out *Nutrin vitamin and mineral capsules* as a treatment and preventive for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded under 502(f)(1) while held for sale after shipment in interstate commerce.

The information alleged also that the defendant caused a leaflet entitled "Nutrin When Food Alone is not enough Nutrin Capsules" to accompany the article as labeling, which act resulted in the article being misbranded under 502(a) while held for sale after shipment in interstate commerce.

LABEL IN PART: (Btl.) "NUTRIN Multi-Vitamins & Minerals Each capsule contains: Vitamins Vit. A (Fish Liver Oil) 5000 USP units Vit. D (Irradiated Ergosterol) 1000 USP units Vit. B–1 (Thiamine Hydrochloride) 3 mg. Vit. B–2 (Riboflavin) 2.5 mg. Vit. B–12 1.5 mcg. Vit. B–6 (Pyridoxine Hydrochloride) 0.75 mg. Vit. C (Ascorbic Acid) 50 mg. Niacinamide 20 mg. Calcium Pantothenate 5 mg. Folic Acid 0.34 mg. Vit. B (as d-alpha Tocopheryl Acetate) 3 int. units Minerals Calcium 215 mg. Iron 13.4 mg. Phosphorous 166 mg. Potassium 5 mg. Iodine 0.1 mg. Manganese 1.5 mg. Sulphur 10 mg. Cobalt 0.1 mg. Molybdenum 0.4 mg. Zinc 1.4 mg. Copper 1 mg. Magnesium 7.5 mg. 30 Capsules Distributed by CHESTER H. NAIRNE CO. 70 Tenth St. Niles, Ohio."

CHARGE: 502(a)—the leaflet which accompanied the article as labeling contained false and misleading representations that the article was adequate and effective for producing perfect health, active brain, steady nerves, happy disposition, strength, vigor, unlimited energy, sturdy growth, and good bones and teeth; that the article was adequate and effective for the regulation of nervous and muscular activity, coagulation of the blood, proper functioning of the heart, muscles, nerves and body tissues, counteraction of acids, healing of wounds, strengthening of mental power, regulation of all of the nutritive processes, prevention of goiter, purifying the system, and regenerating the body by purifying the blood; and that the food supplies generally available are nutritionally deficient and inferior and lack sufficient amounts of the vitamins and minerals for normal nutrition; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use in the treatment and prevention of the diseases, symptoms, and conditions for which the article was intended, namely, the treatment and prevention of sinusitis, catarrh, neuralgia, bursitis, rheumatism, lumbago, sciatica, gout, arthritis, poor eyesight, premature death, obesity, underweight conditions, nervous breakdown, sleeplessness, tiredness, indigestion, heartburn, irregular bowel movements, nervous strain, poor teeth, half dead feeling, irritability in children, heart disease, diabetes, and colds, for the prevention of tonsillitis, polio, appendicitis, gallstones, and kidney stones, for the treatment of the thyroid and parathyroid glands, and reduced sexual powers, which were the diseases, symptoms, and conditions for which the article was held out to the persons present at the aforesaid sales talks.

PLEA: Nolo contendere.

DISPOSITION: The case was transferred to the United States District Court for the Eastern District of Michigan for the entry of the above-mentioned plea and, on 1–10–61, such court fined the defendant $500.

**6446. Figurama device.** (F.D.C. No. 42015. S. No. 21–868 P.)

QUANTITY: 12 devices at Kansas City, Mo., in possession of AAA Distributing Corp.

SHIPPED: Between 6–12–58 and 8–5–58, from Midland, Conn., by Streamform Corp.

LABEL IN PART: (Metal plate on device) "Figurama Streamform Corp. New York, N.Y."

ACCOMPANYING LABELING: Cards designated "Complimentary Invitation"; a folder designated "Figurama"; and an advertising mat designated "Reduce at Home."

RESULTS OF INVESTIGATION: The article was a streamlined box-like metal device equipped with coasters and enclosing a vibrating motor. The device was equipped with two upholstered massage pads and tubular cot-like attachments for conversion for use in a reclining position.

LIBELED: 9–10–58, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the name of the device "Figurama" and the labeling accompanying the device contained false and misleading representations that the device was an adequate and effective treatment for reducing weight, correcting poor posture, firming and toning the body and providing a greater sense of well-being; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of nervous tension and diabetes, improving elimination and circulation, and treatment of a heart condition due to nervous tension, which were the purposes for which the device was offered orally by a sales representative on the premises of the dealer.

