

Food Drug Cosmetic Law

JOURNAL

Health and Food Legislation in

Mexico RAFAEL ILLESCAS FRISBIE
and JUDITH GOMEZ FARIAS

Confectionery Under the Pure Food

Law JOHN L. HARVEY



A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.



The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: \$20 per year. Single copies are \$2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

September, 1961

Volume 16 • Number 9

Second-class postage paid at Chicago, Illinois.

21. W.E.L. 2504

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents September, 1961

	Page
Reports to the Reader	535
Health and Food Legislation in Mexico	
. . . Rafael Illescas Frisbie and Judith Gomez Farias	537
Confectionery Under the Pure Food Law John L. Harvey	549
FDA and the Farmer George P. Larrick	556
Federal Hazardous Substances Labeling Act as It Affects the Ink-Making Industry . Franklin D. Clark	561
FDA's Consumer Consultant Program Carla S. Williams	569
Washington—Action and News In the Food and Drug Administration	576

VOLUME 16

NUMBER 9

© 1961, Commerce Clearing House, Inc., Chicago 46, Illinois
All Rights Reserved

Printed in United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

- Frank T. Dierson**, New York City, *Chairman*; Secretary, The Food Law Institute; General Counsel, Grocery Manufacturers of America, Inc.
- Charles A. Adams**, London, England, former Director, Food Standards and Labelling Division, United Kingdom Ministry of Food
- H. Thomas Austern**, Washington, D. C., General Counsel, National Canners Association
- Fred Bartenstein**, Rahway, New Jersey, Administrative Vice President, Merck & Company, Inc.
- Robert E. Curran**, Ottawa, Canada, Legal Adviser, Canadian Department of National Health and Welfare
- Franklin M. Depew**, New York City, President, The Food Law Institute
- William E. Fairbanks**, New York City, General Counsel, Thomas J. Lipton, Inc.
- A. M. Gilbert**, New York City, Counsel, Best Foods Division, Cora Products Company
- Robert S. Gordon**, New York City, General Counsel, National Dairy Products Corporation
- Edwin L. Harding**, Battle Creek, Michigan, General Counsel, Kellogg Company
- Harold Harper**, New York City, General Counsel, National Wholesale Druggists' Association
- James F. Hoge**, New York City, General Counsel, Proprietary Association of America; Counsel, American Foundation for Pharmaceutical Education
- Vincent A. Kleinfeld**, Washington, D. C., former Food and Drug Law Attorney, United States Department of Justice
- George Link, Jr.**, New York City, General Counsel, Charles B. Knox Gelatine Company, Inc.
- Michael F. Markel**, Washington, D. C., General Counsel, Corn Industries Research Foundation
- Samuel A. McCain**, New York City, Member, Executive Committee, The Food Law Institute; Vice President of Counsel, Corn Products Company
- Bradshaw Mintener**, Washington, D. C., former Assistant Secretary of Health, Education, and Welfare
- Merrill E. Olsen**, Chicago, General Counsel, Quaker Oats Company
- C. Joseph Stetler**, Chicago, Director, Law Department, American Medical Association
- Edward Brown Williams**, Washington, D. C., former Principal Attorney, United States Food and Drug Administration
- John K. Worley**, Detroit, Michigan, General Counsel, Pharmaceutical Manufacturers Association
- Julius G. Zimmerman**, New York City, Member, Executive Committee, The Food Law Institute; Attorney, The Coca-Cola Export Corporation

THE EDITORIAL ADVISORY BOARD advises on policies, subjects and authors. It assumes no responsibility otherwise. Its members render this public service without compensation, in order that the FOOD DRUG COSMETIC LAW JOURNAL may comply with the highest professional standards.

Scientific Editor: Bernard L. Oser

Editor of Comments: Thomas W. Christopher

Editor of Canadian Law: Robert E. Curran, Q. C.

Editor of Foreign Law: Julius G. Zimmerman

Associate Editor for Europe: Ernst Abramson, M. D.

REPORTS

TO THE READER

Mexican Food Legislation.—The Director General of Food, Beverages and Cosmetics of Mexico and a Section Chief of the Mexican Secretariat of Health present an exhaustive examination of the health and food legislation of their country at page 537.

The fundamental law on public health in Mexico is the Federal Sanitary Code, which was first put into force in 1891. The amended version of 1955 is now the law of the land and the basic components of this code are thoroughly outlined by the authors. This article was written for the *FOOD DRUG COSMETIC LAW JOURNAL* by *Rafael Illescas Frisbie* and *Judith Gómez Farias*.

Confectioners and the FDA.—Last June, FDA Deputy Commissioner *John L. Harvey* addressed the Seventy-Eighth Convention of the National Confectioners Association in Chicago. He discussed several items of importance to confectionery manufacturers, including the problem of rot and mold in cocoa beans, current status of artificial coloring, inclusion of nonnutritive substances in confectionery and deceptive packaging. His speech is reproduced at page 540 of this issue.

FDA in the Field.—One of the biggest problems confronting the Food and Drug Administration today is the fact that vast quantities of poisonous materials must be used to protect the nation's food supply from weeds, insects, plant disease and spoilage. Al-

though scientific research has developed means for doing this effectively and safely, the FDA still must be constantly alert to insure that unsafe methods are not used. Field representatives of the FDA are continually on the watch for possible violations of the Pesticide Amendments to the Food, Drug, and Cosmetic Act. The Food and Drug Administration much prefers, of course, to prevent violations of the law rather than to prosecute after they have occurred.

This is the thesis of a speech delivered in Washington, D. C., July 11, by *George P. Larrick*, Commissioner of Food and Drugs. This article appears at page 556.

Hazardous Substances in Ink.—A few years ago, ink manufacturers would have been greatly surprised if someone had told them they would soon be subject to regulation by the Food and Drug Administration. However, some types of inks may fall under the Federal Hazardous Substances Labeling Act, which was passed July 12, 1960. The industry was informed of this possibility by *Franklin D. Clark* at the Fountain Pen and Mechanical Pencil Manufacturers Association Convention on May 19 of this year. Mr. Clark is Assistant to the Deputy Commissioner of the FDA.

Mr. Clark told the ink manufacturers that the Act would affect products which met two tests set up by Con-

gress: (1) the container must be suitable and intended for household use, and (2) the product itself must be a substance that is toxic, an irritant, a strong sensitizer, corrosive, flammable, or one that will generate pressure through decomposition, heat or other means, or *if such substance may cause substantial personal injury during or as a proximate result of any reasonably foreseeable handling or use, including accidental ingestion*. Since there is a possibility that several types of inks might fall into this category, manufacturers will be subject to the labeling requirements of the Hazardous Substances Labeling Act in the future.

Consumers, Foods and Drugs.—A little known but highly effective program administered by the Food and Drug Administration is the Consumer Consultant Program. In each of the FDA's 18 field districts, there are women serving as part-time consultants for the FDA. These highly qualified women are chosen for their professional background and work directly with the consuming public. In face to face contact with consumers, these women help to inform the public on the facts, fallacies and fads in foods, drugs and cosmetics.

The article on the Consumer Consultant Program at page 569 was written by *Carla S Williams*, a member of the Bureau of Program Planning and Appraisal of the FDA. She presented this paper at the Annual Meeting of the Council of Consumer Information in St. Louis, April 6.

Urdang Medal.—The American Institute of the History of Pharmacy has announced that it will confer the seventh George Urdang Medal upon General Rafael Roldán y Guerrero, pharmacist-historian of Madrid, Spain. The medal honors unusually distinguished historical publications on pharmacy.

Food Law Amendment.—During the month of September, the Senate Subcommittee on Antitrust and Monopoly heard testimony on S. 1552, a proposed

bill which would amend the Sherman Act, patent laws and the Federal Food, Drug and Cosmetic Act. The following is excerpted from the testimony of Lee Loevinger, Assistant Attorney General of the United States.

"The objectives which the present bill seek seem clear. The Sherman Act amendments would seek to limit, in the drug industry, anticompetitive agreements entered into by drug manufacturers in negotiations conducted in relation to the settlement of interferences declared by the Patent Office.

"The patent law amendments would endeavor to reduce the number of patents issued by the Patent Office for insignificant modifications and combinations of pre-existing drugs. . . .

"The objectives sought in Section 4 of the bill relating to the amendments to the Federal Food, Drug and Cosmetic Act apparently relate both to economic considerations and health considerations. The health objectives relate to control of conditions of manufacturing and to assurances that drugs which are marketed are efficacious. They also relate to the dissemination of information concerning possible harmful effects to drugs which are marketed. The economic objectives relate to a de-emphasis of proprietary names for drugs so that manufacturers may compete with each other for sales of similar items under official non-proprietary generic names by which physicians would be encouraged to prescribe. It is the apparent intention of the bill that physicians, knowing that all marketed drugs have been manufactured in plants whose standards have been inspected and controlled, may freely prescribe with reference only to the non-proprietary generic names of the drugs and that consumers may know what they are buying and may be able to compare prices.

"The basic objective of the bill is quite clearly a higher degree of competition in the marketing of prescription drugs. With that objective, we are in complete accord."

Food·Drug·Cosmetic Law

Journal

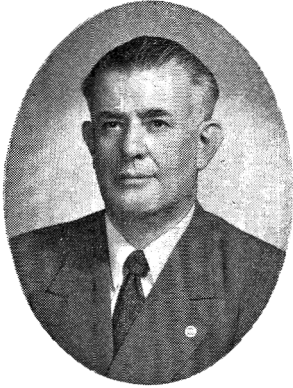
Health and Food Legislation in Mexico

By RAFAEL ILLESCAS FRISBIE and JUDITH GOMEZ FARIAS

This Article Is an Extensive Explanation of Mexican Regulation of Foods, Drugs and Cosmetics. The Authors Trace Briefly the History of Food and Health Regulations, Then Outline the Regulatory Machinery Now in Use.

FROM THE OLD COLONIAL DAYS to the establishment of the Mexican government, after the War of Independence, all public health matters were under the jurisdiction of a type of Board of Health, the so-called "Protomedicato." It had its origin in Spain where it was a tribunal composed of the king's physicians, generally three in number, who examined and judged the qualifications of the young future medical doctors and granted the permission for the practice of medicine. In 1820 the "Protomedicato" was replaced by the Faculty of Medicine (Facultad de Medicina) which was given the responsibility of enforcing all health laws. As was its predecessor, it was a collegiate board.

In 1833, Don Valentín Gómez Farías, then President of the Mexican Republic, founded a new Faculty of Medical Sciences (Facultad de Ciencias Medicas) with a larger scope than the former one. It is considered to be the origin of the present Faculty of Medical Sciences of the National Autonomous University of Mexico (Universidad Nacional Autónoma de México). In 1841 the Superior Council of Health of the City of Mexico (Consejo Superior de Salubridad de la Ciudad de México) was founded and for 70 years handled everything pertaining to public health and sanitation. In 1917, when the new



Rafael Illescas Frisbie Is Director General of Food, Beverages, Drugs and Cosmetics in the Secretariat of Health of Mexico.

Miss Judith Gomez Farias Is a Section Chief in the Secretariat of Health of Mexico.



Constitution was adopted in Querétaro, the council was transformed into the Department of Health of the Republic (Departamento de Salubridad de la República), which, as we shall see, was merged with the Secretariat of Public Welfare (Secretaría de Asistencia Pública) on October 15, 1943 to become the present Secretariat of Public Health and Welfare (Secretaría de Salubridad y Asistencia Pública).

The history of the "Secretaría de Asistencia Pública" began on February 28, 1861 with the creation of a Department for Welfare Funds (Dirección General de Fondos de Beneficiencia) which was founded to take care of hospitals, the asylum for the insane, the foundling hospital, etc. The following year it was reorganized and given a new name, the Department of Public Welfare (Dirección de Beneficiencia Pública). On January 23, 1877 the "Dirección" became the "Dirección General de Beneficiencia Pública y Hospitales," which for 62 years was in charge of all the public welfare problems. On July 16, 1924 it was changed to "Junta Directiva de Beneficiencia Pública

en el Distrito Federal." This last Welfare Board gave way on December 31, 1937 to the Secretaría de Asistencia Pública," which, as we already mentioned, was merged with the "Departamento de Salubridad General de la República" six years later and became the present "Secretaría de Salubridad y Asistencia Pública" (hereinafter referred to as SSA).

