

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
Tampa Division

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FEDERAL TRADE COMMISSION,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL NO.
USA PHARMACAL SALES, INC.,)	
)	
JOHN PENCE, and ARTHUR SUSSMAN,)	
)	
)	
Defendants.)	
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**COMPLAINT FOR PERMANENT INJUNCTION AND
OTHER EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), through its undersigned attorneys, for its Complaint alleges:

1. Plaintiff FTC brings this action under Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), to secure a permanent injunction, consumer redress, disgorgement, and other equitable relief against USA Pharmacal Sales, Inc., John Pence, and Arthur Sussman (“Defendants”) for engaging in unfair or deceptive acts or practices in connection with the advertising, marketing, and sale of products purporting to cause substantial weight loss without dieting or exercising, and products for erectile dysfunction purporting to be safe, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this matter pursuant to 15 U.S.C. §§ 45(a), 52, 53(b) and 28 U.S.C. §§ 1331, 1337(a), and 1345.

3. Venue in this District is proper under 15 U.S.C. § 53(b) and 28 U.S.C. § 1391(b) and (c).

THE PARTIES

4. Plaintiff, the Federal Trade Commission, is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The Commission enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The Commission also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. The Commission, through its own attorneys, may initiate federal district court proceedings to enjoin violations of the FTC Act and to secure such equitable relief, including consumer redress, as may be appropriate in each case. 15 U.S.C. § 53(b).

5. Defendant USA Pharmacal Sales, Inc. (“Pharmacal”) is a closely-held Florida corporation with its principal office or place of business at 1247 Florida Avenue, Palm Harbor, Florida 34683. At all times relevant to the complaint, acting individually or in concert with others, Pharmacal has advertised, marketed, and sold META-BIOLOGICAL, FAT•SPONGE IN A PILL, CALOTROL/MD, and VIRILE V to consumers throughout the United States. Pharmacal transacts business in the Middle District of Florida.

6. Defendant John Pence is president and co-shareholder and director of Pharmacal. At all times relevant to this Complaint, acting individually or in concert with others, Mr. Pence has formulated, directed, or controlled the policies, acts, or practices of Pharmacal, including the acts or practices alleged in this Complaint. He transacts business in the Middle District of Florida.

7. Defendant Arthur Sussman is vice-president, treasurer, and co-shareholder and director of Pharmacal. At all times relevant to this Complaint, acting individually or in concert with others, Mr. Sussman has formulated, directed, or controlled the policies, acts, or practices of Pharmacal, including the acts or practices alleged in this Complaint. He transacts business in the Middle District of Florida.

COMMERCE

8. The acts and practices of defendants alleged in this Complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS’ COURSE OF CONDUCT

9. Since at least 2000, the defendants have advertised, labeled, offered for sale, and sold META-BIOLOGICAL, CALOTROL/MD, and FAT•SPONGE IN A PILL, purported weight-loss products, and VIRILE V, an erectile dysfunction product, to the public. The Pharmacal defendants purportedly advertised FAT•SPONGE IN A PILL only during the period February through August 2001. The defendants primarily advertise and offer the named products for sale through regional newspapers, including free-standing newspaper inserts. Their campaign also includes direct mail.

META-BIOLOGICAL, FAT•SPONGE IN A PILL, CALOTROL/MD, and VIRILE V

10. META-BIOLOGICAL contains ephedrine alkaloids from Ma Huang Extract, caffeine (Guarana extract), Hydroxycitrate (“HCA”)(Garcinia Cambogia extract), Chromium Picolinate, Chitosan, Gymnema Sylvestre, Vitamin E, Magnesium Chelate, Zinc Chelate, and twelve other ingredients. The label directs consumers to take one to two tablets before breakfast and lunch.

11. FAT•SPONGE IN A PILL contains Chitosan, Glucomannan, Acidophilus, fructooligosaccharides (“FOS”), and Lactase.

12. CALOTROL/MD contains Chitosan, Gymnema Sylvestre, Hydroxycitrate (“HCA”)(Garcinia Cambogia extract), and Chromium Picolinate.

13. VIRILE V contains Yohimbine from Yohimbe bark extract, Androstenedione, caffeine (Guarana extract), Siberian Ginseng, Panax Ginseng, and nine other ingredients. The label directs consumers to take two tablets “before physical activity”.

