

Complaint

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IN THE MATTER OF

STERLING DRUG, INC., TRADING AS
WINTHROP LABORATORIESCONSENT ORDER, ETC., IN REGARD TO THE ALLEGED VIOLATION OF
THE FEDERAL TRADE COMMISSION ACT*Docket C-253. Complaint, Oct. 12, 1962—Decision, Oct. 12, 1962*

Consent order requiring New York City distributors to cease representing falsely, in advertising in magazines and otherwise, that their "Isuprel" drug "for oral inhalation only" was safe for use when it had potentially adverse effects on cardiac action and might cause tachycardia, palpitation, nausea, headache, nervousness, weakness, and other toxic side effects.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Sterling Drug, Inc., a corporation, trading as Withrop Laboratories, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent, Sterling Drug, Inc., is a corporation organized and doing business under and by virtue of the laws of the State of Delaware, with its principal office and place of business located at 1450 Broadway, in the city of New York, State of New York.

PAR. 2. Respondent is now, and has been for more than one year last past, engaged in the sale and distribution of various preparations that contain an ingredient which comes within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act. This said drug ingredient is isoproterenol, which respondent designates "Isuprel".

The designations used by respondent for said preparations, the formulas thereof and directions for use are as follow:

(1) *Designation:* "Isuprel Soution 0.25%"

Brand of Isoproterenol HCL with Mistometer Oral Inhaler.

Formula: Contains Isuprel HCL 0.25%

w/w (=2.8 mg./ml.), inert propellants (dichlorodifluoromethane and dichlorotetrafluoroethane), flavor, alcohol 33% and, as preservative, ascorbic acid 0.1%.

Directions: For oral inhalation only.

Usual dose:

1 or 2 inhalations.

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Do not inhale more often than directed by physician.

1. Pull green cap from mouthpiece.
2. Pull white mouthpiece off bottle, turn it sideways and fit hole in flattened end onto metal spout (valve stem) of bottle.
3. Hold assembled unit between thumb and index finger.
4. Invert bottle and close lips around open end of mouthpiece. Inhale deeply while firmly pressing down on bottle. Wait one full minute if second dose is necessary.
5. Replace mouthpiece and cap on bottle to protect it at all times. Fit into your pocket or purse or place it on your bedside table.

During use, the Mistometer must always be inverted as it does not operate properly in an upright position. Do not inhale more often than directed by your physician. Run warm or cold water through mouthpiece once daily to wash it.

You may sanitize it by immersing it in alcohol. Warning: Contents under pressure. Keep Mistometer away from extreme heat. Exposure to temperatures above 130° F. may cause bursting. Do not incinerate.

(2) *Designation:* "Isuprel Solution 0.5% (1:200)

Brand of isoproterenol hydrochloride"

Formula: Contains Isuprel HCL 0.5% in buffered aqueous solution containing sodium chloride, sodium citrate, citric acid and glycerine, with chlorobutanol 0.5% and sodium bisulfite 0.3% as preservatives.

Directions: For oral inhalation only. Not for injection. Usual dose: 5 inhalations. Use an all-glass or plastic nebulizer. Do not inhale more often than ordered by physician.

(3) *Designation:* "Isuprel Solution 1% (1:100)

Brand of isoproterenol hydrochloride"

Formula: Contains Isuprel hydrochloride 1% in buffered aqueous solution (containing sodium chloride, sodium citrate, citric acid and saccharin, with chlorobutanol 0.5% and sodium bisulfite 0.3% as preservatives).

Directions: For oral inhalation only. Not for injection. Usual dose: 3 inhalations. Use an all-glass or plastic nebulizer. Do not inhale more often than ordered by physician.

(4) *Designation:* "Isuprel Glossets 10 mg.

Brand of isoproterenol hydrochloride"

Formula: Each Glosset contains 10 mg. Isuprel HCL, with starch, lactose, sodium saccharin, talcum and, as preservative, 2 mg. sodium bisulfite.

Directions: For Sublingual Use only. Usual dose: 1 Glosset placed under tongue and allowed to dissolve without swallowing saliva. Do not use more often than ordered by physician.

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- (5) *Designation:* "Isuprel Glossets 15 mg.
Brand of isoproterenol hydrochloride"
Formula: Each Glosset contains 15 mg.
Isuprel HCL, with starch, lactose, sodium saccharin, talcum
and, as preservative, 2 mg. sodium bisulfite.
Directions: For Sublingual Use Only.
Usual Dose: 1 Glosset placed under tongue and allowed
to dissolve without swallowing saliva. Do not use more
often than ordered by physician.
- (6) *Designation:* "Isuprel Compound Elixir"
Formula: Each tablespoon (15 cc.) contains:
Luminal (brand of phenobarbital)----- 6 mg.
Warning: May be habit forming.
Isuprel (brand of isoproterenol)
HCL ----- 2.5 mg.
Ephedrine sulfate----- 12 mg.
Theophylline ----- 45 mg.
Potassium iodide----- 150 mg.
Alcohol ----- 19%
Directions: Usual Dosage:
Adults: 1 to 2 tablespoons (15 to 30 cc.) three or four
times daily as needed. Children: 1 to 3 teaspoons (5 to 15
cc.) three times daily as needed.