DISPOSITION: Streamform Corp. appeared as claimant and upon stipulation of the parties, the case was removed to the United States District Court for the District of New Jersey. The claimant then served written interrogatories upon the Government which were answered. Thereafter, the Government served the following written interrogatories upon the claimant:

"The United States of America, libellant herein, by Chester A. Weidenburner, United States Attorney for the District of New Jersey, submits the following written interrogatories pursuant to Rule 33 of the Federal Rules of Civil Procedure:

"1. Give the name and address of the person or firm that manufactured the seized devices, and the date and place of manufacture.

"2. State when the seized devices were introduced into interstate commerce, the name and address of the person or firm who introduced them into interstate commerce, the name and address of the carrier involved, the name and address of the person or firm to whom the devices were delivered and the date of delivery.

"3. State on what date and in what manner the claimant became the owner of the seized devices.

"4. Give the name and address of the person or firm who prepared the cards entitled 'Complimentary Invitation,' the folders designated 'Figurama' and the advertising mats designated 'Reduce at Home.'

"5. State how the aforementioned cards, folders and advertising mats were packed or located in relation to the devices referred to.

"6. If it is alleged in answer to interogatory 5 that the cards, folders and advertising mats, or any of them, were not physically attached to the devices, state where the said cards, folders and advertising mats were located on the premises of AAA Distributing Corp. with relation to the said devices.

"7. Set forth a copy of the aforementioned cards, folders and advertising mats.

"8. State the relationship which claimant has with respect to AAA Distributing Corp.

"9. Does claimant admit that the seized devices are not an adequate and effective treatment:

(a) For reducing weight.
(b) For correcting poor posture.
(c) For firming and toning the body.
(d) Providing for a greater sense of well being.

"10. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response, provide in detail the facts which claimant contends to be true and the names and addresses of all physicians and others having knowledge of such facts.

"11. Is it claimant's position that the seized devices are an adequate and effective treatment:

(a) For reducing weight.
(b) For correcting poor posture.
(c) For firming and toning the body.
(d) Providing for a greater sense of well being.

"12. Does claimant admit that nowhere in the aforementioned cards, folders, and advertising mats or on any imprinting or printing on the devices themselves, is there any statement that the devices are to be used:

(a) In the treatment of nervous tension.
(b) In the treatment of diabetes.
(c) To improve elimination and circulation.
(d) For treatment of a heart condition due to nervous tension.

"13. Does claimant admit that no other written, printed or graphic matter on the premises of AAA Distributing Corp. contained statements representing that the devices are to be used:

(a) In the treatment of nervous tension.
(b) In the treatment of diabetes.
(c) To improve elimination and circulation.
(d) For treatment of a heart condition due to nervous tension.

"14. Does claimant admit that there is no written, printed or graphic matter relating to use of the seized device which suggests its use:

(a) In the treatment of nervous tension.
(b) In the treatment of diabetes.
(c) To improve elimination and circulation.
(d) For treatment of a heart condition due to nervous tension.

"15. Does claimant admit on August 7, 1958, on the premises of AAA Distributing Corp., 3303 Troost, Kansas City, Missouri, the seized devices were offered orally by a sales representative on the premises of the aforementioned firm for:

(a) Treatment of nervous tension.
(b) Treatment of diabetes.
(c) Improvement of elimination and circulation.
(d) Treatment of a heart condition due to nervous tension.

"16. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such response provide in detail the facts which claimant contends the true facts to be and the names and addresses of all persons having knowledge of such facts.

"17. Does claimant admit that on September 11, 1958, the United States Marshal for the Western District of Missouri, pursuant to monition, seized 12 Figurama devices, 12 advertising mats, 22 invitations, and 155 folders of

'Figurama' on the premises of, and in possession of AAA Distributing Corp. and/or Raymond A. Thomas, 3303 Troost, Kansas City, Missouri?

"18. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"19. Does claimant admit that the devices, advertising mats, cards, and folders were shipped by Streamform Corp., Midland, Connecticut, on or about one or more of the following dates: June 12, July 3, July 21 and August 5, 1958.

"20. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"21. Does claimant admit that the mats, cards, and folders relate to use of the seized devices.

"22. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"23. Does claimant admit that the mats, cards and folders were on the same premises as the devices?

"24. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"25. Does claimant admit that the copies of the mats, cards and folders, attached as part of Government's response to claimant's interrogatories, are true and accurate copies of the seized counter-parts.

"26. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"27. Give the name and address of the printers who made up the mats, cards and folders.

"28. Give the dates and the names and addresses of the persons or firms from whom AAA Distributing Corp. received:

(a) The seized devices.
(b) The advertising mats.
(c) The cards.
(d) The folders.