The duties and functions of the SSA are outlined in the decree which created this new secretariat and which was signed at the National Palace the 15th of October 1943 and published in the Federal Gazette (Diario Oficial de la Federación) on October 18, 1943:

Article No. 1—The "Secretaría de Salubridad y Asistencia" is established by the merger of the "Secretaría de Asistencia Pública" and the "Departamento de Salubridad de la República" which are discontinued as individual government secretariats.

Article No. 2—The SSA has the following duties and functions: Those listed in Articles 10 and 13 of the Law on the Secretariats and Departments of State, and which were assigned to the "Secretaría de Asistencia Pública" and to the "Departamento de Salubridad de la República" respectively, and all others that were expressly assigned to them by other laws.

The most important duties and functions of the new SSA in the field of food control are listed in Article 13 of the Law on the Secretariats and Departments of State:

IV. Inspection and sanitary control over the preparation, possession, storage, uses, supply, introduction, traffic, etc., of edibles and beverages.

V. Veterinary control insofar as it is required to protect human health in relation to the use of foods.

XIII. Meetings and Congresses relating to Public Health.

XIV. Coordination of the sanitary services of the states, the Federal District and the Federal Territories.

XV. In general, vigilance over the compliance with the rules and regulations of the Sanitary Code and the study and preparation of new ones.

Federal Sanitary Code

The Federal Sanitary Code of the United States of Mexico (Código Sanitario de los Estados Unidos Mexicanos) is the fundamental law on public health in this country. The first of these codes appeared in 1891 and four amended versions followed in the years 1902, 1934, 1950 and 1955. The last one is now in force. According to this law, activities related to matters of public health and sanitation may be federal in character, in which case the rules are compulsory for the entire country; or local, in which case the rules are applicable

only in the Federal District and the Federal Territories, but not in the states.

According to this same law, the following officials are responsible for Federal action:

(1) The President of the Republic; (2) The General Council of Health (Consejo General de Salubridad), a board that is directly under the orders of the President of the Republic, and not under the jurisdiction of any Secretary of State, and which has the power to issue general sanitary rules which are compulsory for the entire country; (3) The "Secretaría de Salubridad y Asistencia Pública."

The internal organization of the SSA is as follows: The two Under-Secretaries and the Chief Secretary are the three Official Executives, even though the Minister always has the final word. Each Under-Secretary heads an organization consisting of several Sections, Departments, Offices and Laboratories. (For the purpose of this presentation we shall discuss here only the branches that have to do with sanitary food control at the Federal level and locally that is, in the Federal District.)

The Federal Sanitary Police.—This organization is directly under the Minister and has ample powers, since, with the exception of the authority given to the Federal Police of Narcotics, it has the duty of enforcing the execution of all other rules contained in the Federal Sanitary Code and the regulations issued thereunder.

For the execution of sanitary measures at the federal level the SSA has in each state (there are 30 Mexican states) an agency called "Servicios Sanitarios Coordinados" which is administered through its "Dirección General de Servicios de Salud Pública en Estados y Territorios." However, these agencies have another function. As in the United States of America, the Mexican states are free and sovereign and can therefore legislate on all internal matters provided these rules do not interfere with the provisions set forth in the various federal laws, which include the Sanitary Code. If, however, a state decides to apply certain health measures which it alone could not possibly carry out, then the state and federal government (SSA) will conclude an agreement in the form of a contract which sets forth all the conditions. Usually the Deputy assigned to this project will work half of the time for the state and half of the time for the federal government, each of which will contribute one half of the cost.

A few states have issued their own regulations on food, beverages, drugs and cosmetics. Several apply to a certain extent the Federal Sanitary Code and the regulations issued thereunder.

Federal Food Law.—The first ordinance on which our present food law is based is the regulation on the sale of food and beverages in the Federal District (Reglamento para la Venta de Comestibles y Bebidas en el Distrito Federal) which was published November 16, 1912. Although most of its provisions have been amended by the Federal Sanitary Code and the various regulations on special foods (such as those for milk, meat, coffee, pulque, canned foods, etc.) which have since then appeared, it has not been expressly revoked.

Food Registration.—The Federal Sanitary Code of August 20, 1934, in its chapter entitled Sanitary Control of Foods, Beverages and Similar Products (Higiene sobre Comestibles, Bebidas y Similares) contained for the first time a provision requiring the registration of food, which read: "In the Mexican Republic the importation, internal trade, preparation, manufacture, storing, transportation, holding, sale and supply to the public of prepackaged food, beverages and the like that have not been *previously registered* in the Department of Public Health, in accordance with the regulations issued by the General Council of Health, are forbidden. The aforementioned operations with bulk products, unless registered in accordance with the respective regulations, are also forbidden." However, the requirements that had to be fulfilled to register a foodstuff were not fixed until August 31, 1936 when the first ordinance for the registration of foods appeared under the title, First Regulation for the Registration of Foods, Beverages, and Similar Products (Primer Reglamento para el Registro de Comestibles, Bebidas y Similares).

This ordinance may be considered as the first federal food law. The ordinance now in force, with an identical name, was issued on May 5, 1941. The title of its first chapter is General Requirements for the Registration (Condiciones Generales para el Registro). Shortly after the publication of this ordinance a decree of the federal Congress of December 31, 1941 established the payment of a fee for the registration of foodstuffs. It fixed the amount at \$20 (pesos) for each registered product if produced in the country and \$50 (pesos) if imported. The following year, on March 11, 1942, the Secretariat of Finance and Public Credit (Secretaría de Hacienda y Crédito Público) published a decree which required that registered foods, drugs and cosmetics had to be checked

every two years from the date on which they were registered. This periodical check was to verify that the products and all the conditions that served as a basis for their approval had not been changed, unless there had been a previous application and an approval of it to change some or all of these conditions. If the situation was found to be satisfactory, the registered number given to every item could be kept for two more years. This checking involved the payment of the above fees for every registered product. Later the same Secretariat published another decree changing the period of the checking to every five years. This disposition is still in force as far as the checking is concerned but the registered number of the items can no longer be held for five years without an annual payment. The last decree of this Secretariat, published on December 29, 1960, changed the fees for the registration and the retention of the registered numbers as follows:

III. Food, beverages and other similar products.

1. Finished imported products:	<i>Pesos</i>
(a) Registration fee	\$500
(b) Annual fee for keeping the registered number.....	100
2. Imported products to be processed and finished in the country:	
(a) Registration fee	300
(b) Annual fee for keeping the registered number.....	100
3. National Products	
(a) Registration fee	100
(b) Annual fee for keeping the registered number.....	100

The Federal Sanitary Code now in force requires that all food-stuffs that are supplied to the public in a prepackaged form must be registered with the SSA. Special regulations determine what food-stuffs have to be prepackaged to be sold, such as those for butter, cheese and margarine.

The Directorate General of Foods and Medicines (Dirección General de Alimentos y Medicamentos) through its Directorate for Registration and Control of Foods and Beverages (Dirección de Registro y Control de Alimentos y Bebidas) is the branch of the SSA in charge of registering foodstuffs under the law. For an equitable application of the last mentioned decree, this Directorate modified the tariff for national products manufactured by small concerns with a capital of less than \$25,000 (pesos) in the following manner:

	<i>Pesos</i>
(a) Registration fee	\$20
(b) Annual fee for keeping the registered number.....	20

Also, it established a list of 105 groups of foods or foodstuffs which may be registered under the same number. The term "food" or "foodstuffs" includes food, beverages, additives, essential oils, colorings and all sorts of ingredients that go into the preparation of food. It also includes alcoholic beverages, which can be registered under the same number.

Procedure for Registering Foodstuffs

To register a foodstuff with the "Dirección de Registro y Control de Alimentos y Bebidas," the procedure to follow is the one established by the "Regulation for the Registration of Foods, Beverages and Similar Products" of March 5, 1941, which consists of:

- I. Submitting an application form in duplicate giving the following data:
 - (a) Name of the product.
 - (b) Name of the manufacturer (person or commercial firm).
 - (c) Commercial address of the manufacturer.
 - (d) Name of the representative and/or importer.
 - (e) Commercial address of the representative, and/or importer.
 - (f) Composition of the foodstuff (percentage of the ingredients).
 - (g) Manufacturing technique.
 - (h) Intended use.
 - (i) Number of the Health License
Date Issued

Name of the health authority that issued it

The health licenses are issued by the "Dirección de Registro y Control de Alimentos y Bebidas" free of charge to concerns located in the Federal District, Federal Zones and Territories.

Health licenses for firms in the individual states are issued by the delegate of the "Servicios Sanitarios de SSA" and the states determine whether these licenses are to be issued free of charge or are subject to payment of a fee.

The health licenses are issued if the establishment complies with the Sanitary Regulations for Buildings (Reglamento de Ingeniería Sanitaria Relativo a Edificios) and the corresponding regulation concerned with the food in question.

- II. An application for the above license by the following documents:
 - (a) Official receipt for the payment of the registration fee.
 - (b) A chemical and, if required, a bacteriological analysis of the product.
 - (c) If the product is imported, a certificate of free sale in the country of

- origin issued by the Health authorities or the Chamber of Commerce of that country with the visa of the corresponding Mexican Consul.
- (d) Draft forms, for official approval, of the labels, and any kind of advertisement of the product.
 - (e) A power of attorney authorizing another to apply for the registration of the product if the person signing the application form is not himself the interested person or an officer of the interested firm.
- III. A sample of the product must be submitted for laboratory tests if the "Dirección" considers that to be necessary, and the draft forms of the labels must show the following inscriptions:
- (a) Name or, if existing, the commercial trade mark of the product.
 - (b) Name and commercial address of the representative and/or importer.
 - (c) Depending on the kind of product, its chemical or qualitative composition.
 - (d) Name and commercial address of the manufacturer.
 - (e) The textual inscription "Hecho en México" (Made in Mexico) if the product is national, or the name of the country of origin if imported; e. g., "Producto Suizo" (Swiss Product), "Producto Norteamericano" (North American Product), "Producto Holendés" (Netherlands Product), etc.
 - (f) The textual inscription "Reg. S. S. A. No. "A"
 - (g) Net contents in weight or volume expressed in units of the Metric System.

If the application and the documents accompanying it are in order the "Dirección" will issue a number called "Provisional Number" so that the interested person may use it for the purpose only of printing it on the labels. Within 60 days the printed labels showing this number and three photographs (size 16 x 24 cm.) of the product as it will appear on the market have to be submitted to the "Dirección." If approved, the provisional number becomes final and constitutes the authorization for sale.

The labels and advertisement of all products, whether domestic or imported, must be written or printed in Spanish. The inscriptions may be repeated in other languages only if the products are intended for exportation.

The printing of the labels and advertisement must be clear and easily legible. Labels and advertisements must not be misleading.

If a product is subject to deterioration within a certain time, the label must show the date of preparation of the product and the date beyond which it may no longer be wholesome.

If the product contains an additive, this must be declared on the label with a statement of the purpose of its use according to the Regulation on Food Additives (Reglamento de Aditivos para Alimentos).

The following is a list of regulations on food and related matters now in force, with the date of publication in the *Diario Oficial de la Fed.*

1. Reglamento para la Venta de Comestibles y Bebidas en al Distrito Federal (Regulation on the Sale of Food and Beverages in the Federal District). November 16, 1912

2. Disposiciones sobre venta de Comestibles y Bebidas en la vía publica (Regulation on the sale of Food and Beverages on Public Highways). July 3, 1920.

3. Reglamento de Carnes propias para el Consumo, preparados que de ellas se deriven y establecimientos relacionados con los mismos productos (Regulation on Meat which is fit for Consumption, on Meat Preparations, and on Establishments related to these products). March 30, 1927.

4. Reglamento para la Producción, Introducción, Transporte y venta de Pulque (Regulation on the preparation, introduction, transportation and sale of Pulque). March 27, 1928.

5. Reglamento de Ingeniería Sanitaria relativo a edificios (Sanitary Regulations for Buildings). February 25, 1930.

6. Reglamento para los análisis de potabilidad de las aguas en la República (Regulation on the analysis of water in the Republic to determine its potability). September 9, 1935.

7. Reglamento Federal de Aguas Potables (Federal Regulation on Potable Waters). December 5, 1939.

8. Decreto que prohíbe el uso del aceite de nabo como alimento (Decree prohibiting the use of "nabo" oil as food). August 31, 1936.

9. Reglamento para el Registro de Comestibles, Bebidas y Similares (Regulation on the Registration of Foods, Beverages and Similar Products). March 5, 1941.

