Summarizing, it might be noted that the government won four of the seven contested cases brought against cosmetics.

A number of actions were brought against a permanent wave which contained ammonium sulfide; seizures were made. No claimant appeared, so the product was destroyed. Action was brought against lipsticks containing cadmium and selenium; against dental creams containing hard material with sharp edges; against a plastic mask containing clay and benzaldehyde; against a number of products containing uncertified dyes. A number of hair dyes contained lead acetate and cantharides; also, lash, eyebrow and hair colorings contained paraphenylenediamine. Shampoos contained a dangerous or deleterious quaternary compound. Other hair or lash tints contained ammoniacal silver nitrate and pyrogallol. Hair straighteners contained large amounts of sodium hydroxide. Bleaches contained mercuric chloride and urea peroxide. Other products were claimed to beautify the skin and remove wrinkles because of the presence of vitamins or lanolin.

There was some overlapping of claims between the cosmetic area and the drug area. **[The End]**

Notices of Judgment—Foods

F. N. J.'s Nos. 1 to 23,400

NOTICES OF JUDGMENT published in accordance with Regulation 6 of the Federal Food and Drugs Act of June 30, 1906, were screened to permit study of those dealing with foods, in which there were some pharmacological implications. The Federal Food, Drug, and Cosmetic Act of June 25, 1938, separated information on foods into Sections 401-408, dealing with adulteration, misbranding, emergency permit control, exemptions, margarine, tolerances for poisonous ingredients and pesticide chemicals, and certification of

Outcome of Contests: C. N. J.'s 1-205

C. N. J.	Product	Charge A	Charge M	Plea	Action	Comments
76	Lash Tint	?	...	N. G.	J. N. G.	Pyrogallol, Ammon. Ag_2SO_4, $AgNO_3$
105	Permanent Wave	...	?	N. G.	J. N. G.	$(NH_4)_2SO_3$ not tonic
113	Brow Tint	X	...	S.	Ct. G.	CA-5 affirmed; p-phenylenediamine harmful as used
		...	X			
143	Hair Milk	X	...	N. G.	J. G.	Lead acetate; sentence, 57 days in jail
147	Lacquer Pad			G.	Ct. $100 and costs	CA-7 affirmed on contest appeal, United States Supreme Court denied certiorari
151	Miracle Aid	...	X	N. G.	J. G.	CA-7 reversed; manufacturer changed lacquers without notifying company
152	Hair Lotion	...	?	N. G.	J. N. G.	Quinine content only 0.02 per cent

Summary.—As has been indicated, out of seven contested cases the government won in four (one reversed on appeal), the defendant in three. Three cases involved adulteration allegations and four, misbranding.

Abbreviations:
A—adulteration
M—misbranding
?—allegation
N. G.—not guilty
G.—guilty
S.—seizure
J.—jury
Ct.—court

coal-tar colors. Section 705 authorized publication of reports and information regarding foods (as well as drugs, devices and cosmetics). At the time of preparation of this report, a total of 23,400 N. J.'s dealing specifically with foods (F. N. J.'s) have been published.

Of this group of 23,400 F. N. J.'s, a total of 860 were found which had some pharmacological significance. As would be expected, there were a variety of products involved and a number of harmful or deleterious ingredients reported. These included arsenic and lead as spray residues on apples and other fruits and vegetables; in addition, there were reports of the presence of mercury compounds, fluorides, and other pesticides, giving a total of 282. There were 125 actions brought because of the presence of monochloroacetic acid as a preservative and 78 because of the presence of mineral oil in salad dressings or mayonnaise and on popcorn. A lesser number of reports were found regarding the presence of methyl alcohol, dehydroacetic acid, coumarin, cyanides, diethylstilbestrol, *Gonyaulax* toxin and quaternary ammonium compounds, and a scattering dealing with the presence of sand, stones, glass, metal or plastic toys, and filth. There were a limited number in which therapeutic claims made the products responsible under the drug provisions as well as under the food requirements.