14. A one-month supply of each of the three weight-loss products costs \$29.95 and a 2-month supply costs \$49.95, plus \$3.95 shipping and handling on any order size. Sixty pills of VIRILE V costs \$55 plus \$7 shipping and handling. Total sales of the four products were \$5.7 million for 2000-2002 (\$1.86 million in 2000, \$3.3 million in 2001, and \$612,743 thru the first four months of this year.) VIRILE V sales accounted for \$978,806 and \$2.4 million in 2000 and 2001, respectively. META-BIOLOGICAL sales were \$554,693 in 2000, \$848,120 in 2001, and \$337,448 through February 14, 2002.

15. To induce consumers to purchase META-BIOLOGICAL, CALOTROL/MD,

FAT•SPONGE IN A PILL, and VIRILE V, the Pharmacal defendants have disseminated or caused to be disseminated advertisements through newspapers, free-standing inserts, and flyers in direct mail, including, but not limited to the attached Exhibits A-G. These advertisements contain, among other things, the following statements and depictions:

- a. **NO COMPARISON!**
Test, After Test, After Test Proves...
SAFE, ALL NATURAL, DOCTOR-PRESCRIBED
META-BIOLOGICAL SUPPLEMENT IS **THE BEST!**...
It's the Best **FAT BLOCKER**
It's the Best **SUGAR BLOCKER**
It's the Best **CALORIE NEUTRALIZER...**

**SAVE \$20! ONLY THE
META-BIOLOGICAL DIET CAN HELP
YOU SAFELY LOSE UP TO 6 POUNDS
OF FAT, FLUID & FLAB ...
In Just The First 24 Hours Alone!**

Safe and all-natural... The META-BIOLOGICAL DIET is the only doctor-prescribed FAT AND SUGAR BLOCKER that can help you LOSE AS MUCH AS 50% OF ALL EXCESS FAT – in just 14 days!

With META-BIOLOGICAL DIETARY SUPPLEMENT, you lose pounds and inches SAFELY... without counting calories, without depriving yourself of tasty, delicious foods – and most importantly, without dangerous drugs like Phen-Fen or Meridia!

Thousands of men and women across America have tried this amazing breakthrough formula and know that **IT WORKS:**

. . . . **'Loved the results, 23 pounds in 14 days...** D.T. Beaver creek, OH

Doctors are prescribing it to their patients who haven't been able to lose weight safely any other way. . . .If you want to lose weight (and plenty of it) – if you want

to lose inches (4, 6 up to 10" on your stomach, thighs, buttocks and hips)... You don't risk a penny – it's your weight and your health!

- Exhibit A, newspaper advertisement

b. . . . *'Thank you doctor for my brand new body=*

[a photograph of a slim woman eating a brownie and lying on her side appears under this headline, taking up the full width of the advertisement]

'I've been treating overweight patients for over 20 years – but never have I seen anything like this breakthrough development that's been tested at one of America's leading medical schools – and that can help you LOSE UP TO 6 POUNDS OF FAT, FLUID & FLAB IN JUST THE FIRST 24 HOURS ALONE – SHRINK DOWN YOUR WAISTLINE 4 SIZES SMALLER IN AS LITTLE AS 14-21 DAYS!'

[a picture purportedly of a Dr. James Hughes, MD appears next to this statement, with his purported signature underscoring the entire statement.]

NO COMPARISON!

**SAFE, ALL NATURAL, DOCTOR-PRESCRIBED
META-BIOLOGICAL SUPPLEMENT IS THE BEST!**

Exhibit B, free-standing insert, newspaper advertisement

c. *Great New Way to Lose Weight Fast!*

FAT-SPONGE IN A PILL!

Now, Draw The Fat Right Out Of Your Body's Fat Cells...

And Flush It Away By The Hour!

*Lose Pounds By The Day- Inches By The Week, Without
Starvation Diet or Counting A Single Calorie!. . . .*

[depiction of a slim woman standing in a bathroom, with the product in the foreground and an inset of a thumb and forefinger holding a pill, appears on the right side of the ad, for two-thirds of its height.]