10. Reglamento para el control sanitario de ostras y almejas (Regulation on the sanitary control of oysters and clams). March 6, 1941.

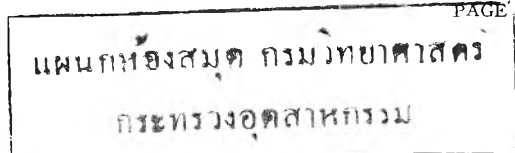
11. Reglamento de Restaurantes, Cafés, Fondas, Loncherías, Torterías, Taquerías, Neverías, Ostionerías, Salones de Té y demás establecimientos (Regulation on Restaurants, Cafes, Inns, Luncheonettes, Pastry Shops, Pool Rooms, Ice Cream Parlors, Oyster Bars, Tea Shops, and other similar establishments). December 16, 1941.

12. Reglamento de Inspección Sanitaria de aves destinadas al público, para alimentación (Regulation on the Sanitary Inspection of fowl destined for consumption by the public. This regulation has become obsolete with the inauguration of the municipal slaughterhouse for fowl, introduced in June 1959. All fowl for human consumption in the Federal District must be inspected and slaughtered there). January 7, 1942.

13. Decreto que adiciona el Reglamento para el Registro de Comestibles, Bebidas y Similares (Supplementary Decree to the Regulation on the Registration of Foods, Beverages and Similar Products). March 11, 1942.

14. Reglamento para la fabricación, transporte y expendio de Hielo para el Distrito, Territorios y Zonas Federales (Regulation on the manufacture, transportation and sale of ice in the Federal District, Zones and Territories). May 2, 1942.

15. Decreto que obliga a yodar la sal en las zonas bociógenas de la República (Decree on the obligation to iodize the salt in the goitrogenic zones of the Republic). May 31, 1942.



16. Ley Vitivinícola (Secretaría de Hacienda y Crédito Público) (Law on Grape Growing and Wine Making). March 25, 1943.
17. Decreto que autoriza la venta de Pulque envasado (Decree authorizing the sale of bottled Pulque). December 22, 1949.
18. Reglamento para la Industrialización de la Carne (Regulation on the Processing of Meat). February 13, 1950.
19. Reglamento de Vinos, Aguardientes y Licores (Regulation on Wines, Brandies, and Spirits). April 29, 1950.
20. Decreto que considera la sacarina como substancia de empleo peligroso (Secretaría de Hacienda y Crédito Público) (Decree Classifying Saccharine as a Dangerous Substance). February 7, 1951.
21. Reglamento sobre Producción, Introducción, Transporte, Pasteurización y venta al Público de la Leche en el Distrito, Territorios y Zonas Federales (Regulation on the Production, Introduction, Transportation, Pasteurization and Sale to the Public of Milk in the Federal District, Zones and Territories). February 8, 1951.
22. Reglamento Federal sobre Obras Provisión de Aguas Potables (Federal Regulation on the Works Providing Potable Water). July 2, 1953.
23. Reglamento de Derivados de la Leche y Substitutos de ellos (Regulation on the Derivatives of Milk and its Substitutes). August 27, 1953.
24. Reglamento de Vinos y Aguardientes de Uva (Regulation on Wines and Brandies made from Grapes). August 4, 1954.
25. Código Sanitario de los Estados Unidos Mexicanos (Sanitary Code of the United States of Mexico). March 1, 1955.
26. Decreto que modifica el Reglamento de Vinos y Aguardientes de Uva (Decree Amending the Regulation on Wines and Brandies made from Grapes). March 7, 1955.
27. Reglamento de Aceites y Grasas Comestibles (Regulation on Edible Oils and Fats). March 27, 1956.
28. Reglamento de Carnes Frías Comestibles (Regulation on Cold Edible Meats). August 28, 1956.
29. Reglamento de Aditivos para Alimentos (Regulation on Food Additives). February 15, 1958.
30. Decreto que aprueba la ley que establece el pago de derechos por el registro y certificación de medicamentos y productos de perfumería y de belleza, así como por el registro (Secretaría de Hacienda y Crédito Público) (Decree Promulgating the law on the Establishment of Fees for the Registration and Certification of Medicines and Cosmetics as well as for the Registration of Foods and Beverages). December 29, 1960.

These regulations are at the federal level and they also apply to products sold in interstate commerce and to imported products.

Enforcement.—The economic status of the majority of the people makes it difficult to enforce the prepackaging of all foodstuffs, which would be most desirable from the point of view of sanitary food con-

trol. Therefore, generally speaking, the same kind of foodstuffs that are sold prepackaged under a registered number are also to be found on the market in loose form. It may be said, with respect to food sold in loose form, that there is practically no official sanitary control. On the other hand, extremely low budget allocations make enforcement of the existing legislation for prepackaged foods quite difficult.

Responsibilities of the "Dirección de Alimentos y Bebidas" at a Local Level.—At the local level the "Dirección" is in charge of the sanitary control of bottled milk and of unbottled "Pulque," an alcoholic beverage obtained from the fermentation of the cactus *Agave Mexicana*.

The sanitary control of bottled milk is exercised through the Department for the Sanitary Control of Milk (Departamento de Control Sanitario de la Leche) and it includes the following:

- I. Clinical examination of bovines:
 - (a) Tuberculin test, which is performed every six months and is being applied to 50 per cent of the animals that provide milk to the city (50,000 head). Prophylactic measures consist of examination of cattle that give a positive reaction and keeping under observation cattle that give a dubious reaction.
 - (b) Detection of mammal glandular mammitis.
 - (c) Clinical examination of fauces, skin, genital organs and lungs.
 - (d) Brucellosis prevention is left to the cattle owner. The great majority of them vaccinate their calves to prevent this disease.
- II. Periodical clinical examination of the working men.
- III. Training in the hygienic milking of animals and the handling of milk.
- IV. Milk sampling from cattle barns, pasteurizing plants, retail stores and transportation vehicles. Milk samples are subject to field tests, such as density, glucose and phosphatase, and to more elaborate chemical and bacteriological studies in the Laboratorio Nacional de Salubridad (National Health Laboratory). A check for adulterants is also made.

The sanitary control of "pulque" is conducted in the places of production and in the custom houses where it is introduced into the city. There, the pulque is subject to field tests. If found abnormal the product is poured immediately from the containers into the sewage. No official sanitary or quality control of this beverage is exercised at the retail premises (Pulquerías).

Health Department of the Federal District (Dirección de Salubridad en el Distrito Federal) Sanitary Control Office for Foods and Beverages (Oficina de Higiene de Alimentos y Bebidas).—The work of this office is practically reduced to the issuing of sanitary licenses

to establishments where food is sold at retail, such as grocery stores, bakeries, markets, supermarkets, meat markets, etc., and to establishments where it is sold for immediate consumption, such as restaurants, coffee shops, food stands, etc. In view of the control exercised by the Dirección de Alimentos y Bebidas, the Oficina de Higiene de Alimentos y Bebidas does not take samples of food sold in the above-mentioned premises.

This office is also responsible for the veterinary inspection of fresh meat in the slaughterhouse of "Ferrería," the municipal slaughterhouse which processes all of the meat consumed in the city.

This office is also responsible for the veterinary inspection of fowl and fish. Annexed to "Ferrería" is the municipal slaughterhouse for fowl. [The End]

BIOGRAPHICAL NOTE

Rafael Illescas Frisbie, presently Director General of the Department of Food, Beverages, Drugs and Cosmetics in the Federal Secretariat of Health in Mexico, was born in Mexico City. He graduated as a chemical engineer from the National University of Mexico in 1921. From 1920 to 1957 he lectured at his alma mater as a Professor of Chemistry, mainly on the subjects of the sugar industry and industrial and technical analyses. He was also given many other important teaching assignments at the Department of Biochemistry, the School of Medicine and other institutions.

In 1927 Professor Illescas founded a private chemical laboratory which specialized in consulting and analytical work of a general nature and he also worked as a consulting chemist for private firms and government institutions until he accepted his present public office.

Miss Judith Gómez Farías, likewise graduated as a chemist from the National Autonomous University in Mexico City in 1947 and worked for three years as a laboratory chemist in a soap factory. In 1951 Miss Gómez became associated with the Department of Food, Drugs and Cosmetics at the Federal Secretariat of Health.

In 1952 she won a scholarship sponsored by the Institute of International Education in New York and attended graduate courses at the University of Michigan and Wisconsin while on leave from her government job.

In 1955 she traveled extensively in Europe and visited the headquarters of the World Health Organization in Geneva and the Food and Agriculture Organization in Rome. She was granted a fellowship by the WHO to study food technology and food law which she did at the University of Illinois during the academic year 1955-1956 where she earned a Master of Science degree. During her stay in the United States Miss Gómez visited Washington and attended several conventions dealing with questions of food and technology. In 1957 she married Mr. John Allyn Jay, likewise a graduate of the University of Michigan. Miss Gómez is presently a section chief in the Federal Secretariat of Health in Mexico and she also lectures on the subjects of her specialty at the School of Public Health and other government institutions.

Confectionery

Under the Pure Food Law

By JOHN L. HARVEY

This Paper Was Presented by FDA Deputy Commissioner Harvey Before the Seventy-Eighth Convention of the National Confectioners Association in Chicago, June 14, 1961.

WHEN YOUR PRESIDENT, some months ago, asked me to address you today, he was kind enough to give me carte blanche authority to choose the specific subject matter and the title of my remarks. I purposely chose the title "Confectionery Under the Pure Food Law" as one broad enough to encompass several individual items I felt it profitable to discuss with you. In one sense they are unrelated; in another, they are all part of the same philosophy that has brought members of the Food and Drug Administration before your national and various sectional meetings in the past. We have always felt that an informed group of manufacturers in any area under our jurisdiction assisted us in our responsibility of consumer protection and resulted in a much stronger feeling of industry and government working towards a common goal.

The first subject I would like to touch on briefly is the cocoa bean situation. As you undoubtedly know, the United States is the largest market in the world for cocoa beans and, on the other hand, must depend entirely upon the output of foreign countries for this commodity so important to your industry.

Problems of insect infestation and mold in cocoa beans have long been recognized by shippers, processors and food law enforcement officials. To the cocoa trade, insect infestation and mold are two of several factors which govern the grade or quality of cocoa beans. The Food and Drug Administration recognizes that complete absence of these defects, although certainly an admirable goal, is not a very practical thing to expect. We further believe, however, that a prac-

tical minimum which should be low enough to be acceptable to the informed consumer should be insisted upon. About 30 years ago this matter was considered and a tentative tolerance was announced in a notice to the trade which said: ". . . On and after October 1, 1933, shipments of cocoa beans containing moldy and wormy beans in excess of 10 per cent, not over one-half of which, or 5 per cent, shall be moldy will be detained." We did not realize that the tentative nature of this tolerance would be quite as permanent as it has since proven to be. In 1958, however, the Food and Drug Administration decided and announced to the trade its intention to study the effect of improved and modern commercial practices on insect infestation and mold in cocoa beans offered for entry into the United States. Although we expected more stringent requirements should be imposed, we really didn't know whether on a statistical basis, the 10 per cent was too low, too high, or just right.

The survey plans were made known to the Association of Cocoa and Chocolate Manufacturers of the United States and details were discussed with the Technical Committee of that Association. Other cocoa and chocolate trade groups were included in our discussions.

During the 15-month period from January 1, 1959, through April 1, 1960, representative sampling of imported cocoa beans resulted in approximately 6,000 samples from 32 producing countries. These were examined by standardized methods and the results subjected to statistical evaluation. It was our tentative conclusion from our survey results that a tolerance of 6 per cent total insect infested and moldy beans, but not more than 3 per cent of either, would be reasonable and proper. In March of this year we published our survey in preliminary form and have held discussions attended by representatives of this association, with trade groups and interested government agencies. We have also been in contact, through the State Department, with the foreign governments of cocoa producing countries. Comments from industry, from consumers and from these foreign governments are now being considered. Formal announcement of a revised tolerance has not as yet been made, but we expect to do so shortly. We see no reason why a tolerance in the order of the proposal now being discussed cannot be made by the producing countries with possibly some improvement in sanitation in some areas. As a sidelight on this matter, I would like to relate a recent occurrence.