"29. Does claimant admit that the seized devices are intended to be used for:

(a) Reducing weight.
(b) Correcting poor posture.
(c) Firming and toning the body.
(d) Providing for a greater sense of well being.

"30. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true, the names and addresses of all persons having knowledge of such facts, and a complete description of each and every purpose, disease, or condition for which the seized devices are intended to be used.

"31. Does claimant admit that the cards, mats and folders recommend and suggest that the devices are to be used for:

(a) Reducing weight.
(b) Correcting poor posture.
(c) Firming and toning the body.
(d) Providing for a greater sense of well being.

"32. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other

response provide in detail the facts which claimant contends to be true, the names and addresses of all persons having knowledge of such facts, and a complete description of each and every purpose, disease, or condition which the cards, mats and folders recommend and suggest that the devices are to be used.

"33. Name and provide a complete description for each and every purpose, condition or disease for which claimant contends the seized device is an adequate and effective treatment.

"34. For each purpose, condition, or disease enumerated in answer to the preceding interrogatory provide:

(a) The names, addresses and professional qualifications of all physicians or other scientists who have knowledge of such facts.
(b) The names and addresses of all other persons who have knowledge of such facts.
(c) Citations to all medical or other scientific literature which supports such facts.

"35. Name and provide a complete description, for each and every purpose, condition or disease for which the seized device is beneficial.

"36. For each purpose, condition, or disease enumerated in answer to the preceding interrogatory provide:

(a) The names, addresses and professional qualifications of all physicians or other scientists who have knowledge of such facts.
(b) The names and addresses of all other persons who have knowledge of such facts.
(c) Citations to all medical or other scientific literature which supports such facts.

"37. For each and every purpose, condition or disease enumerated in response to interrogatories 30, 32, 33, 35, give the names, addresses, and professional qualifications of all experts qualified by training and experience to evaluate the efficacy of the seized device upon whose opinion the claimant has relied, or now relies, in making each such response.

"38. State the name and address of the designer or inventor of the seized devices.

"39. State whether the device is patented.

"40. If interrogatory No. 39 is answered affirmatively, give the patent number and state the name and address of the person or firm who holds the patent.

"41. List all component parts of the device under seizure and state the purpose of function of each part in the operation of the device.

"42. (a) Since the original model of this device was first manufactured and distributed, what alterations have been made on it?
(b) Explain why such changes were made.
(c) State the operating principle by which the device accomplishes its intended purpose(s).

"43. (a) How does the manufacturer of the device determine whether it conforms to specifications after it is assembled?
(b) How is it tested in the factory?

"44. Does the device have Underwriters approval?

"45. (a) Is the patient protected against electrical shock from the device?
(b) How?

"46. What is the name and the address of the insurance firm with whom claimant maintains products liability insurance?

"47. (a) List the names and addresses of all persons or firms who registered complaints about Figurama with claimant since the inception of business.
(b) Give the names and addresses of all Figurama purchasers to whom claimant has made refunds and state the reason for each refund.

"48. (a) State whether Figurama is now being used or has been used in any hospitals or other medically supervised institutions.
(b) State whether claimant ever delivered a Figurama device to any hospitals or other medically supervised institutions.

"49. If interrogatory 48 is answered affirmatively, state the names and addresses of the institutions and the names and titles of the person or persons acquainted with its use.

"50. Set forth the complete directions for use in using this device for:

(a) The treatment of nervous tension, diabetes; improvement of elimination and circulation; and treatment of a heart condition due to nervous tension.
(b) To resize the figure and improve the posture; to remove an inch or more off hips, waist, tummy within minutes. To trim and acquire fashionable slenderness without disrobing, without drudgery, drugs, or strenuous diet.
(c) For figure improvement, figure reducing, and posture improvement as associated by the claimant with the word Figurama.

"51. Set forth copies of all the directions referred to in interrogatory No. 50 and state how all these directions reach the patient.

"52. Give the names, addresses, and professional qualifications of all experts qualified by training and experience to evaluate the efficacy of the said device upon whose opinion the claimant has relied, or now relies, to support its claim that the device is adequate and effective for:

(a) Reducing weight.
(b) Correcting poor posture.
(c) Firming and toning the body.
(d) Providing for a greater sense of well being.

"53. Provide citations to all scientific literature of which claimant is aware which deals specifically with the efficacy of the seized device or its components and any other similar device.