PAR. 3. Respondent causes its said preparations, when sold, to be transported from places of business located variously in the States of Georgia, Texas, Illinois, California and New Jersey to purchasers thereof located in various other states of the United States and in the District of Columbia. Respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial.

PAR. 4. In the course and conduct of its said business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning the said preparations by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in magazines and other advertising media, and by means of circulars and brochures, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations; and has disseminated, and caused the dissemination of, advertisements concerning said preparations by various means including but not limited to the aforesaid media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act.

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PAR. 5. Among the typical of the statements and representations contained in said advertisements disseminated as hereinabove set forth with respect to respondent's preparations are the following:

Isuprel, most potent bronchodilator, is safe and, in contrast with epinephrine, has no potentially adverse effects on cardiac action."

PAR. 6. Through the use of the said advertisements, and others similar thereto not specifically set out herein, respondent has represented and is now representing, directly and by implication, that:

1. "Isuprel" has no potentially adverse effects on cardiac action.
2. "Isuprel" is safe, that is, free from the risk of toxic side effects.

PAR. 7. In truth and in fact:

1. "Isuprel" has potentially adverse effects on cardiac action.
2. "Isuprel" is not safe, that is, it is not free from the risk of toxic side effects, since it may cause tachycardia, palpitation, nausea, headache, nervousness, weakness and other toxic side effects.

The said advertisements therefore were and are misleading in material respects and constituted, and now constitute, "false advertisements" as that term is defined in the Federal Trade Commission Act.

PAR. 8. The dissemination by the respondent of the false advertisements, as aforesaid, constituted, and now constitutes, unfair and deceptive acts and practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

DECISION AND ORDER

The Commission having heretofore determined to issue its complaint charging the respondent named in the caption hereof with violation of the Federal Trade Commission Act, and the respondent having been served with notice of said determination and with a copy of the complaint the Commission intended to issue, together with a proposed form of order; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondent of all the jurisdictional facts set forth in the complaint to issue herein, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as set forth in such complaint, and waivers and provisions as required by the Commission's rules; and

The Commission, having considered the agreement, hereby accepts same, issues its complaint in the form contemplated by said agree-

ment, makes the following jurisdictional findings, and enters the following order:

1. Respondent, Sterling Drug, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 1450 Broadway, in the city of New York, State of New York.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I. *It is ordered*, That respondent Sterling Drug, Inc., a corporation, trading as Winthrop Laboratories or under any other name, and its officers, and respondent's agents, representatives and employees, directly or through any corporate or other device, in connection with the offering for sale, sale or distribution of "Isuprel Solution 0.25%", "Isuprel Solution 0.5%", "Isuprel Solution 1%", "Isuprel Glossets 10 mg.", "Isuprel Glossets 15 mg.", "Isuprel Compound Elixir" or any other preparation that contains the drug isoproterenol whether designated "Isuprel" or any other name, or any other preparation of substantially similar composition, do forthwith cease and desist from, directly or indirectly:

A. Disseminating, or causing to be disseminated, by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which represents, directly or by implication, that any such preparation has no potentially adverse effect on cardiac action.

B. Disseminating, or causing to be disseminated, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of respondent's preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraph I.A. hereof.

II. *It is further ordered*, That respondent Sterling Drug, Inc., a corporation, trading as Winthrop Laboratories or under any other name, and its officers, and respondent's agents, representatives and employees, directly or through any corporate or other device, in connection with the offering for sale, sale or distribution of "Isuprel Solution 0.25%", "Isuprel Solution 0.5%", "Isuprel Solution 1%", "Isuprel Glossets 10 mg.", "Isuprel Glossets 15 mg.", "Isuprel Compound Elixir" or any preparation that contains the drug isoproterenol

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whether designated "Isuprel" or any other name, or any other preparation of substantially similar composition, do forthwith cease and desist from, directly or indirectly:

A. Disseminating, or causing to be disseminated, by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which represents, directly or by implication, through use of the word "safe" or other word or words of similar import or meaning, or in any other manner, that any such preparation can be used without risk of toxic side effect.

B. Disseminating, or causing to be disseminated, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of respondent's preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraph II.A. hereof.

It is further ordered, That the respondent herein shall, within sixty (60) days after service upon it of this order, file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with this order.