The Commissioner of Food and Drugs and his staff recently met with representatives of consumer groups in order to exchange infor-

mation and viewpoints. The cocoa bean situation was discussed with them somewhat as I have covered the matter here. A significant comment was made by one consumer representative in the audience who expressed amazement that a tolerance anywhere near the suggested 6 per cent figure was necessary. She felt one approaching zero would be much more appropriate. Filth in any form is just not popular with consumers.

Next, I would like to turn to the matter of the use of colors in foods in general and confectionery in particular. Drab, indeed, would be our candy counters if the use of artificial colors were denied to your industry and there is no reason why they should be.

The use of artificial color has long been recognized as a part of our way of life. After passage of the Pure Food and Drugs Act of 1906, seven coal-tar colors were listed as suitable for use in foods provided they were pure enough. Some coal-tar colors were found too toxic for such use. A few others were listed later. The use of coal-tar colors in foods gradually developed into a certification procedure which involved batch testing by the Food and Drug Administration of each lot of colors used. Under the 1938 Food, Drug, and Cosmetic Act this machinery was made mandatory for coal-tar colors used in foods, drugs and cosmetics with the additional provision that such color be considered "harmless." This seemingly satisfactory arrangement, since the colors had been deemed harmless, continued until a rather high color content of a particular kind of candy produced illness in a small child. This resulted in retesting by modern pharmacological techniques, of a number of colors which had been sanctioned for use in foods, drugs and cosmetics. They were not all found completely harmless, which the law said they must be. This eventually led to the passage on July 12, 1960, of the Color Additive Amendments to the Food, Drug, and Cosmetic Act. These amendments, patterned after the Food Additive machinery, provide for the listing of color additives, for use in foods, drugs and cosmetics if they are found safe for the intended use and under any restrictions, if such are necessary. "Color additives" are any dyes or pigments which color and include noncoal-tar colors, many of which are used by the confectionery industry.

Congress did not intend to immediately outlaw any color that had been used unless it had been demonstrated to be harmful. It therefore provided a two and one-half year span for a transitional or provisional period. During this period, the status quo for color use

pretty much prevails, unless a color heretofore considered safe suddenly shows some "Dr. Hyde" characteristics. Insofar as the confectionery industry is concerned this means that between now and January 12, 1963, an ingredient used to color candy must have been subjected to sufficient pharmacological testing to prove that it is safe for its intended use. Methods for determining the color content must have been developed or any restriction would be without meaning. Insofar as the Food and Drug Administration is concerned, we are not particularly concerned as to who or what organization takes the lead in obtaining the necessary clearances. In some instances it might be the color manufacturer; in others, it may have to be the color user. But, it is important that each of you individually or collectively determine what steps are being taken to obtain the necessary clearances so that on January 12, 1963, a suitable supply of colors will be available to you. The distinction is that during the provisional period, lack of harmfulness will allow continued use of a color; after January 12, 1963, a positive showing of safety under proposed conditions of use will be necessary. Pharmacological testing for chronic toxicity is not a process that can be speeded up; delay can leave you without a spectrum of safe colors.

Passing from a recently enacted piece of legislation to a proposed one, I would like to discuss for a few minutes H. R. 3548, the Macdonald Bill, to amend Section 402(d) of the Federal Food, Drug, and Cosmetic Act. I should emphasize that the Department of Health, Education, and Welfare has not taken a final position on this bill. The views I express are my own. This proposed amendment appears to have, and in general we agree it does have, a laudable intent. Section 402(d) now reads as one definition of adulterated food:

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except authorized coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

The proposed amendment would change that to read:

(d) If it is confectionery, and it bears or contains—

(1) any alcohol other than not to exceed one-half of 1 per centum by volume derived solely from the use of flavoring extracts; or

(2) any nonnutritive trinket or object (other than a nonhazardous object which performs a useful purpose) unless such trinket or object is separately wrapped.

This would seem to take advantage of modern technology and allow food additives which have been proven safe in sufficient amounts to be added to confectionery for technical reasons. It would seem to preserve the safety feature of precluding or minimizing dangerous trinkets which might be accidentally ingested.

This association has gone on record as favoring this proposed legislation. At the risk of being accused of being overly paternalistic and assuming to know more than the experts, I would like to raise a warning flag or two regarding H. R. 3548. First, would passage of this amendment tend to cheapen a product whose long history has been one which emphasized quality? It might well be that under this wording, technological advantages can be taken of processing discoveries through the use of acceptable food additives. The same language would allow, however, the addition of fairly substantial quantities of talc or other products which responsible management would not approve. Because candy is consumed in such quantity by our children, any cheapening would in our opinion have tremendous impact.

Second, what effect would this amendment have on imported confectionery products? As you know, the rules we lay down would not only apply to domestic confectionery, but to that produced in foreign countries. In this connection we have found it necessary, under the present statute, to deny entry to frequent shipments of confectionery with substantial talc as an ingredient. Under the proposed amendment such merchandise might flow into our domestic market.

We have suggested, and I do so again, that the addition of a provision at the end of section 402(d) will grant relief and still maintain the unique position of confectionery. We have suggested the addition of "Provided, however, nothing in this section shall be deemed to prohibit the use of any nonnutritive substance subject to section 409 of this Act if an appropriate regulation has issued under the provisions of that section especially authorizing the use of the food additive in confectionery."

The final item I would like to discuss with you is one which your Program Committee particularly wanted me to include. This matter is, I am sure, known to you as it is to us as the "Delson Candy Case." Litigation on this case, which involves important principles of slack-fill of container, is still in progress. A review of the facts in the case from an objective standpoint, can still be of considerable value to all of us. A bit of history is also necessary.

Slack-filling has long been a consumer problem and we are sure that many of you can remember the thick glass bottles with false bottoms, oversize cartons and packaged emptiness, observed many years ago.

Prior to the passage of the Food, Drug, and Cosmetic Act in 1938, the Food and Drug Administration had no authority or legal tools with which to combat this consumer problem. The 1938 Act contained a definition for misbranded food which stated: "If its container is so made, formed, or filled as to be misleading." With the threat of action possible under this statute, rather rapid progress was made not only in food packaging, but also in drug and cosmetic packaging which also were covered by parallel sections to the one quoted. The more flagrant abuses were quite rapidly brought under control.

In the two decades following, the Food and Drug Administration tried on several occasions, through court actions, to carry this correction to the practical point to which we felt the consumer was entitled. Without attaching any special significance, we must state that most of the cases brought were on packages of confectionery. The government lost every case. It may be an attempt to oversimplify, but the decisions seemed to point up two deficiencies in our cases. The most important reason seemed to be the lack of consumer survey information that could convince the courts involved that the consumer was actually deceived.

Secondly, was perhaps the subconscious feeling of the courts that modern filling, transportation and marketing practices required a certain amount of extra packing to preclude breakage of the contents and who could tell when this became excessive. The Food and Drug Administration still felt that the law meant what it said and that was that a container filled so as to be misleading was a violation of the statute. Therefore, in 1957 we made a study of the packaging of products on the market. Again candy seemed to have a prominent place in the picture.

The Delson Thin Mint package was selected as being an outstanding offender. We found that 44 per cent of these packages were filled with mints; and only 75 per cent of its practical volume; that the remainder of the usable space was taken up with hollow cardboard dividers and hollow end pieces. The box, with two inches of bulkheads, was about one-quarter empty lengthwise. Very careful

consumer interviews were made which developed, as we thought, convincing evidence that consumers would expect more in the package than was actually present. We also made surveys of competitive products which demonstrated that the Delson Thin Mint package contained less candy and more packing than any other similar product. Therefore, feeling that we had met the obligations raised to previous cases, a seizure was made of a consignment of "Delson Thin Mints." The seizure was contested and in the United States District Court in the District of New Jersey on February 10, 1960, a decision was rendered by a federal judge again finding against the government much to our disappointment. The court, admitting that the government's evidence indicated that certain purchasers of the accused containers were "surprised" to find that there were not more candies therein, was not persuaded that the government had carried the burden of proof necessary to obtain a verdict. Neither did it feel that the government had proven that the packing material in the packages was not entirely necessary for the protection of the merchandise. He felt that the government was entirely too technical and demanding and noted that the quantity of contents of the actual candy was properly stated upon the package.

The government appealed this finding of the lower court to the United States Court of Appeals for the Third Circuit. On February 28, 1961, the circuit court rendered a very significant verdict which although not reversing the lower court, remanded it for further consideration. The circuit court stated that there were two ways in which the trial court could have arrived at the decision which they did. First, they could find as a fact that the accused package is not made, formed or filled in such a way that it would deceive the ordinary purchaser as to the quantity of contents. Uncontroverted evidence had been introduced that the ordinary purchaser was so deceived. Alternatively the court could have found as a fact that even though the form or filling of the package deceives the ordinary purchaser into thinking that it contains more food than it actually does, the form and filling of the package is justified by consideration of safety and was reasonable in the light of available alternative safety features. The circuit court found that the district court did not make either of these findings and therefore remanded it for further consideration. Oral briefs have now been filed on this latter point, and we are awaiting the decision of the district court. The outcome will have a significant impact on our work in this area. **[The End]**

FDA and the Farmer

By GEORGE P. LARRICK

Mr. Larrick Delivered This Speech to the Annual Summer Conference of the National Association of Television and Radio Farm Directors in Washington, D. C., July 11. He Is Commissioner of Food and Drugs of the U. S. Department of Health, Education, and Welfare.

SEVERAL YEARS AGO a Food and Drug Administration Inspector was traveling in one of the leading vegetable and fruit growing sections of the United States. The farmers in that area were growing cabbage, and the inspector learned that they were having trouble with looper worms. The inspector was interested in what kinds of insecticides the growers were using to kill the looper worms. Then he got a tip from a trade source that some of the growers were planning to try an insecticide that is very effective against the looper worm but which has not been cleared as safe for use on food crops. There is no tolerance under the federal pure food law for any residue of this particular insecticide. Under the law any food contaminated with this chemical would be illegal and subject to a federal court order that it be destroyed.

The inspector saw that he would have to try to warn the growers not to use this material and thereby to head them off, so to speak, from trying it. Through a mutual friend he got in touch with a farm radio director.

The radio man understood the problem immediately. He interviewed the inspector on tape for broadcast that evening and the following morning. He also did a live interview with the inspector on TV.

The farmers got the message. Not one of them in that section used the prohibited chemical and there were no seizures of cabbage from that area. This was a quite different story from what had happened previously in several other places where shipments of broccoli, collards and cabbage were seized and destroyed because of the misuse of this particular insecticide. In one instance the broccoli had reached the packing plant and several thousand pounds of frozen broccoli had to be taken to a dump and buried.

This story illustrates a lot of things. For one thing, it shows the importance of fast communication in modern life, especially in reaching a particular group of people.

It also illustrates the point that the Food and Drug Administration much prefers to prevent violations of the law rather than to prosecute after they have occurred. Obviously it is better protection for the consumer to keep our foods from being contaminated rather than to find who is responsible after they have been contaminated. But one of the things we have learned from more than 50 years of experience in enforcing the pure food law is that information and education are not fully effective unless backed up with a strong program of inspection and enforcement. Actually, education and enforcement are two sides of the same operation. One is the individual approach and the other is the mass approach. What the public-spirited farm radio director did was to help keep a lot of growers from following some bad advice that could have caused them to lose their crops and he likewise helped to keep some contaminated food from reaching the consumer.

This story also points up one of the biggest problems confronting the Food and Drug Administration today—a problem that is shared by manufacturers of agricultural chemicals, farmers and consumers, as well as the government. It is one of the paradoxes of modern civilization that we must use tremendous quantities of poisonous materials to protect our food supply from weeds, insects, plant diseases and spoilage. Scientific research has developed the means for doing this effectively and safely. But we must follow the rules if we are going to insure that our foods will continue to be safe. Congress has set up a practical plan for doing this. It is spelled out in the Pesticide Amendment of the Federal Food, Drug, and Cosmetic Act, administered by the Food and Drug Administration. Under this law the U. S. Department of Agriculture determines whether a pesticide chemical is useful in agriculture and the Food and Drug Administration determines what amount of residue from the chemical may safely be permitted to remain on the harvested crop. We have very close cooperation in this area where our respective responsibilities mesh together.

Historically, the farmer has been a strong supporter of the pure food and drug laws of our nation, both state and federal. But the farmer is a producer as well as a consumer and so we had some mutual

problems. In the past these have mainly been concerned with sanitary handling and cleanliness of foods and today we still have our difficulties with spoilage and insect and rodent contamination of foods. But there has been much improvement in these respects. Today, as we have seen, the problem of chemical contamination has become more important.