"54. State if claimant has conducted or has had conducted, or knows of any tests or studies which have been conducted or are being conducted to determine the efficacy of the device under seizure.

"55. If the response to interrogatory No. 54 is in the affirmative, state in detail for each such test or study:

(a) The number of such tests or studies that have been conducted indicating the number of clinical tests or studies, the number of laboratory tests or studies.
(b) A detailed description of the method or procedure employed by each study or test and the results obtained.
(c) The names, addresses, and qualifications of all individuals conducting or participating in the conduction of each such study or test.
(d) The location and name of the clinic, office, institution, laboratory, or building where such tests or studies were conducted.
(e) The name and address of each test subject and the name and address of each control subject used in

such test or study, designating which were test and which were control subjects and the exact condition of each subject, giving complete information concerning the severity, duration, and origin of such condition or disease.

(f) The name, address, and qualifications of each of the physicians who diagnosed each of the test and control subjects prior to and during the test or study.

(g) The frequency, duration time, and method of use of the Figurama device by each subject and the complete description of all the treatments administered to each subject.

(h) The nature, extent, and duration of improvement or deterioration of each of the subject's condition, subsequent to the test or study and for each subject give the name and the address and qualifications of the physician who diagnosed subject's condition, subsequent to the test or study.

(i) The name and the address of the place where the charts, records, and reports of the test or studies are located.

(j) The name and address of the person or persons in whose possession or custody are these charts, records, and reports.

(k) If any such tests or studies are now in progress, please so indicate, and provide as much information in the response to this interrogatory as is now in existence.

"56. (a) State whether clinical measurements have been done to determine the relaxing tension effect of this device.

(b) If the response to (a) above is in the affirmative, provide answers to 55 (a)–(k) at this point with respect to such measurements.

"57. Describe in detail the separate vibratory motions ascribed to this device by claimant.

"58. (a) State whether any type of measurements have been made to determine the depth of the penetration in the body of the vibrations produced by this device.

(b) If the response to (a) above is in the affirmative, provide answers to 55 (a)–(k) at this point with respect to such measurements.

"59. (a) State whether any scientific studies have been done to show that the muscles in the body are affected by the vibratory motions.

(b) If the response to (a) above is in the affirmative, provide answers to 55 (a)–(k) at this point with respect to such measurements.

"60. Referring to the labeling exhibits attached to libelant's answers to claimant's interrogatories, what is meant by:

(a) 'Figurama restores nature's line of figure beauty.'
(b) 'Slenderizing.'
(c) 'Figurama.'
(d) 'Figurama firms and tones the body as it reproportions your figure.'
(e) 'reducing at home.'
(f) 'see the first inch (or more) vanish.'

(g) 'prove that you, too, can have and hold a beautiful figure.'
(h) 'perfected by world-famous reducing authority, Monty MacLevy.'

"61. (a) Give the full name and address of Monty MacLevy.
(b) State in detail his position and responsibilities in the claimant firm.
(c) What scientific studies using the device under seizure has Monty MacLevy conducted and where were they published?
(d) What are the means of conveying to the patient the directions for use of the device as formulated by Monty MacLevy. Set forth such directions.

"62. State the names, addresses, and professional qualifications of all experts with whom the claimant has conferred about the labeling made for this device.

"63. Give citations to all the scientific literature to which claimant has referred in preparing the labeling claims for this device.

"64. (a) State the names and addresses of any newspapers, magazines, journals, or other publications in which claimant has placed advertisements or comments regarding the Figurama device and dates of each.

"65. (a) State whether claimant knows of any scientific data, or has knowledge of any studies made in which the various etiological causes of the overweight were determined in overweight patients using the Figurama device.
(b) If so give citations to or set forth the scientific data and with respect to any such studies provide answers to interrogatory 55 (a)-(k).

"66. (a) State whether claimant knows of any scientific data, or has knowledge of any studies made in which the various etiological causes of the nervous tension were determined in the patients using the device for nervous tension.
(b) If so give citations to or set forth the scientific data and with respect to any such studies provide answers to interrogatory 55 (a)-(k).

"67. (a) State whether claimant knows of any scientific data, or has knowledge of any studies made in which the various etiological causes of poor posture were determined in the patients using the device for poor posture.
(b) If so give citations to or set forth the scientific data and with respect to any such studies provide answers to interrogatory 55 (a)-(k).

"68. State the names and addresses of witnesses whom claimant now intends to call at the trial of this case."