Of this total of 860 F. N. J.'s, there were 28 contests. The charge of adulteration was brought in 14, of misbranding in ten, and of both adulteration and misbranding in four. A plea of not guilty was offered in four cases. In one, F. N. J. 12,995, involving vitamins, was sustained by the court on the basis of valid guarantees. In two cases the trials resulted in verdicts of guilty (F. N. J. 7,926, fluorides in beer, and F. N. J. 11,280, mineral oil in salad dressing). In the fourth case (F. N. J. 19,380), involving the right of factory inspection of a packer of apples, the United States District Court found for the government, but this decision was reversed by the United States Court of Appeals for the Ninth Circuit and by the Supreme Court of the United States.

There were a total of 24 seizures which were actively contested in the courts. The verdicts in 14 were favorable to the government; on appeal, two of these decisions were reversed (F. N. J. 19,101, on a beverage, and F. N. J. 17,804, dealing with the presence of metal trinkets in candy). On the other hand, decisions in favor of the defendant were handed down in ten trials of contested seizures; two of these were reversed on appeal (F. N. J. 8,920, on spray residue on

apple chops, and F. N. J. 13,863, on mineral oil to be applied to popcorn). The over-all picture shows that the government eventually won favorable decisions in 16 of the 28 contests, or somewhat more than half of the contests.

No noteworthy decisions were observed from the pharmacological standpoint in the noncontested cases. On the other hand, a number of points were noted in reviewing the information reported on the contested cases.

The first two contests deal with arsenic and lead spray residues on apples and apple chops. In F. N. J. 19,380, the defendant Cardiff refused entry and inspection of the factory where apples were being packed for shipment. He was brought to court, and the judge returned a verdict of guilty. This was appealed to the Ninth Circuit, which reversed the finding on the basis that the law was not clear:

> Congress by section 374(f) gives the operator the right to refuse inspection and section 331(f) warns him that if he exercises the right so given him he is liable to imprisonment. It is true that "the Lord giveth and the Lord taketh away" in a manner seemingly unjust to the mind of man, but here we are considering an act of Congress. Such a roundabout and unreasonable construction makes an absurdity of the requirement of the inspector of "obtaining permission."

Appeal to the United States Supreme Court led to affirming of the decision of the Ninth Circuit, rejecting the plea of the government that 80 per cent of the violations of the law are discovered by factory inspection and stating:

> Nowhere does the Act say that a factory manager must allow entry and inspection at a reasonable hour. Section 704 makes entry and inspection conditioned on "making request and obtaining permission." It is that entry and inspection which Section 301(f) backs with a sanction. It would seem, therefore, on the face of the statute that the Act prohibits the refusal to permit inspection only if permission has been previously granted.

This decision led to modification of the Act to permit factory inspections under specified conditions.

A shipment of apple chops which contained an average of 0.327 grain of arsenic (as As_2O_3) and of 0.56 grain of lead per pound was dealt with in F. N. J. 8,920. It was charged under Section 402(a)(1) that the article contained added poisonous and deleterious substances which may have rendered it injurious to health. Incidentally, the shipper was the same company that was the defendant in F. N. J. 19,380. Trial was held before the court and jury, including testimony by expert witnesses. In the charge to the jury, the court stated:

> The Court instructs you that the question of whether the apple chops contain any poisonous or deleterious substance which may render them injurious to

health depends on whether or not the quantity of such poisonous or deleterious substance found in the product into which such apple chops would be manufactured may render such manufactured product injurious to health. If you find that the apple butter into which the apple chops in this case would be manufactured would not have an arsenic or lead content which might render the apple butter injurious to health, then your verdict should be that the apple chops are not adulterated by reason of the presence of lead or arsenic and they should be released to the claimant.

The jury returned a verdict for the claimant, and the libel of seizure was ordered dismissed. The government appealed to the Ninth Circuit. When the matter came on for hearing before that court, the product had become rotten and valueless, rendering the decision moot. The Ninth Circuit reversed the decision of the district court and remanded the case for entry of a decree of destruction, which was done.

Following a large number of seizures of Mrs. Price's Compound, which contained between 95 and 100 per cent of boric acid and which was offered for use in the home canning of vegetables, fruits, pickles and preserves and also in the preserving of fish, game, milk and cream, F. N. J. 5,759 reports the findings of the court in an action brought for a permanent injunction. The findings of fact state, in part:

The use of the products labeled in part, "Mrs. Price's Compound" and "Mrs. Price's Specially Prepared Package of Boric Acid," by virtue of being composed largely of boric acid is potentially dangerous to the health of the consumer. The directions recommended in the printed matter . . . do not adequately insure the proper sterilization of the utensils used in the canning procedure, nor do they adequately insure the destruction of heat resistant spore forming bacteria capable of producing spoilage and toxins dangerous to health.