A vast amount of effort and expense goes into the development of effective pesticides which are safe when used properly according to the label directions. But all of this is lost if the grower does not follow the directions. And just as we need constantly to be reminded about such things as safe driving and fire prevention, there is a need to remind growers to use pesticide products properly. Farm radio can help to deliver this message to growers:

Use pesticides properly—According to label directions: In the *amount* specified; On the *crop* specified; At the *time* specified.

There is a real need for more educational materials along these lines. We have only begun to develop such materials. We have a basic leaflet that tells the story of "Protecting Crops and Consumers." This is available for free distribution in reasonable quantities. But rather than try to send a copy to every grower we would like to send one to every farm radio director and we would hope that they could incorporate the material into their programs. We are also making plans for a motion picture on "How to Use Pesticides Properly," to be produced jointly by the Food and Drug Administration and the Department of Agriculture. The Food and Drug Administration does not have any material at this time that is especially prepared for radio or TV, but we do expect to add someone to our information staff who will devote most of his time to preparing materials for farm audiences. In the meantime, our people in Washington and throughout the United States are available for interviews and messages, especially where there is a special need for information.

In this connection, I am glad to say that substantial help is being given by other government agencies and by industry organizations who want to promote the safe and correct use of pesticide chemicals.

Much of what I have said about pesticides applies also to drugs used in livestock feed and to chemical food additives used in food processing and packaging. But I would like to emphasize that today, under new laws, the Food and Drug Administration is now able for

the first time to require that all substances used in food be proved safe *before* they are added to the food supply. Admittedly, the big job of checking or testing all of these thousands of materials has not been completed, but we can say that there are no food ingredients in use today that we have reason to believe are unsafe.

Now I would ask you to consider this topic from another point of view, that of the consumer, including consumers who live on the farm. For today the farm family patronizes the supermarkets and lives in much the same way as the city family.

Many consumers are concerned these days about the safety and nutritive value of our foods. They want to know if the many chemicals used in growing, processing and packaging foods are harmless. They want to know if modern methods of processing take away any of the nutritional value of our foods.

Perhaps you noticed in the newspapers the recent stories about our crackdown against the sale of bottled ocean water at prices from \$1.69 per pint up to \$20 per gallon. This racket began when a certain medical columnist wrote several articles about the supposed health benefits of sea water. The idea was that minerals contained in the sea are necessary to health because our food supply is lacking in these essential mineral elements. The fact is, of course, that our foods contain all of these elements in ample amounts and there is absolutely no medical or nutritional need to supplement the diet with ocean water. It is a 100 percent swindle.

But in no time at all there were a lot of promoters who were rushing to cash in on the sea water fad. And they would have had a lot of customers if the Food and Drug Administration had not acted quickly to nip this budding racket.

Why do so many people fall for this sort of thing? One reason, I suppose, is that they have faith in what they see in print and believe it must be so. Another reason is that many people actually believe that foods today are not as good as they used to be. They believe the cultists and the promoters who are selling the special "health foods" and some popular diet books. And they are impressed by the scare stories in certain magazines and books to the effect that our food supply is being poisoned by chemicals.

What are the facts?

I have already mentioned the amendments to the law which require chemical materials to be proved safe when properly used, before they are marketed for food production, processing or packaging.

Keeping our food supply clean, safe and nutritious is a tremendous task. Our present resources are far from adequate for this. For example, we can get samples and test less than .2 per cent of the more than 1,200,000 shipments of fresh fruits and vegetables that go to market every year to determine whether they have excessive residues of pesticides. While we know that only a small percentage of them violate the law we also know that there are some contaminated shipments that are not being detected.

All of this adds up to a very complicated communication problem. Public understanding lags behind the progress of our rapidly changing technology. On the one hand, we must warn growers and manufacturers of the need for care in their use of the new products that scientific research has developed. On the other hand, we must inform consumers about the changing world in which we live and sustain their faith in progress and in the integrity of the products of our farms and factories.

We are sure that you as farm radio directors understand very well that these alternatives are not mutually exclusive and that each of these objectives must be sought.

I have touched on only a few of our mutual interests and responsibilities—there are many other topics which we could profitably discuss together. I hope your interest in the work of the Food and Drug Administration will be a continuing one and that this will give us many opportunities to cooperate in the interests of the American public.

[The End]

CANADIAN HAMBURGER STANDARDS

The Food and Drug Directorate of Canada has announced the results of a recent survey of all "hamburg and comminuted beef" products sold in Canada. According to the Directorate, "It was evident from the results of this survey that the present standard for hamburger is being abused and circumvented in many instances." A further finding of the survey showed that the various names used to designate comminuted beef products create a great deal of confusion in the minds of the public. The Directorate has proposed an amendment to the Food and Drug Regulations as follows: "Minced or ground beef, sold under any name whatsoever, shall be comminuted beef and shall contain not more than 30 per cent fat which shall be comprised of the fat normally adherent to the beef used"

Federal Hazardous Substances Labeling Act as It Affects the Ink-Making Industry

By FRANKLIN D. CLARK

The Author Is Assistant to the Deputy Commissioner of the Food and Drug Administration. He Presented This Paper Before the Fountain Pen and Mechanical Pencil Manufacturers Association, May 19, in Williamsburg, Virginia.

I AM SURE THERE IS MUTUAL SURPRISE at having your conference addressed today by a representative of the Federal Food and Drug Administration. I am sure that at your last meeting, few in this audience had any idea that they would have any interest in any regulation or law administered by the Food and Drug Administration. I can assure you that a year ago the prospects of addressing representatives of the Fountain Pen and Mechanical Pencil Manufacturers were the farthest from my mind. However, I am here and I believe there is an important reason to all of us for my presence here today.

Congress passed a new statute last year, the Federal Hazardous Substances Labeling Act. Products you manufacture or distribute may come under this statute, which has rather specific requirements. For your part, you would like to know what those requirements are and how they may affect you; for our part, we have found through experience that an informed group of manufacturers can assist us, by voluntary compliance, in our law enforcement activities. It is a matter of communications.

Because our organization itself is undoubtedly new to most of you, before discussing ink and the Hazardous Substances Labeling Act, I would like to tell you briefly about it.

What is now the Food and Drug Administration came into being in 1906, as a part of the Agriculture Department's Bureau of Chemistry. Its founder was Harvey W. Wiley, who campaigned strenuously for foods and drugs free from poisons and adulterants. Then we branched off as the Food and Drug Administration to take care of the regulatory work. In 1940, we became a part of the Federal Security Agency as a logical part of an arm of the executive branch of the government dealing with the personal needs of people. When the Federal Security Agency attained cabinet status in 1953 and became the Department of Health, Education, and Welfare, we were kept as a part of it.

Our organization is small as federal departments go, having this year about 2,000 employees, roughly divided, two-thirds in the field and the remainder at headquarters in Washington, D. C. Our field unit consists of 18 Districts located in leading cities throughout the country and some 40 Resident Inspection Stations in other important industrial centers. In Washington are housed our administrative, technical and research units.

Our main function is the enforcement of the Federal Food, Drug, and Cosmetic Act of 1938, although we do enforce several other less time-consuming statutes. Our inspectors in the field make periodic inspections of food, drug, device and cosmetic establishments to determine their compliance with the law and collect samples of these commodities for laboratory examination. The samples are examined in our field laboratories to confirm inspection observations or discover other less obvious violations. Our inspectors also check on the sale of prescription drugs to determine that they are not sold for non-medical uses. You perhaps have read in the papers about some of our activities against the use of "bennies" by truck drivers and against the sale of counterfeit drugs.

We also consider evidence submitted by drug manufacturers as to the safety of new drugs before they are placed on the market and we check manufacturers' proof of safety of colors used in foods, drugs and cosmetics and of food additives which may become a part of our food supply.

We check all batches of insulin and five of the most important antibiotic drugs and their derivatives for purity and potency before they are sold.

We establish the amount of pesticide residues that may remain on food crops without injury to consumers and we maintain a check on foods, drugs, therapeutic devices and cosmetics that are imported into our country.

This is not a complete inventory of our activities, but will make you briefly acquainted with them.

Misbranded and adulterated foods, drugs, devices and cosmetics are removed from the channels of commerce by seizure and the responsible persons or firms are subject to prosecution in federal court. Imports that do not measure up to our requirements are denied entry. During fiscal year 1960, a total of 1,002 seizures were made, 248 criminal prosecutions were instituted and 4,784 import lots were detained.

A few moments ago, I spoke of other statutes enforced by the Food and Drug Administration. One of these becomes important as a historical beginning of the Hazardous Substances Labeling Act. The Federal Caustic Poison Act was passed in 1927, as a result of general alarm and the crusading zeal of a Philadelphia doctor who had treated many children who had swallowed household lye and experienced tragic suffering. The Federal Caustic Poison Act was, in the light of present day living, narrow in scope, but in 1927 it was a beginning. It covered 12 caustic and corrosive substances which were often found in the household. Mineral acids, ammonia, caustic lye and potash were included, as well as oxalic acid and its salts, silver nitrate, acetic acid, carbolic acid and hypochlorous acid. These products, in containers intended for distribution to the general public, were required to bear certain warning labeling.

About ten years ago the great variety of cleaners, polishes, waxes, detergents and specialty chemical products of various kinds started to come on the market in volume. Hobby shops and the "Do-It-Yourself" clan became popular and prominent. Model builders developed new paints and adhesives and, I suspect, ink-makers—new inks. Many of these products, although toxic substances, were not disagreeable in appearance or odor, and physicians all over the country became alarmed at the increasing number of injuries, sometimes tragic, resulting from the accidental ingestion of some of these products. Many times the container of the offending product was available, but gave the physicians no information as to the contents which would have made treatment less difficult. Delay in some instances meant the

difference between life and death. During one recent year, best available statistics from the Public Health Service indicate 600,000 injuries resulting from accidental ingestion of household aids and 500 deaths.

The medical profession, the Food and Drug Administration and many responsible officials of chemical and manufacturing firms recognized that a stronger and more comprehensive law than the Federal Caustic Poison Act was needed. This feeling resulted in the passage of the Federal Hazardous Substances Labeling Act last July 12. It, too, is a labeling act which has the high purpose of warning users and parents of inquisitive youngsters of inherent dangers in things commonly seen around the home and also, if injury does occur, assisting the attending physician by information as to the contents.

To come under the definition of a hazardous substance insofar as this statute is concerned a product must meet two tests. First, it must be in a container suitable and intended for household use; and secondly, it must be a substance that is toxic, an irritant, a strong sensitizer, corrosive, flammable, or one that will generate pressure through decomposition, heat, or other means, if such substance may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. Insofar as the container is concerned, we intend, by regulation, to set up the strongest kind of consumer protection interpretation on the term "household." If, throughout the normal course of every day living a container is apt to be in or around a household, including garages, barns or other out buildings, we say it is "suitable or intended for household use." Apartments, for instance, would be considered households, and automotive formulations of various kinds would be considered for household use. In regard to the precise definition for the various kinds of hazardous substances, the statute itself defines "highly toxic" substances in terms of an animal test and it also defines "flammable" substances in terms of a standard flashpoint test. Definitions for the other kinds of hazardous substances are less specific and, on April 29, we published in the *Federal Register* proposed regulations for the enforcement of this act which included further definitions.

Two definitions, in particular, may interest this group. The Act defines a "highly toxic" substance by ingestion as that which produces death in one half of a group of laboratory white rats when fed to them at a rate of 50 milligrams per kilogram of body weight. On the advice of our medical advisors, we have proposed to define a "toxic" substance

as one which will produce death in a group of laboratory white rats when fed at the rate of more than 50 milligrams, but less than 5 grams per kilogram of body weight.

The other definition is for an "irritant" substance. The statute defines an irritant as any substance which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction. By regulation we have proposed an empirical test which defines an irritant substance in the terms of the appearance of prepared animal skin after prescribed application of the substance to be tested.

How humans might react to a substance is not always predictable from animal tests. We therefore are also proposing a regulation that will give precedence to human experience in classifying a substance as hazardous.

