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Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
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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.

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FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . October, 1967

VOLUME 22 NUMBER 10

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

Latin-American Food Code: Chapter XV — Spirituous Beverages. — In August, 1964, the Latin-American Food Code Council published the Second Edition of the Latin-American Food Code. Chapter XV, beginning on page 528, is the section of the law concerned with all processes of the distillation of alcoholic beverages and liqueurs and their exact contents. It also discusses the labeling requirements of the Code. A list of previously-published chapters is on page 541. All translations have been by *Ann M. Wolf* of New York City.

Fair Packaging and Labeling—The Cost to Consumers.—The Fair Packaging and Labeling Act has many merits, but it will cost the consumers more in several ways. Financially, it will result in higher prices and taxes. The consumer will also pay a price in terms of increased confusion and some loss of freedom. These views were expressed by *George M. Burditt,* a Chicago attorney, in a speech at a Packaging Institute Forum on October 3, 1967. It begins on page 542.

The Package Insert: Significance, Style, Synthesis.—This paper is one of the few that discusses the many complexions and legal considerations of official drug labeling. It was written by *Paul V. Buday,* the Head of Drug Regulatory Affairs for Sandoz Pharmaceuticals. It begins on page 547.

The Color Additive Amendments of 1960 Revisited—Seven Years of Feast or Famine.—An examination of the seven-year history of the color additive amendments has led *Alan H. Kaplan* to the conclusion that this legislation has not enhanced the public safety to any degree. The article, which begins on page 553, was originally delivered as a speech at the Society of Cosmetic Chemists. Mr. Kaplan is a partner in the law firm of Kleinfeld and Kaplan of Washington, D. C.

FDA's Obligations Under the 1966 Public Information Act.—Guidelines for the disclosure of industry information and data under FDA's control, as set forth in the "Freedom of Information Act," Public Law 89-487, are discussed in an article by *Joseph M. Mamana.* The article, reprinted from the *FDA Papers* (September 1967, p. 16), begins on page 563. Mr. Mamana is with the Office of Policy Management.

Book Review: Use of Human Subjects in Safety Evaluation of Food Chemicals: Proceedings of a Conference, reviewed by Franklin M. Depew. —The book reviewed on page 569 is a compilation of the papers and discussions of a conference sponsored by the NAS/NRC Food Protection Committee and the Food and Drug Law Institute held on November 29-30, 1966. At this conference the problems related to using humans in tests to evaluate the safety of food chemicals were discussed in depth by members of several professions. Mr. Depew, a participant in the conference, is President of the Food and Drug Law Institute.

FDA's New Computer. — Programs utilizing FDA's new data processing system are discussed in the article on page 572. The article, reprinted from the *FDA Papers* (October 1967, p. 4), is by *E. R. Lannon,* Assistant Commissioner for Administration.

Vol. 22, No. 10 October, 1967

Food·Drug·Cosmetic Law
Journal

Latin-American Food Code 1964 Edition

This Article Reproduces Chapter XV of the Second Edition of the Latin-American Food Code. Other Chapters Have Appeared in Previous Editions of the *Food Drug Cosmetic Law Journal*. A Complete Listing of Previously-Published Chapters Appears at the End of This Article on Page 541. The Translation Is by Ann M. Wolf of New York City.

Chapter XV: Spirituous Beverages

Distilled Alcoholic Beverages and Liqueurs

Article 517.—Plants at which spirituous beverages are manufactured shall meet the general standards fixed in this Code and, in addition, shall comply with the following requirements:

1. The name "Distillery" may only be used for establishments which own and operate authorized stills and manufacture distilled alcoholic beverages and/or rectified alcohol.

2. The rooms to be used for the manufacture of distilled alcoholic beverages, the preparation of liqueurs, and the storage of raw materials and finished beverages shall be separated from each other by fixed partitions and have waterproof floors. In addition, the walls of the rooms intended for manufacturing and maceration shall be wainscotted with a waterproof material up to a height of 1.80 m. This requirement shall not apply to basements and other rooms used to store wooden casks with products in the process of aging.

3. Distilleries are prohibited from keeping chemicals (dressings, improving agents, anti-fermentation agents, etc.) intended to improve, preserve, artificially age, or imitate distilled alcoholic beverages and liqueurs; from misleading the purchaser or consumer as to the essential qualities, origin, or class of a product; and from ascribing to a synthetic product the

characteristics of a natural or standard beverage by falsifying analysis results. The presence of the aforesaid prohibited substances on the premises of a distillery, or in distillery annexes, even in sealed containers, shall be subject to penalties, and in addition, the violatory products shall be seized summarily.

