dumping cap-type rubber prophylactics, after testing, into a squirrel cage-type tumbler with hardwood sawdust for drying purposes; the dumping of the cap-type prophylactics and sawdust, after drying, into another tumbler made of hardware cloth and the operation of such tumbler until the sawdust had been removed; the rolling of regular length prophylactics while partly wet, and the presence of untested prophylactics in the room used for the packaging of the tested prophylactics.

The complaint alleged also that the defendants had been warned of the conditions by several inspections and by numerous seizures of defective prophylactics.

DISPOSITION: On 7–3–61, the court entered a temporary restraining order, without notice, restraining the defendants from the acts complained of.

On 9–15–61, the defendants having consented, the court entered a temporary injunction enjoining the defendants from introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce any prophylactics which are (a) adulterated in that they contain holes, and (b) misbranded in that their labeling contains false and misleading representations that the articles are effective in the prevention of disease.

The defendants were enjoined further from introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, prophylactics, unless or until:

(a) Procedures are established which will assure that each prophylactic received by the defendants is adequately tested to determine the presence of holes therein.

(b) Written instructions for the proper operation of the electronic machine used in testing the prophylactics for the presence of holes are posted on, or adjacent to, such machine.

(c) Tests for the presence of holes in the prophylactics are conducted by competent trained employees under the supervision of a designated supervisory employee.

(d) The electronic testing machine is operated with sufficient electric current and sufficient electrolyte solution, and in an otherwise proper manner so as to assure the detection of holes in the prophylactics.

(e) The tested prophylactics are dried in a manner which will remove all moisture and will not cause holes in the prophylactics.

(f) Any untested prophylactics now being held in the packing room of defendants' plant are removed to a different room for storage until tested.

(g) Procedures are established which will assure that no untested prophylactics are placed in the packing room prior to being tested for the presence of holes; and,

(h) All prophylactics which have been the subject of prior detention under the provisions of Chapter 801 of the Act [21 U.S.C. 381], and which purport to have been subsequently tested and packaged under the supervision of representatives of the Food and Drug Administration and released from import detention by the Food and Drug Administration, have been resampled by the Food and Drug Administration for the purpose of determining that the said released lots are free from holes and can be accurately identified with specific lots previously tested by the Food and Drug Administration under the provisions of 21 U.S.C. 381; and any such lots so resampled and retested shall not be introduced or delivered for introduction, or caused to be introduced or delivered for introduction into interstate commerce, if upon the above described retesting they fail to comply with the Act, unless and until such defective lots shall have been processed in the manner set forth in paragraph (i) hereinafter; and all costs of resampling and testing as hereinbefore set forth, shall be borne by the defendants.

(i) All prophylactics which purport to have been tested for the presence of holes, except such detained lots as are hereinbefore described in paragraph (h), and which are now held in defendants' plant in packaged or unpackaged form are retested for the presence of holes, and the retested prophylactics which contain no holes are dried in a manner which will remove all moisture and will not cause holes in the prophylactics, and the retested prophylactics which contain holes are destroyed, with such retesting, drying, and destruction being done under the supervision of an authorized representative of the Food and Drug Administration, Department of Health, Education, and Welfare, and all costs of said supervision being borne by the defendants; and,

(j) All stocks which are to be tested and/or retested as hereinbefore set forth in paragraphs (h) and (i) shall be retained intact in the defendants' plant until a release in writing has been furnished covering said lots by the Food and Drug Administration; such releases to be furnished promptly upon completion of such examinations as may be required.

The decree of temporary injunction provided also that it may be dismissed upon motion of the defendants, jointly and seasonably made, upon a satisfactory showing that the stocks of imported prophylactics now held in the firm's plant, or elsewhere under its control, have been satisfactorily brought into compliance with the Federal Food, Drug, and Cosmetic Act and the terms of this Order and a release in writing furnished by the Kansas City District of the Food and Drug Administration as hereinbefore set forth, and upon further showing that the firm has conducted its operations in compliance with the Act and the terms of this Order for a period of seven months following the release in writing of all stocks of imported prophylactics now held in defendants' plant or elsewhere under the control of the defendants.

DRUG FOR VETERINARY USE

6716. Medicated feed. (F.D.C. No. 45260. S. Nos. 22-364 R, 22-369 R.)

QUANTITY: 132 bags of *Professional Chick Spicer Atoms* and 68 bags of *Professional Broiler Atoms* at Omaha, Nebr.