The claimant filed objections to a number of the interrogatories submitted by the Government and, on 5-26-59, after consideration of the arguments of counsel, the court handed down the following decision:

WORTENDYKE, *District Judge:* "On September 11, 1958, the Government filed a Libel in the Western Division of the Western District of Missouri against 'TWELVE DEVICES, MORE OR LESS, LABELED IN PART (METAL PLATE ON FRONT OF DEVICE) "FIGURAMA STREAMFORM CORP. NEW

YORK, N.Y." (METAL PLATE ON BACK OF DEVICE) "* * * SERIAL NO. * * * MODEL NO. * * *" and TWO HUNDRED CARDS, MORE OR LESS, DESIGNATED "COMPLIMENTARY INVITATION," 1 OR MORE FOLDERS DESIGNATED "FIGURAMA," and 1 OR MORE ADVERTISING MATS DESIGNATED "REDUCE AT HOME," ' in possession of AAA Distributing Corporation, 3303 Troost, Kansas City, Mo., for alleged misbranding while in and while held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(a). Responsive to Monition duly issued, Streamform Corp., a New York corporation, filed notice of claim to the libeled articles and by stipulation between respective counsel for libellant and claimant, the action was removed to the United States District Court for the District of New Jersey.

"The libel charges that the term 'Figurama' in the labeling of the device, together with the 'Complimentary Invitation' cards, 'Figurama' folders, and advertising mats designated 'Reduce at Home' represent and suggest that the device is an adequate and effective treatment for weight reduction, posture correction, firming and toning the body and enhancing the sense of well-being, which statements are false and misleading.

"To certain of the sixty-eight written interrogatories propounded by the libellant, claimant has filed objections, and a hearing upon these objections was held May 25, 1959, pursuant to due notice. A classification of the interrogatories objected to, the grounds for the objections, and my decision thereon, are as follows:

Interrogatories numbered 5, 6, 23 and 24: Information sought is peculiarly within the knowledge of libellant.

"Because a critical question in the case is the relationship between the device itself and the cards, folders and advertising mats, the information sought by this group of interrogatories objected to becomes highly relevant. Even if that information is already known to or has previously been obtained by libellant, claimant may be compelled to furnish the information to libellant if it is available to the claimant. The information is not only relevant to the subject matter of the action, but relates to the claim of the examining party. Rules 33 and 26(b). These interrogatories must be answered.

Interrogatories numbered 15 and 16: Information sought concerns oral statements made by third party out of presence of claimant.

"Claimant objects to these two interrogatories because they seek an admission by claimant of oral representations made by a sales representative of the distributor of the device. While such an admission could be sought under Rule 36, it is equally susceptible under Rule 33. If the answer to interrogatory number 15 is 'No' (a refusal to admit), interrogatory number 16 becomes proper since it invites claimant's version of the 'true facts' constituting the subject matter of interrogatory number 15. If, on the other hand, the answer to any of the subdivisions of interrogatory number 16 is unqualifiedly 'Yes' then number 16 need not be answered with respect to that subdivision, but it is an appropriate interrogatory with respect to the remaining subdivisions of interrogatory number 15. Both of these interrogatories, therefore, should be answered.

Interrogatory number 27: Irrelevance of names and addresses of printers who made the cards, mats and folders.

"The name and address of each of the printers who made the mats, cards and folders is information to which libellant is entitled. It is relevant to the subject matter involved in the action and appears to be reasonably calculated to lead to the discovery of admissible evidence thereon. This interrogatory should be answered.

Interrogatories numbered 29, 30, 31 and 32: Information sought is to be found in the labeling and printed material complained of.

"These interrogatories are proper for the same reasons which support the propriety of numbers 15 and 16 above. These four interrogatories should therefore be answered.

Interrogatories numbered 33, 34, 35, 36 and 37: Irrelevance of information sought.

"Claimant's objection to this group of interrogatories is not well founded. For example, if the device may not be effectively used in the treatment of condition A, claimant's assertion that it may be effectively used in condition B may not only relate to the defense of the claimant, but negate the effectiveness of the device for the treatment of condition A. In their remotest aspect, the answers to the inquiries contained in this group of interrogatories may serve to sustain the charges contained in the libel. They should be answered.

Interrogatories numbered 38, 39, and 40: Irrelevance of information sought.

"The objection to these three interrogatories is based upon the contention that the information sought thereby is irrelevant. Libellant seeks the identity of the inventor of the device and information respecting its patenting. This information is highly relevant to the subject matter of the inquiry because the patent and its file wrapper may constitute relevant evidence upon the question of the effectiveness of the device for any of the purposes alleged to have been represented by the claimant. These interrogatories must be answered.