4. Manufacturers of alcoholic beverages shall exhibit their manufacturing and sales records to the Health Inspectors whenever requested to do so in the course of an official inspection.

Article 518.—The terms "Alcohol," "Neutral Alcohol" and "Rectified Alcohol" mean any alcohol obtained by distilling and rectifying fermented mashes, as well as any alcohol obtained by rectifying natural potable spirits. The alcoholic content of the product ready for consumption shall, at 15° C., never be lower than 95 percent.

"Wine Alcohol" is rectified alcohol prepared from wine or wine products from which the methyl alcohol has been removed. All neutral alcohols are considered suitable for the preparation of beverages, vinegars and perfumes.

Article 519.—The terms "Plain Potable Spirits," "Natural Potable Spirits" and "Natural Distillates" mean any potable spirits obtained by the special distillation of fermented mashes, or their components or by-products, provided that they have not suffered alterations and that no substances extraneous to their nature have been added to them. Their alcoholic content may not in any case be higher than 85 percent. These products shall be labeled "Suitable for Handling," provided that their furfural content does not exceed 0.08 grams per liter of absolute alcohol and/or that their methyl alcohol content does not exceed 3 milliliters per thousand milliliters of spirit. In natural potable fruit spirits which are "Suitable for Handling," the presence of methyl alcohol in an amount of up to 5 milliliters per liter of spirit (Kirschwasser, etc.) shall be permitted.

The term "special distillation" means the distillation performed in a simple pot still, or in a distilling column with partial rectification, at not more than 85° C., so as to obtain a product with specific characteristics whose impurities are within the permitted limits.

Article 520.—The term "Distilled Alcoholic Beverages" means natural potable spirits whose alcoholic content varies between 35 and 60 percent and which have been obtained directly, or by redistillation, blending, or the addition of water. During fermentation or distillation, the mashes or potable spirits may be flavored if this is required to obtain the desired type of alcoholic beverage.

In the same manner, sweetening and coloring with authorized substances shall be permitted when practice makes it advisable or the type of beverage requires it. Distilled alcoholic beverages in which the amount of sweetener does not exceed 2.5 percent (weight/volume) may be named "dry spirituous beverages."

Unless otherwise provided for in this Code, the total volatile impurities or volatile constituents of distilled alcoholic beverages (the term "volatile constituents" means the sum total of aldehydes, volatile acids, esters, furfural and higher alcohols) shall, in general, never amount to more than 1.8 grams or less than 40 mg. per 100 ml. of anhydrous alcohol; the furfural limit shall be 4 mg. and the methyl alcohol limit 0.25 ml. per 100 ml. of anhydrous alcohol. These requirements shall be met by all products listed in Articles 523, 524 and 528 hereof.

Article 521.—The terms "Potable Spirits," "Wine Spirits" or "Brandy," used alone without any other specification, mean a spirituous liquor obtained by the special distillation of wines or potable spirits of wine.

Article 522.—The name "Cognac" means the alcoholic beverage obtained from potable spirits of wine which, aged in suitable wooden containers for not less than 24 months, has acquired the distinctive characteristics of this beverage. It may be colored with caramel. The dry residue of the finished product may not exceed 2 percent, and its total volatile constituents shall not amount to less than 280 mg. per 100 ml. of anhydrous alcohol.

Article 523.—The name "Brandy" followed by the name of the fruit used in the beverage* designates any alcoholic beverage obtained by the special distillation and fermentation of fruit mashes. The term "Brandy" may not be used for beverages prepared with alcohol obtained from cereals, molasses or other carbohydrates. Natural Fruit Brandies shall be named as follows:

1. "Plum Brandy," "Slivovitz," "Quetsch" or "Mirabelle": a brandy distilled from fermented fresh whole plums. Its content in volatile constituents shall exceed 300 mg. per 100 ml. of anhydrous alcohol, inclusive of the hydrocyanic acid content, which may not exceed 40 mg. per liter of beverage ready for consumption. Its acidity,

Note of the Translator:
* In the English language, the name of the fruit precedes (Apple brandy, etc.).

expressed as acetic acid, shall be less than 1.8 grams per liter. The hydrocyanic acid in plum brandy, as in agriot or cherry brandy, must come exclusively from the fermented fruit. The addition, before or after distillation, of vegetable macerations or extracts containing hydrocyanic acid is prohibited.

2. "Agriot or Cherry Brandy," "Kirsch" or "Kirschwasser": a brandy distilled from fresh whole agriots or cherries, fermented with or without the stones. Its content in volatile constituents shall exceed 250 mg. per 100 ml. of anhydrous alcohol, inclusive of the natural hydrocyanic acid which, at the distillery, may vary between 10 mg. and 100 mg. per liter, but in the beverage ready for consumption is not permitted to exceed 50 mg. per liter.

