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]

1401–1450

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 direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., *January 18, 1946.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1401. Action to enjoin and restrain the interstate shipment of UtraJel. U. S. v. Pynosol Laboratories, Inc., Edwin G. Melich, and James J. Melich. Tried to the court. Injunction granted. (Inj. No. 54.)

On October 7, 1943, the United States attorney for the Northern District of Illinois filed a complaint against the Pynosol Laboratories, Inc., a corporation, Chicago, Ill., Edwin G. Melich, and James J. Melich, president and secretary-treasurer, respectively, of the corporation, praying the institution of appropriate proceedings to permanently enjoin the defendants and all persons acting on their behalf from the introduction into interstate commerce of UtraJel, a misbranded drug. For the facts on which the complaint was based, see the court's findings of fact, set forth below.

On October 8, 1943, a temporary restraining order was issued, and on October 25, 1943, the case came on for hearing on the Government's motion for a preliminary injunction pendente lite. After consideration of the arguments of counsel, the court denied the motion and scheduled the case for trial on the question of grant-

*For labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, see No. 1402; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1403; failure to bear a label containing an accurate statement of the quantity of the contents, No. 1403; omission of, or unsatisfactory, ingredients statements, Nos. 1403, 1411, 1412, 1438, 1443; deceptive packaging, Nos. 1431, 1432, 1438; cosmetic, subject to the drug provisions of the Act, No. 1445.

ing a permanent injunction. The trial commenced on December 9, 1943, and at its conclusion the case was taken under advisement by the court. On January 6, 1944, the court entered the following findings of fact, conclusions of law, and order for judgment:

SULLIVAN, *District Judge:*

FINDINGS OF FACT

I

"The defendant, Pynosol Laboratories, Inc., is a corporation organized and existing under the laws of the State of Illinois and has its principal place of business and office in the city of Chicago, State of Illinois; the defendant, Edwin G. Melich, is president of said Pynosol Laboratories, Inc.; and the defendant, James J. Melich, is Secretary-Treasurer of said Pynosol Laboratories, Inc. The said defendants, Edwin G. Melich and James J. Melich, have for some years last past been president and secretary-treasurer, respectively, of said Pynosol Laboratories, Inc.

II

"The defendants, for several years last past, and presently, have been and now are introducing and delivering for introduction into interstate commerce and have been and now are causing the introduction and delivery for introduction into interstate commerce an article of drug upon the label of which appears, among other things, the legends 'UtraJel' 'Regular' or 'UtraJel' 'Mild'. Said drug has been shipped by said defendants from the aforesaid place of business in the city of Chicago, State of Illinois, or from Los Angeles, California, to, into, and through States other than the State of origin of the shipments.

III

"The drug is a semi-solid, amber-colored paste with an odor of pine oil. The quantities bearing the label legend 'Regular' consist essentially of castor oil, potash soap, pine oil, alkali combined iodine and water. The quantities bearing the label legend 'Mild', are essentially the same as the foregoing, except that the alkali combined iodine is not present. The formula and composition of said drug has not been consistent. The amount of castor oil potash soap in the drug has varied from 35.1 percent to 47.5 percent; that of pine oil from 10.3 percent to 25.2 percent; that of water from 34.9 percent to 44.5 percent; and in the drug labeled in part 'Regular', the alkali combined iodine has varied from 1.1 percent to 1.6 percent. Since for the purposes of this case there is no difference between 'UtraJel' 'Regular' and 'UtraJel' 'Mild', wherever hereinafter reference is made to 'Utra-Jel' or the 'drug' such reference will apply equally to both. Said drug is offered, among other things, for injection into the uterus for such purposes, among others, as a uterine evacuant, in terminating pregnancy at any stage of gestation, for inducing labor at term, in incomplete abortions, mis-carriages, and for removing retained portions of the products of conception and as a medicament in the treatment of minor infections of the cervix and cervical canal, cervical erosions, cystic cervix, cervicitis, Trichomonas vaginitis, and minor vaginal ulcerations.

IV

"In connection with the interstate distribution of the said drug, the defendants have distributed written, printed, and graphic matter in the form of circulars, containing suggestions and recommendations as to the usage, technique of use, specifying dosage, frequency and duration of administration. At times, the defendants have enclosed such circulars in retail cartons containing said drug and at times by enclosing the same in the shipping carton in which several of said retail cartons have been shipped. At the present time, the defendants are enclosing, and have so enclosed since July 15, 1942, in said retail cartons, a slip-in, the legend on which is as follows:

'DOCTOR: Directions are available ONLY TO THE MEDICAL PROFESSION. If you do not have a copy, make request on professional stationery or prescription blank, direct to

PYNOSOL LABORATORIES, INC.