Interrogatories numbered 42(a) and 42(b): Irrelevance.

"These two subdivisions of interrogatory number 42, as well, are entirely relevant because any changes which may have been made in the device between the date of the issuance of a patent thereon and the date of the alleged misbranding, relate directly to the critical issue presented by the misbranding charge. These should also be answered.

Interrogatories numbered 43, 44 and 45: Irrelevance.

"Because one of the objectives of the Act is the protection of the consuming public, I consider interrogatories numbered 44 and 45 relevant and proper; but number 43, in my opinion, is irrelevant and improper. Numbers 44 and 45, therefore, should be answered.

Interrogatory number 46: Irrelevance.

"This interrogatory seeks the name and address of claimant's products liability insurance carrier. This need not be answered because it is irrelevant.

Interrogatories numbered 47(a) and 47(b): Irrelevance.

"This interrogatory seeks the names and addresses of purchasers of the device who have complained about it and sought a refund of the purchase price. Information responsive to this interrogatory may lead to evidence supportive of libellant's charges and hence it should be answered.

Interrogatories numbered 52, 54, 55, 56, 58, 59, 65, 66 and 67: Information sought is result of work performed by experts shielded from interrogation, and may be readily obtained by libellant.

"The objection to this group of interrogatories is induced by the reluctance of claimant to disclose the products of its experts. Upon the authority of *Sachs* v. *Aluminum Company of America*, 6 Cir. 1948, 167 F. 2d 571, the product of such experts is not privileged matter. These interrogatories should also be answered.

Interrogatory number 60: Labeling speaks for itself.

"This interrogatory is clearly relevant to the issue of labeling. It seeks claimant's meaning and intent in the use of the words and phrases employed in the labelling exhibits referred to. It must be answered.

Interrogatory number 64: Irrelevance.

"I agree with claimant that the information sought by this interrogatory is not relevant to the charges laid in the libel. This interrogatory need not be answered.

"An order in conformity with this opinion may be presented."

The claimant thereafter submitted certain answers to the Government's interrogatories, after which the Government filed a motion to compel the claimant to make further and more adequate answers to the interrogatories. On 9–17–59, the court advised counsel for the parties of its decision in the matter by letter which reads as follows:

WORTENDYKE, *District Judge:* "This letter will serve to embody my decision upon the motion of the libellant, United States of America, to compel further and more complete answers to written interrogatories propounded by it to claimant, Figurama Streamform Corp. At the conclusion of the oral argument on September 14, 1959 I undertook to examine the motion papers, together with the memoranda submitted by the respective parties, and determine the questions presented within the next succeeding few days. My determination is, therefore, as follows (the successive numbers referring to the interrogatories and answers to which libellant's motion is directed):

"5. Answer should disclose information obtained and efforts made to obtain information from AAA Distributing Corp.

"6. State all responsive facts, rather than incorporating by reference matter of allegation presently expressed in No. 5.

"10. State as fact, rather than as an allegation, all matter responsive to the question and give the names and addresses requested.

"13. Answer categorically Yes or No to each subdivision.

"16. Disclose fully all facts and the names and addresses of persons sought by this question.

"17. Answer categorically Yes or No.

"18. Answer with full responsiveness if the answer to No. 17 is not Yes.

"19. This answer is sufficient.

"20. Answer with full responsiveness in view of the negative answer to No. 19.

"22. Answer this with full responsiveness in view of the negative answer to No. 21.

"23. This should be answered Yes or No.

"24. Answer with full responsiveness if answer to No. 23 is not Yes.

"25. This should be answered Yes or No.

"26. Answer with full responsiveness if answer to No. 25 is not Yes.

"32. Answer with full responsiveness with relation to any of the subdivisions of interrogatory No. 31 not answered affirmatively.

"33. Answer with full responsiveness.

"34. Answer with full responsiveness.

"35. Answer with full responsiveness.

"36. Answer with full responsiveness.

"37. Answer with full responsiveness.

"38. The answer to this interrogatory is sufficient.

"47(a). Secure the information sought and set it forth in a fully responsive answer.

"48. Answer each subdivision with full responsiveness upon the assumption that the interrogatory refers to ALL or ANY Figurama products.

"49. Depending upon the answers to the subdivisions of interrogatory No. 48, answer interrogatory No. 49 responsively.

"50(b). This must be answered responsively. If no directions for use for such purposes, so state.

"50(c). This must be answered responsively. If no directions for use for such purposes, so state.