The use of boric acid as a preservative either for canned foods or fresh foods is specifically recognized as dangerous to health in that the consumption of as little as one half gram of boric acid per day over long periods of time is deleterious to health in that serious chronic poisoning will result. Use of the products labeled in part . . . in accordance with the direction contained in the printed matter can result in the consumption by an average family of five receiving five servings to a quart of home canned food, of as much as 1.24 grams of boric acid daily for each quart used.

The injunction was granted.

A permanent injunction against a cheese factory (F. N. J. 13,264) because of the presence of filth in the milk which might render the finished product injurious to health was appealed from the district court to the Eighth Circuit and modified; when factory inspections showed that the conditions had been corrected and capable personnel placed in charge of the operation, the injunction was dissolved. In

hearing testimony regarding alleged adulteration of dried whole eggs (F. N. J. 8-887), including references to the Hipolite Egg Company (N. J. 508), it was brought out that the egg powder in question, when seized, was not injurious to health. This lot and another were used for baking cakes, and no difference in the finished products could be noted nor were there any ill effects from eating such cakes. The claim of the government that this egg product was partially decomposed, irrespective of possible injury to health and based on secret tests not adopted by the Association of Official Agricultural Chemists led to rejection by the court and to a verdict for the claimant, with dismissal of the libel.

A number of cases were brought against beer and ale containing fluorides; contests developed in two. In F. N. J. 7,926, trial was had before a jury on the basis that the beer contained 15 parts of Fluorine per million. Dr. McNally testified that he would not be apprehensive unless he drank 15 bottles at one time; on the other hand, Dr. Carlson testified that eight parts per million would be harmful. The charge of the judge to the jury stated, in part:

> I want to point out to you that it is entirely unimportant and irrelevant how much the quantity of fluorine was which was added to the beer. The issue is, Was fluorine in some form added as an ingredient? If, as one of the Supreme Court cases say, it is an added deleterious ingredient, the statute denounces that. It is an added deleterious ingredient the statute denounces, not an added quantity of the deleterious ingredient. Thus the gravamen or material charge in the section of the statute with which we are concerned is the addition of the deleterious substance and the quantity of the deleterious substance is of no moment. . . . if you find fluorine in any form was added . . . the Government has sustained its burden.

The court said that it was of no importance that an expert witness who took fluorine into his system testified that he was not harmed by it so far as he knew; the witness was not in a position to know whether he was harmed or not. It was of no importance in this case that tea or salt contained fluorine in quantities not harmful to health as used. The jury returned a verdict of guilty and fines of $5,000 were returned against each defendant, with suspended sentence of six months in jail against the manager.

The desire to produce loss in body weight while consuming mayonnaise or salad dressing led to replacement of a large part of the oil with mineral oil. This was the basis of a number of actions by the government and of three contests, all won by the government. In the decision in F. N. J. 11,280, the court held that mineral oil is non-

nutrient, generally sold in drug stores "to oil up the alimentary canal of the human body," and has no nutritive value. In the charge to the jury (F. N. J. 11,484) the same question is put as in an action against mayonnaise (F. N. J. 11,482): "Is mineral oil a deleterious substance which may render mayonnaise injurious to health?" In the mayonnaise case, the judge found for the government. In the salad dressing case, the judge pointed out that this is a product used as a food by man and that the question was whether mineral oil, which "may be consumed as a food by the strong and the weak, the old and the young, the well and the sick . . . may possibly injure the health of any of these." The jury decided that it might, and returned a verdict for the government.

With the shortage of butter during the war period, mineral oil was used—sometimes with an added yellow color—on popcorn. A substantial amount was ingested, and the question arose as to whether this would be harmful and deleterious to health. In F. N. J. 5,635, the court stated: ". . . there is no evidence before the Court showing that mineral oil in the quantities used would be injurious to the public health." The case was accordingly dismissed. On the other hand, F. N. J. 8,831 reports granting by the court of a permanent injunction to restrain interstate shipment of popped popcorn containing mineral oil. It was stated in the findings of fact that such mineral oil absorbs fat-soluble vitamins A, D and K, and also that it tends to cause rectal irritation, with the further finding:

> That the popped popcorn which is the product of the defendant contains mineral oil in sufficient quantities to be harmful; that such mineral oil is a deleterious substance which renders the popcorn injurious to health; that the popcorn is therefore adulterated within the meaning of the Food, Drug and Cosmetic Act.