3. "Apple Brandy": a brandy distilled from fermented apple juice or apple pulp.

4. "Pear Brandy": a brandy distilled from fermented pear juice or pear pulp.

5. "Cider Brandy" or "Calvados" (Applejack): a brandy distilled from genuine ciders, suitable for consumption. Its content in volatile constituents shall exceed 400 mg. per 100 ml. of alcohol, not less than 175 mg. of which shall be esters. It may be colored slightly with caramel.

6. "Grape Brandy" or "Pisco"*: a brandy obtained by distilling a fermented grape mash in the presence of grape pulp and dregs. The names of Piscos to which fruits have been added during fermentation or distillation shall include the name of the fruit used: "Cherry Pisco," "Mango Pisco," etc. Their alcoholic content shall not be less than 42 percent.

7. "Raki": a type of ardent spirits distilled from a fermented mixture of fruits, such as figs, dates, plums, etc.

Article 524.—The spirituous liquors named hereinafter, in the preparation of which no fruit juice or fruit pulp is used, shall meet the following specifications:

1. "Anise Brandy": a brandy distilled from a maceration of aniseed (common aniseed, star-anise, or a mixture of the two) in wine spirit, with or without the addition of other substances or aromatic extracts.

Note of the Translator:
*A higher brandy prepared in Chile and Peru. The name is drawn from the Peruvian port Pisco.

2. "Arac," "Arrac," "Arrack," or "Sunchou": a spirituous liquor distilled from a fermented rice mash, to which palm juice, sugar cane molasses and flavors derived from pineapple, catechu or aromatic barks may have been added.

3. "Sugar Cane Brandy," "Aguardiente" ("Tafia," "Cachaza," "Branquina," or "Pinga"*): a brandy distilled from fermented sugar cane syrups or molasses.

4. "Grain Brandy": a brandy obtained by the special distillation of a sweetened fermented mash of grain.

When grain brandy is to be used in the preparation of Geneva (Article 528, numeral 9), the grain mash must be sweetened with barley malt and the spirits obtained (Malt Wine) must be redistilled in whole or in part in the presence of juniper berries, in which case the product may be named "Geneva Concentrate" (a product still to be processed).

5. "Grappa Brandy," "Grapa," "Marc Brandy," "Graspa" or "Bagaceira": a beverage obtained from grape dregs left over from vinification. The use of the name "Grape Brandy," or of any advertising which implies that the product is made from grapes, not from dregs, is prohibited. Its content in volatile constituents shall not be less than 300 mg. per 100 ml. of anhydrous alcohol. It may be sweetened and colored.

6. "Sotol," "Bacanora," "Chorrera" and "Cocuy Brandy": potable spirits obtained by the special distillation of mashes prepared with parts of the tips and ends of the joints of various magueys (varieties of Agave Americana L.) which are ground and then left to ferment and distill. The addition of up to 30 percent of sugar cane juice is optional.

"Pulque" or "Mescal" is prepared in the same manner, but from Agave tequilana Weber (blue pulque). Pulque, and the beverages named in the preceding paragraph, are distilled in one single operation and have a pronounced herbaceous flavor and aroma.

"Tequila" is prepared like Pulque, from Tequila maguey, but undergoes a second distillation whereby it is refined, so that its aroma and flavor are milder.

The alcoholic content of agave brandies fluctuates in general between 44 and 54 percent.

Note of the Translator:

* The last four names, used in Central America and Brazil, are not translatable.

7. "Rum" or "Rhum": a type of potable spirit distilled from fermented raw or boiled sugar cane juices and other by-products of sugar manufacture. To be ready for consumption, rum must have been aged in wooden barrels suitable for the purpose. It may be colored with caramel.

8. "Malt Spirits" or "Malta": a potable spirit distilled from a fermented mash of barley malt. It may be named "Pure Malt Whiskey" when it has been aged in wooden containers suitable for the purpose for more than two years.

Article 525.—Distilled alcoholic beverages may contain only one type of spirituous liquor; beverages of the same type may be blended without any statement to that effect in the labeling.

Neutral spirits may be blended, without a declaration in the labeling, only with other spirits of the same origin, and only in the proportion required to reduce their impurity or volatile constituent content to the limits specified in Article 520 hereof. In all other cases, the blending must be declared in the labeling.

Article 526.—Names such as "Paraguay Caña," "Hollands Gin," "French Cognac," "Scotch Whisky," "Jamaica Rum," "Martinique Rum," "Danziger Goldwasser" and similar names which specify the geographic origin of a spirituous beverage may be used only if the finished product comes from the country or locality named in the designation.