Now, what are the requirements for substances that are hazardous and in containers suitable or intended for household use? They will have to bear plain and conspicuous labeling which will list the name and place of business of the manufacturer, distributor, packer or seller; the common or usual name of the hazardous substance; the signal word "danger," on substances which are "extremely flammable," "corrosive," or "highly toxic," or the signal word "Warning" or "Caution" on all other hazardous substances; an affirmative statement of the precise hazard or hazards; precautionary measures describing the action to be followed or avoided; instructions when necessary or appropriate for first aid treatment; the word "Poison" for any highly toxic substance; instructions for handling and storage of packages requiring special care; and the statement "Keep out of the reach of children" or equivalent. These are rather fulsome and inclusive labeling requirements to be sure. But for products which are hazardous, Congress believed all of them to be very necessary.

Now the Act has certain penalties for those who ignore its requirements. First, a hazardous substance in a container suitable or intended for household use not bearing the required labeling, is subject to seizure by the federal court. This would not necessarily mean a complete loss of merchandise because the courts have certain procedures whereby it can be taken out under bond and later returned to the owner if brought into compliance with the law.

Secondly, the introduction or delivery for introduction into interstate commerce of any misbranded package of a hazardous substance

subjects the persons who do so to the criminal provisions of the statute. For each infraction, a person, upon conviction, might be sentenced to a fine of not more than \$500 or imprisonment for not more than 90 days, or both. With offenses committed with intent to defraud or mislead, or for second or subsequent offenses, the penalty is imprisonment for not more than one year or a fine of not more than \$3,000, or both.

When the Act was passed last July, it was made effective upon signature, but six months was allowed before any seizures or criminal action could be instituted. The Commissioner of Food and Drugs was given authority to further extend this effective date for an additional year if such was necessary. Because on February 1 we had not been able to publish the definitions which were lacking in the statute, the Commissioner did extend the effective date of the Act until August 1, 1961, except as it applied to substances which were "highly toxic" "extremely flammable" and "flammable." The Act was made effective on these substances because they were already adequately defined in the statute itself. Our regulations were published on April 29 and 60 days were granted to receive comments from interested parties. After these are studied and evaluated, it will be around August 1 before our final order can issue. There may be a further extension, but this cannot be definitely promised. We can promise that we will not expect the impossible.

Now, how is the Food and Drug Administration going about its business of enforcing this new law? We are now in contact, as this meeting attests, with an entirely new group of clients who are not familiar with us or with the statute. We are dealing with a new subject matter, new labeling concepts and chemistry which is not always intimately familiar to our scientists. Our inspectors are visiting manufacturers of products which might be hazardous, leaving copies of the Act and obtaining formulae, injury experience, labels and comment. The inspections are made pursuant to a section of the Hazardous Substances Labeling Act which grants authority for our inspectors to enter at reasonable times, any factory, warehouse or establishments in which hazardous substances are manufactured, processed or packed for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or haul such hazardous substances in interstate commerce.

We may obtain samples and labeling. Our inspectors are required to give receipts for any samples obtained and if an analysis

is made of such, a copy of the results shall be furnished promptly to the management. There has been some reluctance of manufacturers not used to our inspections to furnish formula information, and we can readily understand why. However, for those of us who have wondered about this, there is a provision in the Act which makes it a violation for any person to use to his own advantage or to reveal other than to the Secretary, or officers or employees of the Department or to the courts, when relevant, any information acquired under the factory inspection authority concerning any method or process, which has a trade secret and is entitled to protection. You will find that when called upon by a Food and Drug Inspector you run no risk when giving him complete information. By so doing, it may rather quickly result in a decision that a product being discussed is not a hazardous substance.

Just before leaving Washington I reviewed the rather substantial number of inspection reports so far received on ink manufacturers. Frankly, the information in most cases is too sketchy to conclude firmly whether or not inks are hazardous substances. We doubt if a general statement can ever be made. It would seem from some of the ingredients in marking inks, printing inks and ink eradicators that they will come under the definitions of hazardous substances by being either toxic, irritant or flammable.

In the case of fountain pen and ballpoint inks the picture is just not clear. Some of the ingredients, including pigments may well be toxic enough to render the ink a hazardous substance. Surely, it is in a container intended or suitable for household use. It may be that even though toxic, ballpoint ink may have a very minor hazard because of its method of packaging. However, let me read to you a clipping in one of our files:

PEN FILLER KILLS E. BAY GIRL, 2

A 2 year old child died yesterday—the victim of a ballpoint pen filler.

Cheryl Ann Wiseman, one of the three children of Mr. and Mrs. Charles Wiseman, of 5040 Bonnell Drive, Clayton Valley, near Concord, was stricken when she bit off the point of a broken ink filler her father had tossed in a waste basket.

When she began to cry with stomach pains she was taken to the Kaiser Foundation Hospital in Walnut Creek where she died. Doctors tentatively diagnosed the cause of death as poisoning from the filler dye. An autopsy was ordered.

The Act very wisely does have procedures for exempting particular substances or classes of substances which although hazardous by

definition may be exempted from full labeling requirements because of a very minor hazard or because of other good sufficient reasons. The exemption must be based on a finding by the Commissioner that full labeling is not necessary for the adequate protection of the public health and safety.

May I suggest three things:

(1) That you render full cooperation to our representatives if and when they call upon you. They will assist you in complying with the law if you have a problem;

(2) Have your products studied in the light of the various definitions of hazardous substances. If they are hazardous, take appropriate steps to label them in compliance with the law;

(3) If you have any questions at all, please write to us and we will do our best to give you sound advice. [The End]

FISH PROTEIN DEFINITION PUBLISHED

The Food and Drug Administration proposed establishment of a definition and standard of identity for fish protein concentrate and whole fish flour September 14.

The announcement, published in the *Federal Register*, stated that a manufacturer had visited FDA to discuss a process he has developed for manufacturing a fish flour product which could be used as a source of protein to be marketed at a price "that would be most attractive when compared with the cost of other sources of protein." The "whole fish flour" was to be made by taking whole fish of varying sizes, grinding them and, after removing the fat by a chemical process, drying the flour so produced.

The Food and Drug Administration informally expressed the opinion that this "whole fish flour" should be regarded as an adulterated article under the provisions of the Federal Food, Drug, and Cosmetic Act, because it was to be made without the removal of those portions of the fish, including the intestines and intestinal contents, that are not normally regarded as acceptable for human food in the United States.

The proposed standard includes the following specifications: (1) Protein content measured by methods of the Association of Official Agricultural Chemists shall not be less than 70 per cent by weight of the final product and biological values of the finished fish protein concentrate, (2) Moisture and ash contents shall not exceed 6 per cent and 25 per cent by weight of the final product, (3) Fat content shall not exceed 1 per cent. (4) The final product should have no more than a faint fish odor and taste and when baked in bread in the ratio of one part of fish protein concentrate to 11 parts of grain flour, there should be no detectable fish odor or taste, (5) The fish protein concentrate, after six months storage at temperatures prevailing in areas of intended use but not exceeding 100 degrees F. and when packed in metal containers or in polyethylene bags, should show no spoilage as judged by the development of off-flavors, mold growth, etc.

FDA's Consumer Consultant Program

By CARLA S. WILLIAMS

The Food and Drug Administration Now Has at Least One Consumer Consultant in Each of Its 18 Field Districts. The Author, a Member of the Bureau of Program Planning and Appraisal of the FDA, Outlines the Activities of the Consumer Consultant Program. This Paper Was Delivered at the Annual Meeting of the Council of Consumer Information, April 6, in St. Louis.

WHEN DR. RAY PRICE offered me the privilege of speaking to you tonight, I quickly recognized the challenge before me. First of all, I have been preceded at this lectern, both last year and at your meeting in Washington in 1959, by two spokesmen much more qualified than I to discuss FDA and its many programs—namely, Commissioner George P. Larrick and Deputy Commissioner John L. Harvey. Additionally, when I first learned of your organization some time ago, I was told on good authority that CCI was comprised of the “best informed consumer representatives in America today.”

However, despite the vast experience represented here this evening, I come before you to discuss something that perhaps even *you* do not know about FDA—the agency you all know so well—and that is FDA's Consumer Consultant Program.

I sincerely doubt if many of you know that today—yes, at this present time—there are women located throughout the Food and Drug Administration's 18 Field Districts who are working for us *not* in administrative jobs, *not* in the laboratories, *not* out in the field as inspectors, but rather, as part-time consultants for the Food and Drug Administration. These highly qualified women, carefully chosen for their professional background, are adding a very real contribution to the Food and Drug Administration's work, and are supporting the enforcement of food, drug and cosmetic laws by working directly

with the public. In *talking* about drugs, cosmetics and food, they are giving the consuming public "food for thought," we believe, and they are finding that the public is vitally interested in—in fact, hungry for—information about foods: their facts, fallacies and fads, about drugs and devices, cosmetics and caustics, the laws behind the label, pills and packaging. But before I tell you more about the Consumer Consultant Program I would like to go back a few years.

While Mr. Charles W. Crawford was Commissioner of the Food and Drug Administration he became deeply convinced that there was a very great need for the Food and Drug Administration to know better what the public was thinking about the protections it enjoyed: how well acquainted it was with the Food and Drug Administration's work, its regulatory program, its laws, its jurisdictions. He fully realized that the public was, in many areas, grossly uninformed in the protections offered them, their families, their health and their pocketbook! Because they were uninformed, the public seemed to be apathetic, or disinterested. But Mr. Crawford believed that there was tremendous latent interest which would spring to life if people knew about our problems and our programs. He realized that public interest and sentiment, properly expressed, could serve to guide FDA in the administration of the law, and in requesting new legislation when needed. Archibald MacLeish once said—and I believe these words, paraphrased a bit, express very well this wise conviction of Commissioner Crawford's—"We have learned all the answers; it's the questions that we do not know. We are not wise." If I may, I'll use that quote to read this way: "FDA has learned *most* of the answers; it's the questions that we do not know."

At any rate, Mr. Crawford's sincere belief that the consumer's opinion could be of great help to FDA in guiding its programs along the way, resulted in today's Consumer Consultant Program.

Fortunately, this program has continued since its inception in 1953 because today Commissioner Larrick believes as deeply in the "power" of the consumer and his interest as did Mr. Crawford. In fact, only recently Commissioner Larrick stated that consumer interest is at a new peak and has undergone a resurgence not seen since the early 1930s and the depression years. This feeling is clearly justified as one looks back on 1959, then through '60 and now into 1961—a year which promises to be a decisive year for the consumer.

Commissioner Larrick is right—as all of us in this room recognize—consumer interest is at its most vigorous in years. We must only

look around to see that in this period of greatest productivity in history, thanks to advanced technology and countless new marketing frontiers, consumer awareness is on the increase. Part of this new alertness or arousal, if you will, may come as a result of the Blatnik Hearings in 1958, the exposure of fraud and deceit which came out of the television industry in 1959 and Senator Kefauver's recent hearings on monopolies and price maneuverings.

Recognizing this new acuity on the part of the public, and the need for meeting its challenge, former Attorney General William Rogers called and presided at a Consumer Conference, held in Washington last March and attended by Attorneys General from all over the United States. Since then, market place frauds and deceptions have undergone further scrutiny at similar meetings called by several state Attorneys General. These were held locally to include community, county and state representatives of law enforcement agencies, consumer-type organizations and related business and industry. The most recent of these conferences was held in Lansing, Michigan, in September and one which I was most privileged to attend.

The AFL-CIO has an energetic and ever-growing consumer-interest movement which holds weekly meetings for its members and publishes market bulletins, health capsules, "Best Buy" advice and self-protection pointers.

Interestingly, the American Medical Association announced last October that it was launching a "comprehensive study and action program" to guide the consumer in spending his health care dollars more wisely. And the Better Business Bureau tells us that its consumer query response has doubled in recent months.

FDA's Bureau of Program Planning and Appraisal was gratified when recently the representative of another federal department sought advice on how to set up a comparable Consultant Program within one of its own branches. Though it too has been engrossed in consumer protection through the years, it now realizes, in watching the progress of FDA's Consumer Consultant Program, that the consumer can perhaps render assistance to them in furthering their programs, also.

Former Federal Trade Commissioner Earl W. Kintner more closely related that agency's program to the consumer when assuming office two years ago. He stated at the mentioned Lansing, Michigan, conference that in the past year FTC had intensified its monitoring of labeling and identification, of false claims and misrepresentations.

including those made in direct mailing and of all illegal practices foisted on the unsuspecting consumer.

We all know that there are Senate resolutions pending, one of which provides for a Select Senate Committee on Consumers, this bill having been sponsored by Senator Javits of New York, and one sponsored by Senator Kefauver which would provide for a new Department of Consumers.