"52. Answer this interrogatory responsively.
"54. The answer to this interrogatory is sufficient.
"55(a) through 55(k). Answer this interrogatory and its subdivisions responsively, since the answer to interrogatory No. 54 discloses that tests are being conducted.
"56. Answer this interrogatory responsively in view of the answer to interrogatory No. 54.
"60. Answer each of the subdivisions of this interrogatory responsively by defining the words and phrases respectively therein set forth, irrespective of the claimant's denial that the exhibits referred to constitute labelling.
"61(a). The answer to this sub-interrogatory is adequate.
"61(d). Amplify this answer, irrespective of the description of the users of the device as patients.
"62. Answer this interrogatory responsively, irrespective of claimant's denial.
"63. This interrogatory should be answered responsively irrespective of claimant's denial.
"65. Answer this interrogatory responsively, irrespective of the reference to users as patients.
"66. Answer each of the subdivisions of this interrogatory, responsively, without reference to the answer to any other interrogatory.
"67. Answer each of the subdivisions of this interrogatory, irrespective of the designation of the device users as patients.
"An appropriate order embodying my determination as aforesaid may be presented after submission to adversary counsel for approval as to form."

In accordance with the views expressed by the court in its letter of 9–17–59, an order was entered by the court on 9–24–59 directing the claimant to amplify its answers. The claimant thereupon submitted supplemental answers. The Government subsequently asserted that the answers were insufficient and filed a motion for default judgment. On 12–8–59, the court handed down the following opinion in the matter:

WORTENDYKE, *District Judge:* "In this action, instituted under the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, et seq., seizure was made of the articles indicated in the caption, to which claim was duly made by answer filed, charging misbranding of the device referred to by reason of failure of compliance with the provisions of § 352(f)(1). The Government prayed condemnation of the devices, including the cards, folders and advertising mats accompanying the same, all of which had been introduced into, were in, and were being held for sale after shipment in interstate commerce.
"In due course claimant served interrogatories upon libelant, which were responsively answered. Thereafter libelant served interrogatories upon counsel for claimant. These included some sixty-eight questions, several of which contained numerous subdivisions. To these interrogatories claimant served objections and noticed hearing thereon, after which the Court, by directive of June 5, 1959, ordered that all of the Government's interrogatories be answered except those numbered 46 and 64 respectively. Claimant proffered purported compliance with the Court's order by serving certain answers to the interrogatories with which the Government was not satisfied. Libelant thereupon moved for an order requiring claimant to make more specific answers to certain of its interrogatories, and, on September 24, 1959, after a hearing upon such motion, claimant was ordered to amplify its answers to conform with the views expressed in the Court's letter to counsel dated September 17, 1959. Again by way of response to the Court's latest order, claimant further supplemented its answers. Once more asserting the insufficiency of these latest supplementary answers, the Government noticed a motion for judgment of default in favor of libelant. The particular answers of the inadequacy of which the Government still complains are those respectively to libelant's interrogatories numbered 55, 10, 22, 34 (a), (b) and (c), 36 (a), (b) and (c), 37, 52 and 63.
"While there is ample authority to penalize claimant's apparent unwillingness to answer certain of the interrogatories which the Court has found proper

and which its prior orders required to be answered—*United States* v. *42 Jars, etc. Bee Royale Capsules*, 3 Cir. 1959, 264 F. 2d 666, F.R.C.P. 37(b)(2)(iii)—the drastic nature of such a penalty makes the Court reluctant to apply it if other relief may possibly be available. The Court has, therefore, again reviewed the interrogatories and answers with respect to which the parties are in disagreement.

"Interrogatory No. 55, with its 11 subdivisions (which referred back to question numbered 54), sought information respecting tests or studies made by claimant to determine the efficacy of the device under seizure. To this inquiry the claimant ultimately responded by stating that the tests referred to in interrogatory number 54 had been discontinued and terminated without producing any bases for conclusions therefrom. Under these circumstances, claimant will be deemed to have bound itself to an admission that NO such tests were ever made and, therefore, its affirmative answer to the inquiry in interrogatory number 54 shall be deemed amended to a negative.

"Claimant's answer to interrogatory number 9, upon which interrogatory number 10 is made to depend, was in the negative, i.e., claimant refused to admit that the seized devices were not an adequate and effective treatment for reducing weight, curing poor posture, firming and toning the body and providing a greater sense of well-being. And in its answer to interrogatory number 10, claimant affirmatively asserts the adequacy and efficacy of the device for the stated purposes when the device is used 'as a part of claimant's slenderizing plan which includes a program of reduced caloric input. It is generally recognized by authorities that a reduced caloric program with massage is effective and adequate for the purposes enumerated.' The Government contends that the foregoing is not responsive to its tenth interrogatory, which requires that the claimant provide in detail the facts which claimant contends to be true among the subdivisions of interrogatory number 9, and the names and addresses of all physicians and others having knowledge of such facts. Claimant still fails to answer interrogatory number 10 responsively. It must give the names and addresses of the persons referred to in the interrogatory, who have knowledge of the asserted adequacy and efficacy of the device.