Article 527.—The terms "Liqueur," "Elixir" and "Cordial" mean any alcoholic beverage prepared by mixing or redistilling rectified alcohol or potable spirits with, or over, substances of vegetable origin, or with extracts obtained from infusions, percolations, macerations or distillates of such substances, and sweetened with sugars or honey. When the amount of sweetener added is less than 10 percent (by weight/volume), the liqueur may be called "Dry"; when it is less than 2.5 percent (by weight/volume) it may be called "Dry spirit"; when it contains between 10 and 20 percent of sweetener (by weight/volume), "Sweet," and when the sweetener exceeds 20 percent (by weight/volume), it may be called "Fine." The name "crème" may only be given to liqueurs of a syrupy consistency in which the sweetener exceeds 35 percent (by weight/volume). The name "frosted liqueur" may only be used for products oversaturated with sugar which crystallizes with time.

Liqueurs may be colored with authorized colors without stating such coloring in the labeling.

Liqueurs prepared with a base of fruit juices or parts of fruits may be named "Ratafias." The words "Cherry," "Apricot," "Peach" etc. may be used on liqueurs made from the fruits.

Liqueurs shall have an alcoholic content of not less than 15 percent and may be designated by distinctive names ("nombres de fantasía") whenever none of the generic names provided for in this Code fit the product exactly.

Article 528.—Hereinafter a list of generic names with definitions of the products distinguished by them:

1. "Anise" or "Anisado": a liqueur distilled from a maceration of aniseed (ordinary aniseed, star-anise, or a mixture of the two) in neutral alcohol, or obtained by mixing neutral alcohol with, distilled or undistilled, natural aniseed essence. Other aromatics may be added to it.

An Anise to which sugars in an amount exceeding 20 percent (by weight/volume) have been added shall be named "Sweet Anise" or "Carabanchel Anise," and when the amount of sugar added exceeds 35 percent (by weight/volume) it may be named "Crème d'Anis" or "Anisette."

Anise brandy and dry anise liqueur whose alcoholic content exceeds 40 percent may be named "Arabian Anise" or "Turkish Anise."

2. "Aquavit," "Akvavit" or "Acqua Vitae": an alcoholic beverage with a base of neutral alcohol, flavored with infusions or distillates of aromatic seeds or herbs.

3. "Blackberry Liqueur": a liqueur prepared with the juice or a maceration of blackberries and other fruits.

4. "Noisette Liqueur": a cordial obtained from the alcoholic maceration of green walnut hulls and lemon peel.

5. "Caña"* (Sugar Cane): This term applies not only to the distilled beverage so named (Article 524, numeral 3), but also to an alcoholic beverage prepared with rectified alcohol, diluted with water, to which authorized essences may have been added. The name "Caña Doble" may only be used for products whose alcoholic content is higher than 45 percent.

The name "Fruit Caña" (plum, peach, mandarin, kumquat, orange, tangerine, grape, etc. Caña) applies to beverages prepared from the maceration of these fruits in rectified alcohol.

Note of the Translator:

* The word "Caña," which translated literally means sugar cane, is used in Latin America to designate a type of white spirit made from sugar cane.

The name "Burned Caña" means a liqueur sweetened with sugars or honey in a proportion of more than 10 percent (by weight/volume) and flavored with authorized essences and/or, distilled or undistilled, infusions or macerations of oranges or other fruits.

6. "Cassis": a liqueur prepared from the juice and/or a maceration of red currents and raspberries.

7. "Curaçao": a liqueur prepared from an alcoholic infusion or maceration of bitter and sweet orange peel, to which permitted aromatics (tangerine, mace, cinnamon, lemon, etc.) may be added and which may be distilled in whole or in part. Strongly flavored "Curaçao" may be named "Triple Sec" or "Extra Dry."

8. "Chuchuhuasi": a liqueur prepared by the alcoholic maceration of chayote* peel (see Article 406, numeral 5).

9. "Geneva"**: an alcoholic beverage obtained by mixing "Geneva Concentrate" (Article 524, numeral 4) with neutral spirits of a suitable alcoholic content. The addition of sugar in amounts not exceeding 2 grams per 100 grams is optional. Its alcoholic content shall not be lower than 35 percent.

10. "Gin": a beverage obtained by the alcoholic maceration of juniper berries followed by distillation, with or without the addition of aromatics. The designation "Sweet Gin" ("Old Tom Gin") may be used for gin containing 10-15 grams of sugars per liter, and the name "Dry Gin" for gin containing a smaller amount of sugars. These products may not be named "Geneva," "Dry Geneva" or "Sweet Geneva."