In a further action against a mineral oil product (F. N. J. 13,863), the district court found for the claimant and ordered the libel dismissed. This was appealed to the Fifth Circuit, which rendered a majority decision reversing the findings. It is concluded that the popcorn being sold might contain 12.5 per cent of mineral oil, and expert testimony recognized the harmful effect on the system by removing the fat-soluble vitamins. In dissenting opinions, it was stated:

> Zeal for enforcement, I think, is here outrunning common sense and the true intent of the law. The seizure was made in 1943, in the midst of the late war. . . . Because of war conditions, cocoanut oil could not be had at all, butter and cottonseed oil, soybean and Wesson oil, which had food value, became scarce and practically unobtainable because of the war demand for foodstuffs. Something else had to be substituted in the popcorn business, carried on at movie theatres and similar places of amusement, where popcorn is eaten in idleness

and not for nutriment. Mineral oil . . . came into general use for the popcorn dressing . . . . in a nickel package of popcorn, which weighs one ounce, there would be only one-sixteenth of an ounce of dressing, say a half-teaspoonful. That is, by common experience with mineral oil, negligible.

A fermentation inhibitor, monochloroacetic acid, was developed for use with various types of beverages, particularly beers and ales. In general, the solution contained 11 to 34 per cent of the active ingredient, for addition to the food products. It was stated by the judge (F. N. J. 8,502) that this product is a poisonous and deleterious ingredient—even though "when used in proportions not to exceed 500 parts per million, [it] does not render foods or beverages injurious, deleterious or unsafe for human consumption." This same standard was repeated in the decision condemning this product (F. N. J. 10,001) and in F. N. J. 12,833, in which the label failed to declare the presence of this poisonous, toxic and caustic substance.

Although a number of seizures were made without contest, based upon the presence of monochloroacetic acid in beer, there was a contest (F. N. J. 19,102) which was based upon the presence of the product in beer, with the claim that the defendants knew it to be a poisonous or deleterious substance. The court dismissed this charge; upon hearing of the amended information, it was ruled that the most recent offense charged had occurred more than three years before such filing and, therefore, prosecution was barred by the statute of limitations. The court dismissed the action.

The question arose in F. N. J. 12,781 as to whether saccharin is a food. This was submitted to the court, which ruled that it was. A number of products were seized and destroyed without contest because of the presence of sand, dirt, and other nonnutritive contaminants. In F. N. J. 3,721 is the report of a seizure of canned oysters, alleged to contain added deleterious shell fragments which might render the product injurious to health. This case was brought to interpret a portion of Section 402 dealing with adulteration, reading:

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health . . . .

The judge's opinion indicated that some food products might contain deleterious substances, such as bones in fish or fragments of shell in oysters. Shell fragments cannot be entirely separated from

an oyster food product. It was noted: "It is the character, not the quantity, of this substance that controls its ability to injure." Since this shell is not "added" nor can it be "avoided," it was concluded that the presence of these shell fragments does not ordinarily render oysters injurious to health, and the libel was dismissed.

A similar decision was reached in F. N. J. 8,917—that, regardless of the care used, some hidden parts of the viscera or the shell of hard crabs may not be eliminated by the cook in preparing the item for consumption. While it makes the material unattractive and unpleasant, it cannot be said to be "filthy" nor definitely injurious to health. Therefore, the court dismissed a seizure of canned herring roe.

A somewhat different approach was used for the interpretation of this same section regarding the presence of poisonous or deleterious substances which may render a food injurious to health and of subsection (d) which states that confectionery should not contain any nonnutritive substance except harmless coloring, flavoring or glaze. In F. N. J. 17,804 it was alleged that candy and chewing gum were adulterated because they were mixed in a slot machine with metal trinkets or with plastic animals, boots, etc. The district court condemned the products in the vending machines as adulterated. On appeal, the Fourth Circuit reversed this decision on the basis that neither the gum nor the candy contained the trinkets, but was mixed with them in the bowl of the vending machine by the operator; therefore, neither the gum nor the candy was adulterated.