Even current book sales reflect a new consumer interest—or more accurately, a new interest in the consumer. Some of these books are good, some are poor. But we'll hope that through exposure their readers become more perceptive consumers, or, at the least, *intelligent* skeptics!

Vance Packard, in his recently published book, *The Wastemakers*, coins the word "consumerism" and while the author is largely pre-occupied with the problems of over-commercialism, misleading advertising and the Madison Avenue mores which are reflected in today's buying habits, perhaps we should at least be grateful to Mr. Packard for this word. For though there is much of interest to the reader—and indeed, the book *is* thought provoking—I personally have much more faith in the intelligence of today's consumer and the *power* of today's consumer, than does Mr. Packard. And, I should add, so do all of us in this room for is not the CCI itself founded on the very premise of public service and public protection? And, too, has not the Food and Drug Administration dedicated its entire effort to protection of the consumer throughout its 54 year history?

Yes, FDA through the years has acquitted itself well. Though a low-budgeted, understaffed agency, it has relentlessly sought a record of excellence in this field of public service. We can, indeed, hold our heads high. But does the average consumer know this? We think not. But neither do we think that consumers know of the perplexing problems still facing us: nor do they realize how valuable it would be to have their reaction to some of the situations on which we must make decisions. Through speaking engagements before community groups, appearing on radio and television interview shows, putting together and manning FDA exhibits and conducting consumer survey work, these women create a two-way flow of information between FDA and the consumer. They explain, on one hand, the Food and Drug Administration's regulatory programs and jurisdictions and, on the other hand, by tapping consumer opinion, they determine the reactions and attitudes of the American public toward the food, drug

and cosmetic products which come under FDA's jurisdictional purview. In this way the consumers have a better understanding and appreciation of the protection offered them and, at the same time, their response is helpful to the Food and Drug Administration in planning and conducting its regulatory programs, today and in the future.

We have had a sampling of public opinion in recent months which illustrates the potential of this largely untapped reservoir of consumer opinion in giving us administrative guidance.

For example, we have received literally thousands of letters on the subject of the chemicals used in the growing and processing of foods. Many of these have shown some misunderstanding of the problems confronting us. However, they were overwhelmingly in agreement on the proposition that our programs must assure the safety of the hundreds of chemicals being added to our foods.

We had another interesting reaction on an industry proposal for amendment of the standards for jams and jellies to allow the use of certain liqueurs and rum as flavoring agents. Hundreds of individuals and organizations wrote us in opposition to this proposal. The amendment never came to pass!

Then, of course, we have received a tremendous volume of inquiries about the lipstick-color situation. These leave no doubt that most women want their lipsticks—but also that they want the government to do whatever has to be done to make them safe.

This then is the type of information which our Consumer Consultant Program is obtaining from consumers for the Food and Drug Administration. I am in the Bureau of Program Planning and Appraisal, which would like to compile this information and use it in the planning and as a part of the "appraisal" of the effectiveness of our regulatory programs; and we would like to build it right into new programs so they will give better consumer protection.

One of the chief obstacles in doing this heretofore has been our concern that the consumer views we were getting were not sound. We have been afraid that the consumer did not really understand our problems or his own problems and that we were getting ill-considered or nonrepresentative views. However, through the Consumer Consultants, we have a mechanism for explaining these problems to consumers, for thorough discussion of them and for stimulating the expression of truly authoritative consumer opinion and response to the Food and Drug Administration. They are telling an *accurate* story

about additives, giving a *positive* explanation of pesticides. They clarify the public's bewilderment regarding supplements and they give *instructions* on the value of reading the label. They tell the "fair story," not the SCARE story! With this positive approach, then, FDA is receiving a positive response.

One of the most obvious areas for undertaking this program is that of food standards work. We have recently tried to encourage more consumer participation in food standards making, by setting up a special consumer mailing list for proposed changes in food standards, or proposed new standards. And we have tried to explain to these consumers, in releases geared to consumer-level understanding, just what was involved. But the written word is often not enough. We must *meet* with consumers and talk about these things. Only then can we be sure that we know what consumers expect in a standardized food; or whether they would be deceived by a particular label statement; or whether a label is truly informative, as the law requires.

Another obvious program area is that of labeling of foods. We sometimes lose lawsuits—but more often hesitate to bring them—because we are not sure what some particular labeling means to consumers.

And the same applies to labeling of vitamins and drugs. How many consumers know how to read a vitamin label intelligently? How many understand the key phrase "minimum daily requirement"? Are the wordings of directions for use and warnings on drugs understandable to the anxious mother of a sick child?

Consumers are giving us many valuable suggestions on these and countless other matters.

The Consumer Consultants provide us with channels for contacting consumers, for explaining the technical aspects of a problem and then for "brainstorming" ideas for improved consumer protection.

So it is that the activities of our Consumer Consultant Program have been stepped up in recent months. In fact, where we had only 13 consultants at the time of my appointment, we now have 18. This means that each of FDA's Field Districts has at least one consultant and soon we hope to have two in each district.

Interestingly, Commissioner Larrick's interest in the consumer, from a federal level, is shared by several Governors throughout the United States. New York was the first state to set up a Consumer Counsel, which was inaugurated by Averill Harriman who was then

Governor and directed by Dr. Persia Campbell. That was in 1955, and since then the idea has rapidly spread to other states. In June of 1959 Abraham Ribicoff, then Governor of Connecticut, now our Secretary of Health, Education, and Welfare, created the first Department of Consumer Protection in the United States. The commissioner of that department shares the platform with me tonight. Then in October of 1959 Mrs. Helen Ewing Nelson became the first Consumer Counsel for California; Massachusetts has just created an identical department and Minnesota has a similar recommendation now under study by the state legislature. This is true also in the states of Pennsylvania and Michigan.

So you see, consumer recognition is on the upsurge. And well it should be. Public opinion molds the law—both in its enactment and in its enforcement—and public opinion is what we seek! [The End]

NEW LABELING REQUIREMENT ANNOUNCED

The Food and Drug Administration recently published a regulation requiring manufacturers to provide the medical and pharmaceutical professions with more information in the labeling of most drugs and devices that are sold only on prescription.

The regulations will require a "package insert" that will provide all necessary information for safe, effective use of the drug or device, including any information as to when its use would not be safe.

The regulation published in the September 6 *Federal Register* is the final action in an extensive revision of FDA labeling regulations on drugs and devices. It is effective March 5, 1962.

Final regulations were published December 9, 1960, and January 14, 1961 with respect to all provisions of a proposed amendment to the labeling regulations except a proposal for so-called package inserts to provide full information about the drugs. Comments were invited on this proposal.

Commissioner of Food and Drugs George P. Larrick said that it has now been concluded, after review of the comments, that the requirements of a package insert is needed to promote safety and efficacy in the use of prescription drugs and devices.

"When this requirement becomes fully effective, it will make the complete information readily available to practitioners at every drug store and hospital pharmacy throughout the country. Additionally, the industry commonly distributes samples directly to physicians, and the new requirement will call for full information about the drugs to accompany these packages as well," Commissioner Larrick said.

There were objections based on the contention that the insert requirement will substantially increase costs. FDA said that furnishing reliable information for the professional use of prescription drugs in the package will constitute only a small fraction of the cost of promotion.

Another objection was that use of package inserts may result in professional literature reaching laymen with undesirable consequences.

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

August Report of Food Seizures.—Over 600 tons of contaminated food were seized in 32 actions in July.

Two seizures of hollandaise sauce were made in California and one in the District of Columbia after a number of cases of food poisoning had been reported to the Food and Drug Administration by state officials. An investigation showed that the sauce was contaminated with a salmonella organism. The FDA issued a public warning and the product was recalled from all distribution channels.

The largest seizure, over 117 tons of rice, was contaminated with insect and rodent filth. Approximately 110 tons of wheat and over 64 tons of various foodstuffs stored in warehouses were seized because of filth contamination.

Over eight tons of food found to be economic cheats were seized in 19 actions. Two and one-half tons were puffed rice and puffed wheat from 6 to 15 per cent short weight. Approximately 4.5 tons of such foods as pretzels, macaroni, glazed fruit and olive oil were also seized because of short weight. The seizures were a part of FDA's concentrated effort to crack down on short weight and short volume packages. Sixteen seizures this month made a total of 106 actions against economic cheats, in the FDA drive.

Another economic cheat was canned oyster stew seized because of false and misleading claims that it was effective in promoting mental and physical vigor.

Drug and Device Seizures.—Thirty-one actions were taken against drugs and devices during July. Fourteen were on charges of false and misleading

therapeutic claims and involved re-packaged physicians' samples; other violations involved inadequate labeling and substandard drugs.

The labeling of three devices failed to give adequate directions for use. "Erasurage," a device, bore false and misleading claims that it was effective for retarding and preventing facial lines, wrinkles, double chins, and restoring facial beauty and contours.

A lot of 3 million units of crystalline procaine penicillin G was seized because it was not in conformity with standards of the United States Pharmacopoeia.

Two seizures were made of eye cosmetics because they contained synthetic colors not listed for cosmetic use.

Voluntary Actions by Industry.—Over 54 tons of food unfit for human consumption were destroyed or converted to animal feed in 68 actions in July. The largest single destruction, by a firm in Chicago, was 14 tons of color sirup containing a prohibited red color.

Approximately \$52,000 worth of drugs and cosmetics were destroyed, including fire-damaged drugs, repackaged physicians' samples, outdated and substandard drugs, and drugs containing ingredients dangerous to health.

About \$45,000 was spent in plant improvements in eight actions. An egg plant in California spent \$35,000 for remodeling and installing new equipment.

Inconspicuous Labeling of Net Weight.—The Food and Drug Administration is undertaking to stop the practice of some food companies in hiding the statement of net contents in

the labeling of their packaged food products so that it is difficult for consumers to find it.

This is the latest development in the agency's nationwide campaign against short weight. Charges of inconspicuous labeling of net contents are included in 16 out of 106 short weight cases filed by FDA since June 15.

Examples of the inconspicuous labeling included black licorice candy packed in a clear cellophane bag on which the mandatory information was printed in black. A spaghetti product had the net weight information printed in black against a dark green background. In another case the net weight information was printed on the key strip of a can containing peanuts which would be removed as soon as the can was opened. In some of the other cases the required information appeared in the same type as the nonmandatory labeling or advertising, thus making it inconspicuous.

Seizure of Short Weight Products.—A seizure of approximately \$20,000 worth of packaged seasonings and spices on charges of short weight up to 34 per cent was made by United States marshals.

Among the items seized was a lot of 28 cases of marjoram leaves 34 per cent underweight. Mint flakes was 24 per cent underweight, and sweet basil was 29 per cent underweight. Black pepper totaling 4,752 cases of varying sized cans was 5.75 per cent, 6 per cent and 7 per cent underweight, and a shipment of 2,121 cases of cream of tartar was 13 per cent underweight.

Other products seized at the plant included minced onion, paprika, celery seed, caraway seed, pumpkin pie spice, anise seed, ground and rubbed sage—all underweight.

The court action filed in St. Louis states that the articles were misbranded in that they are food in package form and they fail to bear a label containing an accurate statement of the quantity of the contents.

The seizure actions are being brought by FDA in cases where the average

weight is below the net weight declared after allowance is made for moisture loss and other unavoidable variations.

Import Inspection Activities.—Imports of foods, drugs and cosmetics are being more thoroughly scrutinized than ever before, reports the Food and Drug Administration. For example, 1,550 shipments to the port of New York over a three-month period were examined and 283 detained from entry because they did not meet standards set by the Federal Food, Drug, and Cosmetic Act.

Field districts which have ports in their areas have increased their import inspection activities about 25 per cent. This has resulted in increased examinations and sampling of entries of as high as 50 per cent and detentions of as high as 60 per cent over a corresponding period last year.

Larger scientific and inspection staffs and improved testing facilities in the field districts have made it possible to step up the amount of attention given to imports, FDA said. The increased staffs and improved facilities have enabled additional manpower to be devoted to imports—specifically, more extensive wharf examinations are made, which increase actions on visible violations such as decomposition or filth contamination of foods. The improved programs have also made it possible for inspectors to visit regularly ports where FDA has no laboratory to confer with customs officials and to observe import problems.

Incubator-Reject Eggs.—A federal indictment of four leaders of the incubator-reject egg racket has put the Food and Drug Administration a step closer in its effort to stop the sale of such eggs for food purchases.