...it's the latest medical breakthrough that can help you soak up and flush away 50, 60, even 100 lbs. of ugly fat, or even more...

...as much as 2 lbs. of unwanted fat soaked up and flushed away in just 24 hours. As much as 4 waistline inches soaked up and flushed right out of your body in just 2 weeks! Medical Science's thrilling new lifetime slimness program, featuring the amazing "Fat-Sponge In A Pill" that lets you eat more, weight (sic) less and finally... yes, thank heavens, finally... slim down for good for the rest of your life!And mind you... without brutal diet or heavy duty exercise. . . .[depiction of cells with arrows pointing out of the body through the skin, under which appears the statement: **Draws the Fat out of your body's fat cells!**]. . . .

Let's face it. The medical research is done. The amazing weight-slashing concept of this incredible "Fat-Sponge In A Pill" has been proven beyond the shadow of a doubt on scores of overweight patients. Now the final step is up to you. . . . ask yourself... how would I look one week from today as much as 7-10-15 pounds lighter?"

Exhibit C, newspaper advertisement

d. **Eat Everything You See Here and Still Lose Weight!**

[depiction below the headline and spread across the page of various food items, including hamburgers, hotdogs, french fries, steak, ice cream, sausage, bacon, eggs, and cheese. In the middle of the advertisement appears a depiction of a slim woman, almost as tall as the ad.]

'My "formula for living" lets you eat: Hamburgers, Hotdogs, Fries, Steak, Ice Cream, Sausage, Bacon, Eggs, Cheeses! And **NOT GAIN WEIGHT!**

[next to this statement appears a boxed picture of a Dr. James Hughes, M.D.]

Doctor tested and all-natural "Fat Blocker"

You're about to start on a journey to slimness with a no-diet treatment for obesity featuring a bio-chemical discovery that's been tested at the National Institute of Health, the UCLA Medical School and University of Michigan School of Medicine, that makes it possible for you to eat as much as you always have and still lose as much as 50% of all excess fat in just 14 days. And if you need to...go

on to lose as much as 40, 50, 60 even 100 lbs as you:

- Lose up to 10" off your waistline
- Lose up to 6" off your thighs
- Lose up to 8" off our buttocks
- Lose up to 9" off our hips
- Lose up to 8" off your stomach

...This breakthrough treatment has patients losing one full pound every 8 hours, 3 pounds more each day and all without counting calories, without missing a single meal and without giving up those delicious, mouthwatering foods they love the most.

You Don't Diet! So There's No Slide Back

...No yo-yo effect, just pounds and inches effortlessly. Because you eat and because you're full it's easier to keep the weight off forever! . . . You'll feel healthier and you'll end years of frustration of going from diet to diet.

Exhibit D, newspaper advertisement

- e. **...Now Boost Your SEX DRIVE Instantly** *With 100% Safe Herbal VIRILE V!*

. . . . **VIRILE V** is NOT dangerous for your health. . . . Just take two tablets one hour before lovemaking and...BINGO! **VIRILE V** is the safe, all-natural aphrodisiac that is revolutionizing sexual pleasure for the 21st century!. . . . *100% Safe & Natural!...No Side Effects!*

Exhibit E, newspaper advertisement

- f. Now for the very first time, **VIRILE V** gives you a lower-cost, ALL-NATURAL alternative to high-priced prescription VIAGRA. And best of all, you don't have to worry about harmful side effects (and even death), as reported about Viagra. **VIRILE V** is NOT a drug. It's NOT dangerous for your health. It's NOT habit-forming No Side Effects!

Exhibit F, newspaper advertisement

- g. . . . **NOW DISCOVER THIS 100% NATURAL NON-PRESCRIPTION WAY TO RESTORE YOUR SEXUAL POTENCY – INSTANTLY**

Dear Friend:

With **VIRILE V**, the right time for sexual passion ... can be ANY TIME!

Herbal **VIRILE-V** works like a miracle to restore your sexual vigor 100% safely – and naturally!

It's NOT dangerous, NOT a drug, NOT habit-forming and there are NO side effects or interactions with other medications. . . .

A note from Dr. Hughes...