The name "Sloe Gin" designates a gin prepared from a maceration of sloeberries, and the name "Lemon Gin" a gin prepared from a base of lemon peel or natural lemon essence.

11. "Agriot liqueur": a liqueur prepared from agriot juice, or from the maceration of agriots in rectified alcohol sweetened with sucrose, glucose or honey, to which water in an amount of not less than 24 percent has been added.

12. "Cacao Liqueur": a liqueur prepared from an alcoholic, distilled or undistilled, maceration of de-fatted cacao, to which vanilla and other aromatics have been added.

Notes of the Translator:

* A pear-like edible fruit that grows in Latin America, the Canary Islands and Valencia.

** A Dutch gin, at times referred to as "Schnapps" or "Hollands Gin."

13. The names "Cocktail," "Grog" and "Punch" are used to designate mixtures of different alcoholic beverages, to which juices, fruit chunks and syrup may have been added. They are usually sold in ready mixes or are mixed immediately before serving. Cocktails are usually served ice-cold or with ice, whereas grogs and punches* are prepared with hot water or tea.

14. "Cherry Brandy": a liqueur prepared mainly from a maceration or the juice of cherries or agriots and permitted aromatics.

15. "Coffee Liqueur": a liqueur prepared from a, distilled or undistilled, coffee tincture to which vanilla and other aromatics have been added.

16. "Caraway Liqueur" or "Kümmel": a liqueur obtained from an alcoholic maceration of caraway seeds, aniseed, cumin seeds and other aromatics, which may be followed by distillation. The name "Allash" distinguishes a "Kümmel" of superior quality, flavored with orris, angelica root, etc.

17. "Gold Liqueur": a liqueur prepared from an alcoholic maceration of angelica root, cinnamon, mace, coriander, caraway seeds, cloves, figs, rose water and other aromatics, to which a few gold leaves were added during the bottling process.

18. Fruit Liqueurs (banana, plum, peach, orange, tangerine, grape, etc. liqueurs) must be prepared from crushed fruits, alcoholic solutions, tinctures or, distilled or undistilled, alcoholic macerations of the fruit named. The addition of essences with a flavor similar to that of the starter fruit is prohibited.

19. "Pennyroyal Liqueur" ("Pulioll"): a liqueur prepared from a, distilled or undistilled, alcoholic maceration of pennyroyal (Lippia turbinata, Griseb), to which other aromatics may be added and which may be colored with chlorophyll or other authorized substances.

20. "Maraschino" or "Marraschino": a liqueur prepared with cherry or agriot brandy or with a, distilled or undistilled, alcoholic maceration of cherries or agriots, to which other aromatics may be added.

21. "Mint" or "Peppermint Liqueur": a liqueur prepared with natural peppermint essence and rectified alcohol, or from a, distilled or undistilled, alcoholic maceration of mint leaves, which may be colored with chlorophyll or other authorized substances and to which other aromatics may be added.

Note of the Translator:

* In the United States, a "punch" is usually a mildly alcoholic mixed beverage served cold.

22. "Peperine Liqueur": a liqueur prepared with an alcoholic maceration of peperina (Minthostachys verticillata Griseb*) to which other aromatics may be added and which may be colored with chlorophyll or another authorized substance.

23. "Prunelle": a liqueur prepared from a maceration of plums in neutral alcohol, cognac, or other natural spirits, to which aromatics may have been added.

24. "Vespetro": a liqueur prepared from alcoholic macerations of angelica root, coriander, aniseed, fennel, badian and other authorized aromatics.

25. "Vodka" or "Wodka": an alcoholic beverage made from grain or tubercle spirits, or from diluted neutral spirits. Vodka is usually filtered through charcoal to obtain a product that has no distinctive aroma or taste. Its alcoholic content fluctuates between 42 and 60 percent.

26. "Whisky" or "Whiskey": an alcoholic distillate from a fermented mash of grain sweetened with malt, stored for not less than two years in barrels of oak or another suitable wood, as provided for in Article 529 of this Code. Whiskies may be blended with neutral grain spirits aged for not less than two years.

The alcoholic content of whiskey shall not be lower than 42 percent; the total volatile impurity content of the finished product shall not be less than 0.4 grams per liter. It may be colored with caramel and sweetened with sugars in an amount of up to 0.5 grams percent.

"Blended Whiskey" is a mixture of several whiskies.

"Straight Whiskey" is whiskey not blended with other whiskies.

The various types of whiskey must meet the following characteristics:

a. "Scotch Type Whisky" is whiskey made from a Malt Spirit (Pure Malt Whiskey), which may be mixed with a Grain Spirit (Grain Whiskey), and has been aged for not less than two years in barrels of oak or another suitable wood. The name "Pure Malt Whiskey" may also be used for the "Malt Brandy" defined in Article 524, numeral 8 hereof, when the product has been aged for not less than two years.