Chicago, Ill., U. S. A.'

"In compliance with a doctor's request, referred to in the foregoing slip-in, for directions for the use of UtraJel, the defendants immediately dispatch, and have

for some time last past dispatched, such directions to the doctor requesting the same, by United States mail. The point of origin and the point of destination of the drug and the said circulars containing directions for use have been identical. The drug is valueless to a doctor unless he has available the defendants' directions for use, which set forth, among other things, the conditions for which the drug is offered, the manner and method of use and the dosages, duration and frequency of administration for the respective conditions with respect to which it is offered for use. The device employed by the defendants of enclosing the above-mentioned slip-in in the retail cartons containing the drug causes said circular to be incorporated by reference in the labeling of the drug.

V

"The name UtraJel which appears on the container and carton labels of the drug, and in the aforesaid circulars, and which name appears more specifically in Exhibits 'A' to 'J,' attached to plaintiff's complaint, represents and suggests that said drug is safe and appropriate for introduction into the uterus.

VI

"The aforesaid circulars, as well as various labels, more specifically Exhibits 'F' and 'G' attached to plaintiff's complaint, which have, from time to time, been affixed to containers and cartons of said drug, represent and suggest that said drug is an appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations, and as a uterine evacuant.

VII

"UtraJel is not an effective or appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations or as a uterine evacuant.

VIII

"UtraJel is not safe and appropriate for introduction into the uterus, but is unsafe and dangerous to health and has caused serious injuries. Among the specific injuries which have resulted from its use are extensive destruction of tissue, hemolysis, that is, the destruction of the red corpuscles of the blood, systemic poisoning affecting the heart, lungs, liver, spleen and kidneys, extensive hemorrhage and prolonged bleeding, peritonitis, pulmonary emboli, serious damage to various other internal organs, and the danger of increased susceptibility to infection.

IX

"The dangers to health and to living tissue hereinbefore enumerated in Paragraph VIII, for the most part, are due to the pharmacological action of the potash soft soap ingredient present in UtraJel, or any article of drug having potash soft soap as a base.

X

"The dangers to health hereinbefore enumerated in Paragraph VIII are present when UtraJel is used by licensed physicians or anyone, in any quantity, or for any duration, or with any frequency of usage, for the treatment of any conditions which prevail in the uterus.

XI

"Experiments were conducted with UtraJel on female animals. The results of these tests disclosed that the use of UtraJel on the experimental animals caused: respiratory difficulties upon injection, inflammation of all portions of the female genital tract, including vagina, cervix and uterus, necrosis or death of tissue described as ulceration of the vagina, necrosis of cervical tissue, necrosis of the lining of the uterine cavity and degeneration through the wall of the body of the uterus, resulting in perforation into the peritoneal cavity, the formation of scar tissue of the uterus resulting in permanent sterility, peritonitis with extensive adhesions, damage to blood vessels, to neighboring tissue, to the heart, lungs, and liver. Additional work on animal tissue showed that UtraJel is an hemolytic agent, that is, it destroys the red corpuscles of the blood. It is a recognized scien-

tific fact that the results obtained in such animal experimentation are comparable to the effects which will obtain if the drug is administered to humans.

XII

"The dangers to health, and life itself, inherent in the use of UtraJel, or any other drug having a potash soft soap for its base, or any base, with or without pine oil and with or without small quantities of alkali combined iodine, and water when used in or on the uterus and its ineffectiveness and inappropriateness when used for the treatment of minor cervical infections, cervical erosions, and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations and as a uterine evacuant, make essential the issuance of a permanent injunction restraining henceforth the interstate distribution of UtraJel for use in or on the uterus or in the vagina.

CONCLUSIONS OF LAW

I

"The Court is specifically authorized by Section 302 (a) of the Federal Food, Drug, and Cosmetic Act to restrain the introduction or delivery for introduction or the causing of the introduction or delivery for introduction into interstate commerce of a drug which is misbranded.

II

"Cause has been shown which warrants the issuance of a permanent injunction.

III

"The article of drug whether labeled in part 'UtraJel' 'Regular' or 'UtraJel' 'Mild' is a drug within the meaning of Section 201 (g) (3) of said Act.

IV

"The written, printed or graphic matter, in the form of circulars, distributed by the defendants enclosed either in retail cartons containing the drug or within shipping packages containing cartons containing the drug accompany said drug within the meaning of Section 201 (m) of the Act and hence constitute 'labeling'.