Dr. James Hughes, M.D.
Originator Of The VIRILE-V Formula

Dear Friend:

. . . . I'm proud to say that my exclusive, proprietary VIRILE-V formula is the result of years of research into human sexual function. VIRILE-V is SAFE, non-habit-forming and has absolutely NO SIDE EFFECTS. . . .

Dr. James Hughes, M.D.

[Dr. Hughes purported signature appears above the signature block]

Exhibit G, direct mail advertisement

THE FTC ACT

16. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, META BIOLOGICAL and other ephedrine alkaloid products, CALOTROL/MD, FAT•SPONGE IN A PILL, and VIRILE V and other products containing yohimbe and/or androstenedione are either

“foods” or “drugs” as defined in Sections 15(b) and (c) of the FTC Act, 15 U.S.C. §§ 55(b), (c). As set forth below, the defendants have engaged and are continuing to engage in such unlawful practices in connection with the advertising, marketing and sale of META BIOLOGICAL and/or other ephedrine alkaloid products, CALOTROL/MD and FAT•SPONGE IN A PILL for weight loss, and VIRILE V and/or other products containing yohimbe and/or androstenedione for erectile dysfunction.

**UNFAIR OR DECEPTIVE ACTS OR PRACTICES
IN VIOLATION OF THE FTC ACT**

COUNT I

**False Claims for META-BIOLOGICAL, CALOTROL/MD,
FAT•SPONGE IN A PILL, and VIRILE V**

17. Through the means described in Paragraph 15, including through the statements contained in the advertisements attached as Exhibits A through G, the defendants have represented, expressly or by implication, that:

- a. META-BIOLOGICAL causes rapid and substantial weight loss without the need to reduce caloric intake, enabling users to lose as much as 6 pounds in 24 hours, 50% of excess weight in 14 days, and 23 pounds in 14 days.
- b. FAT•SPONGE IN A PILL causes rapid, substantial, and permanent weight loss without the need to exercise or reduce caloric intake, enabling users to lose as much as 15 pounds in one week and 100 pounds overall.
- c. CALOTROL/MD causes rapid, substantial, and permanent weight loss without the need to reduce caloric intake, and while eating such fatty foods as hamburgers,

hotdogs, french fries, steak, ice cream, sausage, bacon, eggs, and cheese, enabling users to lose as much as a pound every 8 hours, 3 pounds a day, and 100 pounds overall.

- d. VIRILE V has no harmful side effects and no adverse interactions with other medications.
18. In truth and in fact:
- a. META-BIOLOGICAL does not cause rapid and substantial weight loss without the need to reduce caloric intake, enabling users to lose as much as 6 pounds in 24 hours, 50% of excess weight in 14 days, and 23 pounds in 14 days.
 - b. FAT•SPONGE IN A PILL does not cause rapid, substantial, and permanent weight loss without the need to exercise or reduce caloric intake, enabling users to lose as much as 15 pounds in one week and 100 pounds overall.
 - c. CALOTROL/MD does not cause rapid, substantial, and permanent weight loss without the need to reduce caloric intake, and while eating such fatty foods as hamburgers, hotdogs, french fries, steak, ice cream, sausage, bacon, eggs, and cheese, enabling users to lose as much as a pound every 8 hours, 3 pounds a day, and 100 pounds overall.
 - d. VIRILE V does have harmful side effects and adverse interactions with other medications. For example, yohimbe, an active ingredient in Virile V, can substantially increase blood pressure and can interact adversely with other drugs that may be taken by men with conditions that cause erectile dysfunction.

19. Therefore, the making of the representations set forth in Paragraph 17 constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT II

False Establishment Claims for META-BIOLOGICAL, CALOTROL/MD, FAT•SPONGE IN A PILL, and VIRILE V

20. Through the means described in Paragraph 15, the defendants have represented, expressly or by implication, that:

- a. Clinical tests prove that META-BIOLOGICAL safely prevents the body's absorption of fat, sugar and calories from whatever the user eats.
- b. A clinical test by one of America's leading medical schools shows that META-BIOLOGICAL causes rapid and substantial weight loss.
- c. Medical research has proven that FAT•SPONGE IN A PILL causes substantial and permanent weight loss.
- d. CALOTROL/MD is an obesity treatment tested at the National Institutes of Health, the UCLA Medical School, and the University of Michigan and shown through those tests to cause rapid and substantial weight loss generally and substantial weight loss and reduction in size of the waistline, thighs, buttocks, hips, and stomach.