Grain Whiskey may be distilled to 95° C.

b. "Irish Type Whiskey" is whiskey made from grain spirits distilled from a mash sweetened with malt. It does not have the peat flavor characteristic of Scotch whisky.

Note of the Translator:

*A mint variety found in Argentina.

c. "Bourbon Type Whiskey" (American Whiskey) is whiskey made from a grain spirit distilled from a mash containing corn and sweetened with malt. It is aged in charred containers. A dry residue of not more than 0.5 grams percent is permitted.

d. "Rye Whiskey" is whiskey distilled from a mash of grain that contains rye grain and is sweetened with barley and/or rye malt. Canadian Whisky is one such type of whiskey. The total volatile impurity content of Rye Whiskey shall not be less than 0.3 grams per liter of finished product.

On Bourbon and Rye Whiskey, the percentage of the cuts must be stated in the labeling.

Article 529.—In labeling domestic products which, because of their organoleptic characteristics, are equivalent to products originating in other countries, reference may be made to this fact by placing the word "Type" before* the geographic appellation, in a print not larger than the type used for the name of the product. For instance: "Scotch, American or Irish type" Whiskey, "Hollands type" Gin, "French type" Cognac, etc.

Article 530.—Any alcoholic beverage not specifically provided for in this Code and sold with a foreign indication of origin must be equivalent to the original product with regard to raw materials, special manufacturing technique and distinctive characteristics. Merchants who sell beverages as imported from abroad must prove such origin to the health authorities by means of analysis certificates or aging certificates from the country of origin, and import documents.

Article 531.—The labeling and advertising used for spirituous beverages (distilled alcoholic beverages and liqueurs) are prohibited from containing references to properties or names which may mislead the consumer by causing him to believe that the product has therapeutic properties or qualities, such as: "restorative," "tonic," "stomachic" or "digestive." When terms referring to such properties are used, the beverages so designated shall be considered "pharmaceutical specialties" and, as such, require the approval of the health authority.

Spirituous beverages are prohibited from being promoted in radio, television, oral, or written advertising with claims that they provide stimulation, well-being, or good health or have therapeutic, hygienic or sanitary properties.

Note of the Translator:
* In English, it would read "after."

Article 532.—The time of aging of alcoholic beverages may only be mentioned in labels and advertisements if the aging took place under official control. The time of aging means the period during which a beverage was stored at an appropriate location in suitable wooden vessels of a capacity not exceding 1,000 liters. If the aging takes place in larger vessels it cannot be mentioned.

The adjectives "Aged," "Old," or similar terms may be used only on beverages stored or matured for not less than three years, and the adjectives "Extra old," "Extra aged," and similar terms only on beverages more than five years old. The age of blended beverages shall be taken to be the age of the component stored for the shortest time.

Article 533.—Harmless clarifiers may be used in the preparation of spirituous beverages (distilled alcoholic beverages and liqueurs). Racking, blending of spirits or distillates of the same type, charcoal treatment, filtration and washing (alcoholic content) and, under certain conditions, the application of cold or heat to beverages requiring such treatment shall likewise be permitted. Artificial aging processes may be used only if authorized by the health authority, with the provision that such aging cannot be mentioned in the labeling and advertising of products thus treated.

Article 534.—The manufacture, holding and sale of Absinthe (an alcoholic beverage prepared from a base of wormwood, peppermint, and fennel) and of similar beverages containing or imitating absinthe are prohibited.

This prohibition applies likewise to any beverage, whose name resembles the word "absinthe" or a similar word in a national or a foreign language, or whose labels, announcements and other advertising matter contain a direct or indirect reference to absinthe, the principles of absinthe, or derivated principles.

The classification "absinthe-like" shall apply to alcoholic beverages with an outspoken anise odor and flavor, which turn cloudy when four volumes of distilled water are added to them slowly, drop by drop, at 15° C and remain cloudy until another three volumes of distilled water are added to them at the same temperature. It shall also apply to beverages containing an essence with a ketonic effect, even if they do not turn cloudy when subjected to the cloud test.

The classification "absinthe-like" shall not apply to alcoholic beverages containing aniseed (anise brandy, anise liqueur, anisette) even

when the cloud test is positive, provided that they are colorless, or that their only color is that of the spirits or aromatics used; that they do not contain essences with a ketonic effect; and that they do not violate the provisions contained in the second paragraph of this article. Nor shall this classification apply to apéritifs which contain a small amount of Artemisia Absinthium L. among the vegetable substances used in the infusion or maceration from which the apéritif was prepared.