"The Government has asked, in its interrogatory number 21, for an admission by the claimant that the seized mats, cards and folders related to the use of the seized devices, and in interrogatory number 22, in the event that the answer to number 21 was not unqualifiedly affirmative, that the claimant state in detail the facts supporting any negative or partial negative in the answer to question 21, with the names and addresses of persons having knowledge of such facts. Since claimant's answer to number 21 is an unqualified negative, it is obviously not an unqualified affirmative, and claimant will be required to answer number 22 with full responsiveness.

"Interrogatory number 34 seeks the names, addresses and professional qualifications of all physicians, other scientists or individuals having knowledge of every purpose, condition or disease which claimant contends may be adequately and effectively treated by the seized device. Claimant's purported response to this interrogatory is obviously unresponsive and must be modified and/or amended to a degree of complete responsiveness.

"Incorporating its present answer to interrogatory number 34, in lieu of answering interrogatory number 36 independently, is insufficient, and compliance must be made with the Court's previous directive respecting this interrogatory and its subdivisions.

"A similar requirement applies in the case of the answer to interrogatory numbered 37.

"Claimant's answers to interrogatories numbered 52 and 63 still fail to comply with the Court's previous directives. A fully responsive answer to question 63 will not be deemed a waiver by claimant of its contention that the documentary material seized does not constitute labelling.

"Libelant may present an order directing the claimant to supplement its answers to the Government's interrogatories in the manner and form, and to the extent and degree indicated by the foregoing views, such supplement to be served and filed within ten days after the date of said order, which shall also provide that failure of claimant's full compliance therewith shall entitle libelant to a judgment by default without further notice."

An order in accordance with the foregoing opinion was entered on 1–25–60, following which the claimant submitted further answers to the interrogatories. On 10–20–60, the claimant having consented to the entry of a decree, judgment of condemnation was entered, and the article was ordered released under bond for relabeling under the supervision of a representative of the Department of Health, Education, and Welfare. The claimant failed to file the bond as provided in the above decree and, accordingly, an order was entered on 1–20–61 directing that the article be turned over to the Food and Drug Administration.

## DRUG AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

**6447. Sodium dehydrocholate injection.** (F.D.C. No. 45087. S. Nos. 26–251 R, 26–421 R.)

QUANTITY: 1,184 ampuls at Los Angeles and Downey, Calif.

SHIPPED: On 7–5–60 and 7–27–60, and subsequent thereto, from Philadelphia, Pa.

LABEL IN PART: "3 Ml Ampul Sodium Dehydrocholate N.F. 20%."

RESULTS OF INVESTIGATION: Analysis showed that the contents of the ampuls had a pH of 7.0 to 7.1, whereas, the National Formulary requires a pH between 8.5 and 9.5. Examination showed also that some of the ampuls contained varying amounts of suspended matter which, upon separation and analysis, proved to be dehydrocholic acid.

LIBELED: 11–10–60, S. Dist. Calif.

CHARGE: 501(b)—while held for sale, the quality of the article fell below the standard for *sodium dehydrocholate injection* set forth in the National Formulary; and 502(a)—the labeling of the article was false and misleading as applied to an article that purported to be of a quality represented in the standard established in the National Formulary for *sodium dehydrocholate injection*, but was not of such quality.

DISPOSITION: 12–5–60. Default—destruction.

**6448. Rubber prophylactics.** (F.D.C. No. 44836. S. No. 42–007 R.)

QUANTITY: 72 gross ctns., in pkgs. of 2 each, at Reno, Nev.

SHIPPED: 8–26–60, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Package of Two Spartans Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 2.6 percent of the units examined were defective in that they contained holes.

LIBELED: 10–25–60, Dist. Nev.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "For the Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 12–15–60. Default—destruction.

**6449. Rubber prophylactics.** (F.D.C. No. 44713. S. Nos. 32–774/5 R.)

QUANTITY: 3 ctns., each containing 72 boxes of 2 cellophane-wrapped units each, and 3 ctns., each containing 48 3-unit boxes, at Middle Village, N.Y.

*See also No. 6442.