21. In truth and in fact:

- a. Clinical tests do not prove that META-BIOLOGICAL safely prevents the body's

absorption of fat, sugar and calories from whatever the user eats.

- b. A clinical test by one of America's leading medical schools does not show that META-BIOLOGICAL causes rapid and substantial weight loss. In fact, there have not been any clinical tests of META-BIOLOGICAL.
- c. Medical research has not proven that FAT•SPONGE IN A PILL causes substantial and permanent weight loss. In fact, there has not been any medical research on the weight loss effects of FAT•SPONGE IN A PILL.
- d. CALOTROL/MD is not an obesity treatment medically tested at the National Institutes of Health, the UCLA Medical School, and the University of Michigan and shown through those tests to cause rapid and substantial weight loss generally and substantial weight loss and reduction in size of the waistline, thighs, buttocks, hips, and stomach. In fact, there has not been any medical testing of the weight loss effects of the CALOTROL/MD product.

22. Therefore, the making of the representations set forth in Paragraph 20 constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

COUNT III

Unsubstantiated Claims for META-BIOLOGICAL, CALOTROL/MD, FAT•SPONGE IN A PILL, and VIRILE V

23. Through the means described in Paragraph 15, the defendants have represented, expressly or by implication, that:

- a. META-BIOLOGICAL:
 - (1) Prevents the body's absorption of fat, sugar and calories from whatever the user eats.
 - (2) Causes substantial loss of weight and reduction in size of the stomach, thighs, buttocks, and hips.
 - (3) Is safe.
- b. FAT•SPONGE IN A PILL draws fat out of the body's fat cells, causing substantial weight loss.
- c. CALOTROL/MD:
 - (1) Prevents fat absorption and weight gain, regardless of what the user eats.
 - (2) Causes substantial loss of weight and reduction in size of the stomach, thighs, buttocks, and hips.
 - (3) Eliminates the "yo-yo" syndrome experienced by many dieters of repetitive weight loss followed by weight gain.
- d. VIRILE V is safe.

24. The defendants did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 23 at the time the representations were made. Among other reasons, there is no competent and reliable evidence that:

- (1) META-BIOLOGICAL, FAT•SPONGE IN A PILL, or CALOTROL/MD, or ephedra, the primary active ingredient in META-BIOLOGICAL, can produce substantial, rapid weight loss (e.g., an average of about one pound per day for two weeks) or can cause

reduction in size of specific areas of the body, such as the stomach, thighs, buttocks, or hips;

(2) FAT•SPONGE IN A PILL draws fat out of the body's fat cells;

(3) CALOTROL/MD prevents fat absorption, regardless of what the user eats, or eliminates the "yo-yo" syndrome; or

(4) ephedra and VIRILE V, which contains the steroidal hormone androstenedione and yohimbe, are safe; ephedra has not been clinically proven to be safe, and ephedra, androstenedione, and yohimbe have in fact been associated with certain health risks.

25. Therefore, the making of the representations set forth in Paragraph 23 constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

INJURY

26. Consumers throughout the United States have suffered and continue to suffer substantial monetary loss as a result of defendants' unlawful acts or practices. In addition, the defendants have been unjustly enriched as a result of their unlawful practices. Absent injunctive relief by this Court, the defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

27. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of the FTC Act. The Court, in the exercise of its equitable jurisdiction, may award other

ancillary relief, including consumer redress, consumer education, disgorgement, and restitution, to prevent and remedy injury caused by defendants' law violations.

PRAYER FOR RELIEF

WHEREFORE, plaintiff requests that this Court, as authorized by Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and pursuant to its own equitable powers:

(1) Enjoin defendants permanently from violating Sections 5 and 12 of the FTC Act, in connection with the advertising or sale of food, drugs, dietary supplements, or other products or programs;

(2) Award such equitable relief as the Court finds necessary to redress injury to consumers resulting from defendants' violations of the FTC Act, including but not limited to redress, refund of monies paid, or disgorgement of ill-gotten gains; and

(3) Award plaintiff the costs of bringing this action and any other equitable relief the Court may determine to be just and proper.

Dated:

Respectfully submitted,

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