Article 535.—The term "Apéritif" (Fernet, Bitters) means also spirituous beverages (see Article 508, par. 3, letter f) which contain certain bitter principles considered as stimulating the appetite. They may be derived from distillation or infusion, maceration or digestion in rectified alcohol of plants, or parts of plants: bitter oranges, ginger, gentian, quinine, chicory, angostura, absinthe, holy thistle, sweet flag, common erythraea, calumba, quassia, juniper, hops, with or without the addition of natural essences, sugars, and other authorized substances. Their total dry residue shall not be less than 10 grams per liter.

The name "Orange Bitters" designates the bitters prepared from sweet and/or bitter oranges and other authorized aromatics.

The name "Angostura Bitters" designates the bitters prepared from the bark of angostura (Galipea cusparia, Saint Hilaire) and other authorized aromatics.

Article 536.—Spirituous beverages intended to be synthetic imitations of the beverages listed herein or prepared in a manner other than the one described in this Code are prohibited from being held, distributed, or sold.

Article 537.—Spirituous beverages shall be considered unfit for consumption if: Their free acidity, expressed as acetic acid, exceeds 1.5 grams per liter; or if they contain: Methyl alcohol, higher alcohols, volatile acids and aldehydes in amounts exceeding the proportions authorized in Article 520 hereof; Isopropyl alcohol, benzol, homologous hydrocarbons, pyridine or any other substances officially used as alcohol denaturizers; Mineral or organic acids extraneous to the standard composition of the beverage; Hydrocyanic acid in amounts exceeding 50 milligrams per liter; Essences, extracts or aromatic compounds containing toxic ingredients the use of which has been prohibited specificially; Artificial sweeteners; Coloring matters the use of which is prohibited; Unauthorized preservatives; Irritating, purgative or drastic bitters, the use of which has not been authorized or been forbidden specifically.

Authorized substances, such as black pepper, pimento, mustard, rhubarb, aloe, senna and white agaric, may not be present in amounts exceeding 2 grams per liter; if a beverage contains more than one of these substances, their aggregate may not exceed 4 grams per liter.

[The End.]

Information concerning the Latin-American Food Code, whose second, or 1964 Edition was published by the Latin-American Food Code Council in August, 1964, and a complete Table of Contents appeared in the April, 1965 Edition of the FOOD DRUG COSMETIC LAW JOURNAL. English translations were published in the JOURNAL of the following chapters:

I	General Provisions	September, 1965
II	Food Factories and Outlets	September, 1965
III	Storing, Preservation and Processing	September, 1965
IV	Containers, Wrappers, Machinery, etc.	September, 1965
V	Labeling	September, 1965
VI	Meats and Similar Foods	August, 1967
VII	Edible Oils and Fats	June, 1966
X	Sugar and Sugar-containing Foods	December, 1965
XII	Aqueous Beverages	October, 1965
XIII	Other Refreshing Products	October, 1965
XVI	Stimulating Products	May, 1967
XVII	Food Additives	November, 1965
XVIII	Foods for Regimens	August, 1966

All translations have been prepared by Ann M. Wolf, New York, N.Y.

FDA REJECTS REQUESTS FOR PUBLIC HEARING ON FOOD LABELING REGULATIONS

The Food and Drug Administration has evaluated objections and comments received from industry in response to the food labeling regulations issued to implement the Fair Packaging and Labeling Act and has rejected requests for a public hearing and revised the regulations to meet some of the objections. Reg. § 1.8a(d) was amended to provide that the zip code of the manufacturer need only be added when new printing plates are made, and Reg. § 1.8b(f) was amended by making optional the location of combination statements of net quantity on the principal display panel. These food labeling regulations will become effective on July 1, 1968. The effective date for all new packages, new label designs and reordered labels will be December 31, 1967. CCH FOOD DRUG COSMETIC LAW REPORTS Reg. §§ 1.1b, 1.1c, 1.7, 1.8a, 1.8b, 1.8c, and 1.10, ¶ 9853, 9854, 9875, 9880, 9881, 9882, and 9887 and FDA Ruling on Objections, ¶ 40,273.

Fair Packaging and Labeling—The Cost to Consumers

By GEORGE M. BURDITT

The Author, a Member of the Law Firm of Chadwell, Keck, Kayser, Ruggles & McLaren of Chicago, Illinois, Presented This Speech on October 3, 1967, at the 29th Annual Packaging Forum of the Packaging Institute, in Chicago, Illinois.

THE PACKAGING INSTITUTE'S National Packaging Forum is an appropriate occasion to discuss an aspect of the Fair Packaging and Labeling Act (FPLA) which has been sadly neglected: The cost to consumers. A great deal has been said about the merits of the bill—and it certainly does have substantial merit—but, like most legislation, it is going to cost something. This is the subject I would like to consider with you today.