In the field of vitamin products, most of the actions were taken under the drug classification. The question of guarantees was the basis of action reported in F. N. J. 12,995. The product was labeled to indicate that six tablets furnished 10 mg. of niacinamide; the tablets in question contained a lesser amount. Since they were manufactured in Hollywood, California, and shipped under a continuing guaranty to San Diego, California, which constituted an intrastate shipment, it was charged that the provisions of Section 301(h) did not apply, as that section covered only interstate shipments. The district judge followed this reasoning and ruled that the libel should be dismissed. On appeal, the United States Supreme Court reversed this decision, arguing that such shipments might later enter interstate commerce and that a false guaranty should not be permitted.

There was a seizure of blackstrap molasses, since a book *Look Younger, Live Longer*, by Gayelord Hauser accompanying the article

allegedly constituted labeling, and contained false and misleading statements regarding the value of the product in supplying many B vitamins, with a series of therapeutic claims handled under a drugs-and-devices notice of judgment (D. D. N. J. 3,658). In this proceeding, reported in F. N. J. 17,852), the basic question was as to whether or not this book, which had been published before the product came on the market and which did not specifically refer to this brand of molasses, should be considered as "labeling." The original libel was amended to show the relationship between claims on the product and statements in the book, including payments of royalties to the author for use of this association, and the district judge ruled that the book was a part of the labeling of the product.

In another action involving the claims made for an orange beverage (F. N. J. 19,101), the question developed as to whether this product was a complete replacement for orange juice. The case was submitted to a jury, which returned a verdict for the government. On appeal to the Third Circuit, the decision of the lower court was reversed. This had to do with the relationship of any imitation product to a natural food. Evidence was submitted in the district trial that the orange beverage did not contain vitamin C and assays on guinea pigs were admitted to show that this product led, in the test animals and in children, to scurvy, which did not develop following the ingestion of true orange juice. For various reasons, the decision of the lower court was reversed and the United States Supreme Court denied certiorari. The case was then dismissed.

Several products were offered as foods, but with the added plea that they would aid in the reduction of weight. A combination of vitamins and minerals (F. N. J. 12,996) was shown to be a mixture of dextrose, wheat germ and a small amount of malt. The district judge ruled that the ingestion of these tablets to curb appetite and aid in diminishing hunger pains was not false or misleading and that the product should be returned to its owner.

One form of candy was being sold for free consumption as part of a weight-reducing program; a permanent injunction was granted against it after a hearing (F. N. J. 3,623). Another candy, consisting of a hard caramel, and containing vitamins A, B and D was sold as a part of a reducing plan. An action against the company was barred (F. N. J. 13,697), on the basis that the witnesses had given testimony in a case involving the same charges, in a prior hearing before the

Outcome of Contests: F. N. J.'s 1-23,400

F. N. J.	Product	Charge A	Charge M	Plea	Action	Comments
19,380	Apples	?	?	N. G.	Ct. G.	CA-9 & United States Supreme Court reversed; spray
8,920	Apple Chops	X	..	S.	J. N. G.	CA-9 reversed; As & Pb
5,759	Mrs. Price's Compound	..	X	S.	Injunction	Boric acid harmful
13,264	Cheese	X	..	S.	Injunction	Contained filth
8,887	Eggs, Dried	?	..	S.	Dismissed	Filth, not dangerous
7,926	Beer	X	..	N. G.	J. G.	Contained F
9,601	Beer	X	..	S.	Ct. G.	Contained F
11,482	Mayonnaise	X	..	S.	Ct. G.	Contained mineral oil
11,280	Salad Dressing	X	X	N. G.	Ct. G.	Contained mineral oil
11,484	Salad Dressing	X	..	S.	J. G.	Contained mineral oil
5,635	Popcorn	?	..	S.	Ct. N. G.	No evidence mineral oil harmful
8,831	Popcorn	X	..	S.	Injunction	Mineral oil harmful
13,863	Pop'n Oil	X	?	S.	Ct. N. G.	CA-5 reversed; mineral oil
19,102	Beer	?	..	S.	Dismissed	Monochloroacetic acid
8,502	Esterex	..	X	S.	Ct. G.	Monochloroacetic acid
10,001	Esterex	..	X	S.	Ct. G.	Monochloroacetic acid
12,833	Esterex	..	X	S.	Ct. G.	Monochloroacetic acid
12,781	Saccharin	..	X	S.	Ct. G.	Saccharin food
8,917	Herring Roe	?	..	S.	Dismissed	Contained shell, harmful
3,721	Oysters	?	..	S.	Dismissed	Contained shell, harmful
17,804	Candy	?	..	S.	Ct. G.	CA-4, reversed; trinkets
12,995	Vitamins	?	?	N. G.	Ct. N. G.	Guarantees
17,852	Molasses	..	X	S.	Ct. G.	Book as labeling
12,862	Candy, Ayds	..	?	S.	Dismissed	*Res judicata*
13,697	Candy, Ayds	..	?	S.	Dismissed	*Res judicata*
3,623	Candy, Slend-R	..	X	S.	Injunction	Weight reduction
12,996	Vitamins	..	?	S.	Dismissed	Weight reduction
19,101	Orange Beverage	?	..	S.	J. G.	CA-3 reversed; no vitamin C