V

"The written, printed or graphic matter, in the form of a circular, dispatched by the defendants by mail in compliance with a request of a doctor is, as a result of the statement made in the slip-in enclosed in the said retail cartons, thereby incorporated by reference and constitutes labeling within the meaning of Section 201 (m) of the Act. The various labels which have been affixed by said defendants to the containers and cartons containing the drug and the said slip-in also constitute labeling within the meaning of said Section 201 (m).

VI

"Said drug is misbranded within the meaning of Section 502 (a) of the Act in that the name 'UtraJel' which appears in the labeling of the drug is misleading since said name represents and suggests that said drug is safe and appropriate for introduction into the uterus; whereas, in truth and in fact, it is not safe or appropriate for introduction into the uterus but is unsafe and dangerous and has caused serious and fatal consequences.

VII

"Said drug is misbranded within the meaning of Section 502 (a) of said Act in that the following statements appearing in the labeling of the drug:

(Tube and carton)

'UtraJel * * * For Cervical and Intra-Uterine use * * * For Specific and Non-Specific Infections of the Cervix and Cervical canal. * * *

'Utra-Jel * * * Indicated as an aid . . . In the treatment of minor infections of the cervix and cervical canal * * * as a uterine evacuant * * *'

(Circulars)

'UTRAJEL * * * CERVICAL INFECTIONS AND CERVICAL EROSIONS (Minor). * * * INFECTIONS OF THE CERVICAL CANAL (Minor). * * *

'CYSTIC CERVIX. * * * AS A UTERINE EVACUANT. * * *

'UTRAJEL * * * cervicitis, cervical erosions, Trichomonas vaginitis and minor vaginal ulcerations * * * uterine evacuant * * *'

and words of similar import appearing in the labeling are false and misleading since said statements represent and suggest that UtraJel is an appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations, and as a uterine evacuant, whereas, in truth and in fact, said drug is not an effective or appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonal vaginitis, minor vaginal ulcerations, or as a uterine evacuant.

VIII

"Said drug is misbranded within the meaning of Section 502 (j) in that it is dangerous to health when used in the uterus in any dosage or with any frequency or with any duration of administration prescribed, recommended or suggested in its labeling.

ORDER FOR JUDGMENT

"Upon the basis of the foregoing Findings of Fact and Conclusions of Law,

"It is hereby ORDERED, that a Permanent Injunction be entered accordingly, with costs against the defendants."

On January 7, 1944, a permanent injunction was entered in accordance with the court's order.

1402. Misbranding of Grover Graham Remedy. U. S. v. S. Grover Graham Co., Inc., and Henry Wilson. Pleas of guilty. Corporate defendant fined $250; individual defendant sentenced to 6 months' imprisonment and fined $250. Execution of prison sentence suspended and individual defendant placed on probation for 1 year. (F. D. C. No. 12560. Sample No. 47774–F.)

On October 23, 1944, the United States attorney for the Southern District of New York filed an information against S. Grover Graham Co., Inc., Newburgh, N. Y., and Henry Wilson, president of the corporation, alleging shipment of a quantity of the above-named product from the State of New York into the State of Missouri on or about December 21, 1943.

Analysis of samples disclosed that the article consisted essentially of sodium bromide (approximately 8.5 grains per tablespoonful), magnesia, sodium bicarbonate, alcohol, chloroform, and water flavored with oil of peppermint and colored with a red dye.

The article was alleged to be misbranded (1) because of false and misleading statements on its label which represented and suggested that it would be efficacious in the cure, mitigation, treatment, and prevention of indigestion, dyspepsia, and other ailments due to imperfect and retarded functioning of the digestive organs, and that it might be taken with perfect safety as often as necessary; (2) in that certain information required by law to appear on the label was not placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the statement, "Sodium Bromide U. S. P. 3½%," would not be understood by the ordinary individual and would not inform that individual of the number of grains or other measure understood by him in a tablespoonful dose; (3) in that its labeling did not bear adequate directions for use, since the directions on the label, "Take a large tablespoonful after meals three times a day or whenever symptoms of indigestion occur * * * Dose should be half a wineglassful followed by another dose in a half hour if necessary. The remedy may be taken with perfect safety as often as necessary," provided for the consumption of an excessive amount of sodium bromide and placed no limitation on the number of doses to be taken daily, whereas consumption of an excessive amount of sodium bromide might be dangerous, and limitations on the number of doses of the article to be taken daily should be contained in the directions; (4) in that its labeling failed to warn that frequent or continued use of the article might lead to mental derangement, skin eruptions, and other serious effects, and that it should not be taken by those suffering from kidney disease; and (5) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recom-