The indictment followed the seizure of 580 cases of incubator-reject eggs after the shipment crossed the Michigan-Indiana line enroute to New Jersey. A hatchery worker reported to FDA that he had been approached by members of its ring and offered a substantial sum to hold the incubator rejects for pickup. Intercepting the shipment and

obtaining the evidence on which the defendants were indicted involved undercover work by FDA inspectors cooperating with Indiana food and drug officials and police.

September Report of Food Seizures.—Approximately 226 tons of contaminated food were seized in 30 actions during the month of August.

Filth and decomposition accounted for more than half of these actions, and the rest was made up of a shipment of wheat (60 tons) alleged to contain a poisonous mercury compound for seed treatment, and one of milo maize (26 tons) alleged to contain unpermitted insecticide chemicals—captan and heptachlor.

Continuing its campaign against economic cheats, FDA inspectors have reported seizures of over 48 tons of food in 76 actions on charges of short weight, inconspicuous labeling of net contents, and nonconformity with standards. Short-weight rice and wheat led the list with ten tons, followed by products representing nearly every food commodity, all of them failing to conform with requirements of the Federal Food, Drug, and Cosmetic Act.

In most cases the label was inaccurate; sometimes the ingredient statements were not placed conspicuously enough, or products were not labeled by their common names. One product was labeled "country style egg dumplings" but was actually "enriched egg noodles," a name specified in the official definition and standard. Canned peaches violated standards for fill of container, and a product labeled "Early June Peas" was actually soaked dried peas which should have been labeled "Dried Early June Peas." Vitamins and mineral tablets were not up to labeled strength. Three diet aids were seized because they contained folic acid in excess of that permitted by food additive regulations.

Drug and Device Seizures.—Thirty-eight actions were taken against drugs and devices. Thirteen of these involved repackaged physicians' samples. Nine were on charges of false and misleading

therapeutic claims for effective treatment of ulcers, regulation of retarded menses and restoration of facial beauty and contours. Among the products seized were:

An herb "used by the Shesione Indians for rheumatism, prostate trouble, lame back, and night urination";

An herbal preparation "capable of preventing spasms, curing rheumatism, expelling worms, and dispelling tumors"; and

Ocean water "containing 44 water-soluble trace elements" and claiming to "benefit the user because of its special therapeutic and dietary supplementation properties that 'add life to years' and 'add years to life.'"

A wetting solution for contact lenses was seized because it was not cleared for safety. Four seizures were made of a diarrhea syrup for children, distributed under a new-drug application that did not cover all of the uses for which it was being promoted to the medical profession. It was also charged to be misbranded because the promotional material contained false and misleading claims about the safety and efficacy of the product. Clinical thermometers, vitamin tablets, B-12 injections and Secobarbital Sodium capsules were among articles seized because they did not meet labeled standards.

Voluntary Actions by Industry.—Over 336 tons of food unfit for human consumption were destroyed, or converted to animal feed in 125 actions. The largest single destruction, by a firm in Virginia, was 37 tons of frozen honey buns manufactured under insanitary conditions.

Approximately \$196,000 worth of drugs and cosmetics were destroyed, including repackaged physicians' samples; outdated, substandard, improperly labeled drugs; and drugs containing ingredients dangerous to health.

About \$450,000 was spent in plant improvements in 29 actions. A grain company in Ohio spent about \$150,000 for construction of a new, all steel, rodent-proof grain elevator and feed mills.

A firm which had been prosecuted two years earlier for shipment of adulterated walnut meats installed cement block fumigation silos—each holding 50 tons of unshelled walnuts—and a conveyor system for getting the nuts to and from the silos. The silos were installed at a cost of \$69,000. At the additional cost of \$2,000, the firm provided for fumigation of burlap bags following use.

A company brining maraschino cherries found heavy infestation of fruit flies. They made renovations and secured equipment to control this infestation, at a cost of \$8,500. The firm plans to spend \$15,750 each year for pest control and additional labor to keep the plant in a sanitary condition.

Seizures of Physicians' Drug Samples.—The Food and Drug Administration announced that it has instituted 30 seizure actions against sale of physicians' samples of prescription drugs in ten states.

FDA said that while a dollar value had not been placed on all the seizures, it estimated that the total was in excess of \$500,000.

Commissioner of Food and Drugs George P. Larrick said that the agency's drive against the mishandling of physicians' samples was being continued on a nationwide basis.

"Our continuing survey in this area is uncovering gross carelessness in the handling of extremely potent and life-saving drugs," the Commissioner said.

"Our inspectors continue to report abuses such as:

"(1) Disregard for the expiration dates of antibiotics.

"(2) Mixup of drugs not only as to identity but also with respect to strength.

"(3) Destruction of essential labeling containing directions, warnings, and precautions for the safe and effective use of the drug."

FDA said that inspectors have reported several instances where firms had drugs intended only for investigational use on their shelves. They were labeled: "Caution: Limited by United

States law to investigational use." Distribution of such drugs is legal only to persons conducting research.

Commissioner Larrick said that the abuses found are serious. He recommended the following action:

(1) That pharmaceutical manufacturers curtail and control the distribution of physicians' sample drugs and supply physicians only with the drugs they want and will use.

(2) That the medical profession through its medical societies request their members to stop accepting physicians' samples unless they intend to use them in their practice and to destroy all samples they do not use so they will not be diverted from their intended use.

(3) That physicians and representatives of pharmaceutical manufacturers (detail men) discontinue distributing physician sample drugs to retail pharmacists for dispensing.

(4) That pharmacists discontinue using physicians samples to fill prescriptions.

(5) That drug firms immediately check on their systems of accounting for new drugs for investigational use to be certain that any not used in clinical investigation are destroyed.

(6) That physicians and others engaged in the evaluation of new drugs destroy any stocks of investigational drugs not used.

Commissioner Larrick said it should be clearly understood that the Food and Drug Administration does not intend to interfere in any way with the legitimate distribution of samples to physicians and their use by physicians.

"What we are concerned with is the distribution and use of physicians' samples outside their proper and intended channels which frequently results in the nullification of all safeguards provided by the Federal Food, Drug, and Cosmetic Act," he said.

The Commissioner also said that the Food and Drug Administration has no objection to drug manufacturers furnishing pharmacists with free pre-

scription drugs samples but recommends they do so by supplying pharmacists with fully labeled and packaged products and not with physicians' samples.

A number of druggists have voluntarily destroyed physicians' samples when FDA Inspectors pointed out that they were not intended to be sold, FDA reported.

Such voluntary actions have taken place at Denver, Colorado; Windsor Lock, Connecticut; Decatur, Georgia; and Brooklyn, New York.

"Bennie" Racket Broken.—The bootleg amphetamine drug ("bennie") racket was dealt a crushing blow by heavy sentences handed down in federal court actions terminated last week against a major ring of conspirators and a wholesale supplier of millions of the illegal tablets, the Food and Drug Administration announced September 24.

At Waycross, Georgia, Judge Frank M. Scarlett sentenced Robert Lee Clure to three years, and Mildred A. Clure, his wife, and James W. Altman to a year and a day in the penitentiary on conspiracy charges in connection with the large scale distribution of "bennies" to truckstops throughout the United States. Mr. Clure and Mr. Altman pled guilty and Mrs. Clure pled *nolo contendere*. There are other cases pending against the Clures.

Also sentenced as co-conspirators with the Clures and Altman were Elmer Cecil Crews, Peter Crews, and Willie Stevens. Each pled guilty and was fined \$250 and put on probation for three years. All defendants were of Greensboro and Folkston, Georgia.

In an action at Fayetteville, North Carolina, De Witt Clinton Bowman of Salemburg, North Carolina, pled guilty to charges of selling amphetamine tablets without prescription, and was sentenced to a total of two and one-half years in the penitentiary and \$1,000 fine by Judge Algernon Butler. FDA said that investigation by the North

Carolina State Bureau of Investigation, Walter F. Anderson, Director, and by its own agents showed that Bowman had sold 6 million tablets in a short period of time and that Clure and other large bootleg peddlers were among his customers. There was other evidence indicating that additional millions of tablets may have been involved, FDA said.

In passing sentence, Judge Butler referred to Bowman's supplying of a large drug peddling syndicate and observed that Bowman had sold enough amphetamines to supply all of the North Carolina drug stores with their legitimate needs for 12 years. Judge Butler also noted that after Bowman's arrest in March he had attempted to buy additional large quantities of amphetamine drugs from pharmaceutical houses in Philadelphia.

Amphetamine drugs (also called "pep pills," "bennies," "co-pilots," and "west-coast turn-arounds") are dangerous drugs that may legally be sold only on prescription, FDA said. Bootleggers peddle them through filling stations and truck stops to truck drivers and motorists who wish to drive for exceptionally long periods without rest. Use of the drug without medical supervision may impair judgment, cause serious illness ranging from gastrointestinal upset to severe emotional disturbance and hallucinations, FDA said, and a number of fatal highway accidents have been attributed to use of the drugs.

Commenting on the court actions, Commissioner of Food and Drugs George P. Larrick said:

"The heavy sentences meted out to the principals in these cases will, we believe, make a major contribution to our efforts to break up the bennie-peddling racket.

"We think that these actions and cases now in progress will break up a major drug-peddling syndicate which has been operating throughout the southeast."



Announcing . . .

New, Improved CCH TRADE REGULATION REPORTS

Expanded Explanations . . . Weekly Reporting

Just when it's needed most, CCH has completely revised and expanded its time-tested, full-scale TRADE REGULATION REPORTS. With trade, antitrust and price laws hotter than ever, with the Justice Department on the prowl for antitrust violators, with the FTC reorganized and its rules revamped to speed enforcement and casework and using its "mass production" mail technique in a vigorous investigation of food, drug and cosmetic advertising, plus the raft of proposed legislative changes, *now's the time to get set with full reporting protection.*

Reflecting all new policy changes and enforcement trends and clearly explaining federal and state rules as they stand now, this brand-new Reporter offers immediate and continuing information for those who need everything on antitrust and trade regulation law—plus easy-to-understand guidance and explanation.

Here's Why TRADE REGULATION REPORTS Should Be in Your Office:

*** Each Week—52 or more times a year**—an issue of TRADE REGULATION REPORTS rushes to subscribers full details and explanations of all new changes concerning new laws and amendments, regulations, court and administrative decisions relating to federal and state "antitrust" regulation, "price" rules, "fair trade" and "unfair practices." Always, the "Reports" speak with authority, speak plainly for complete understanding.

*** Every week a separate "Summary"** quickly highlights important new antitrust and trade regulation developments to keep you on top of everything, no matter how busy you are.

*** Bound Volumes of TRADE CASES**, reproducing for permanent reference decisions originally issued in weekly "Reports" go out to subscribers periodically as published, without extra charge.

*** FIVE Big "Background" Volumes**, included without extra charge, bring together and explain federal and state antitrust and trade regulation rules in force today.

Ready now, these full-scale Volumes analyze everything pertinent to governmental regulation of business practices. Explanations weave together the statutory rules, decisions and FTC rulings to show what the law means, how it applies. A special "Antitrust Guide" helpfully explores the various statutory prohibitions, restrictions and requirements and ties them to business activities.

Other special features offer special help on other problems, such as "customer relations," "price fixing," "corporate acquisitions," and the like. How these rules affect relations with competitors, customers, suppliers and the public, as well as internal business policies and operations is fully explained.

Write for Complete Details Now!

Fill in and mail the handy tear-off Request Card today! You'll be sent complete details on CCH's brand-new TRADE REGULATION REPORTS—without obligation, of course.

COMMERCE, CLEARING, HOUSE, INC.,

PUBLISHERS of TOPICAL LAW REPORTS

CHICAGO 46
4025 W. PETERSON AVE.

NEW YORK 17
420 LEXINGTON AVE.

WASHINGTON 4
425 13TH STREET, N. W.



A C O M M E R C E C L E A R I N G H O U S E P U B L I C A T I O N

BUSINESS REPLY MAIL

NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY-

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS *of* TOPICAL LAW REPORTS

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

REQUEST CARD



Mail today for full
information.

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.



REQUEST CARD



Mail This Card
Today



COMMERCE CLEARING HOUSE, INC.
4025 W. Peterson Ave., Chicago 46, Ill.

Please send full information about CCH's brand-new, expanded and improved
TRADE REGULATION REPORTS, covering all angles of federal and state
antitrust and trade regulation law. No obligation, of course.

Signature & Title

Firm

Attention

Street & Number 070-868

City, Zone & State