Summary.—Out of 28 contested cases, the government won in 17 (three reversed on appeal), the defendant in 11 (two reversed on appeal). Eighteen cases involved adulteration allegations and 14, misbranding.

Abbreviations:
A—adulteration
M—misbranding
?—allegation
N. G.—not guilty
G.—guilty
S.—seizure
J.—jury
Ct.—court

Federal Trade Commission (FTC Docket No. 4,898). Subsequently, an action was had before a district judge to decide the merits of the case. It was pointed out that the product contained vitamins A and D, and also B_1, B_2, calcium, phospherous and iron, in significant amounts. After hearing evidence, the court handed down findings of fact and dismissed the libel.

In the survey of the first 23,400 notices of judgment on foods, 860 had some pharmacological implications, and the government won somewhat more than half of the 28 contests. **[The End]**

• FDA—COURT ACTIONS DURING APRIL, 1959 •

A new high was reached in April in the seizure of foods possibly hazardous to health when a total of 227 tons was removed from the market. The Food and Drug Administration reported seizure of 210 tons of mercury-contaminated wheat and 14½ tons of frozen spinach with an unsafe amount of the pesticide DDT. The mercurial compound in the wheat is a known poison having legitimate use only as a seed treatment, FDA stated. The chopped spinach was representative of a similarly contaminated total pack of 4 million pounds in 10-ounce packages. The remainder of the pack was to be voluntarily recalled from retail stores by the packer.

The Administration acted to remove two shipments of imported nitrite-treated fish, totaling 1½ tons, from the market; it also stopped entry into the United States of an additional 28 tons, in nine shipments. This action was a follow-up resulting from a tragic incident which occurred on March 24, when a Haddon Heights, New Jersey child died after eating flounder fillet treated with a large amount of sodium nitrite. Also seized as hazardous to health were 5,900 packets of powdered scrambled eggs contaminated with salmonella bacteria. Four vitamin products failing to contain vitamins and minerals essential in human nutrition were likewise removed from the market.

Wheat and flour contaminated by rodents accounted, in carloads and warehouses, for 91 of the 300-ton total of otherwise unfit foods. Fifty-two tons of fresh and frozen seafood in four shipments, mostly imported, contained parasitic cysts. One shipment of spoiled frozen sperm-whale meat accounted for 45 tons. Nearly 20 tons of tomato juice, tomato cocktail and tomato paste made from spoiled tomatoes were seized in warehouses. Breading mix with insects and insect parts and a shipment of rice contaminated by rodents and insects accounted for another 24 tons of unfit warehoused foods. Rodent-gnawed Swiss cheese with dirt, rodent pellets and mold was another example of unfit foods seized.

Sixty-six tons of foods were seized as economic cheats.

Of 15 drugs and devices seized in April, eight were alleged to be misbranded with false and misleading claims. Two were vibrator-massage devices. Another seizure was of a liquid preparation offered directly to the public as a cosmetic treatment for radiation fallout injuries, as well as for a number of disease conditions.

Altogether, 83 seizure cases were instituted in the federal courts. Fifteen prosecutions were terminated.