The Statute

The FPLA was passed in November 1966 and went into effect on July 1, 1967. It is administered by three agencies: the Department of Health, Education and Welfare, which means the Food and Drug Administration (FDA) with jurisdiction over food, drugs, devices and cosmetics; the Federal Trade Commission (FTC) with jurisdiction over all other consumer goods covered by the Act, and the Department of Commerce with jurisdiction over any commodity if the Secretary determines there is an undue proliferation of package sizes of that commodity.

The Act requires the promulgation of some regulations and permits the promulgation of others. Time doesn't begin to permit a detailed review of the Act, but let me just mention three of the regulations which are required to be promulgated:

First, a regulation requiring the net quantity of contents of a package to appear "in a uniform location upon the principal display panel" of the label;

Second, a regulation requiring the net quantity on packages of between one pound and four pounds, or between one pint and one gallon, to be stated in two different ways, for example "16 oz. net wt. (1 lb.)";

Third, a regulation requiring that the net quantity statement be "in a type size which shall be (i) established in relationship to the area of the principal display panel of the package, and (ii) uniform for all packages of substantially the same size."

The regulations permitted include those:

First, to "establish and define standards for characterization of the size of a package";

Second, to "regulate the placement upon any package" of any cents off or similar labeling;

Third, to "prevent the nonfunctional-slack-fill of packages."

All of these regulations are required to be, or may be, promulgated by FDA and FTC. Meanwhile, if the Secretary of Commerce determines that there is an undue proliferation of the weight, measure or quantities in which any consumer commodity is sold, and that the undue proliferation impairs the reasonable ability of consumers to make value comparisons, he is directed to request manufacturers, packers, distributors and consumer representatives to cooperate in the development of "voluntary product standards." If this does not work out satisfactorily, he is directed to report back to Congress with a recommendation as to whether further legislation should be enacted. In fact, the Act is so detailed, complicated and restrictive in solving the problem that I am reminded of the story of the legislator who had a nervous breakdown because he had found the solution to the problem but he'd forgotten what the problem was!

Regulations

So much for the statute itself. As to regulations, all three agencies are hard at work. The food regulations are now final; the drug and cosmetic regulations, and the FTC regulations, have been proposed and commented on; the Department of Commerce regulations are partially final, with certain implementing provisions being in the proposal stage.

There are, of course, many similarities between the FDA and FTC regulations, but there are also some differences. For example, the FDA regulations require that the quantity statement appear in the bottom 30 per cent of the label, whereas the FTC regulations re-

quire that it appear "in close proximity to the most conspicuous statement of the trade or brand name." The FDA regulations require that the signature copy include the zip code; the FTC regulations merely require "an adequate and sufficient mailing address." In the case of odd shaped containers, FDA requires that the area of the principal display panel be measured by "40% of the total surface of the container," whereas FTC uses the "total actual area of the surface of the principal display panel." The regulations are necessarily complicated; with less reason, they are ambiguous and unduly restrictive in some respects, perhaps because of some unfortunate choices of words in the Act.

The Cost

Now let me get to the cost to the consumer. The first obvious cost is financial. Virtually every package of food, drugs and cosmetics is going to have to be redesigned. And many of the redesigns are substantial. For example, the quantity statement has to be moved to the bottom 30 per cent of the label; it has to appear in the two forms I mentioned a moment ago; it must appear in a new and specific type size which in a good many cases is twice as large as the type size put into effect about two years ago by the National Conference on Weights and Measures; and it must be separated from other printed matter according to a specific formula. Similar, although not identical, changes are going to have to be made on other consumer commodities under the jurisdiction of the FTC.

In terms of dollars, how much will it cost to redesign and reprint virtually every single consumer commodity label in the United States? Obviously it is going to cost many, many millions of dollars. The returns are not all in. Costs can be influenced dramatically by the degree of reasonableness exercised by the regulatory agencies. Haste will be extremely costly because it will necessitate the destruction of unused labels and plates and cylinders which are not worn out. Under any circumstances, the new art work, new sales, production and legal approvals, new plates and cylinders and duplicate inventories necessitated by the signature clause provisions will be expensive. Work on container standards will be costly. Also, the administrative costs of government will inevitably be high, since all three agencies will have to add personnel to handle the questions of interpretation, requests for exemptions and the myriad of other administrative problems. So the consumer is going to have to pay, both in terms of higher prices and in terms of increased taxes.

You may have heard the story about the Congressman—and this may have occurred after the FPLA was passed—who was worried about a particular bill which had just been approved and said to one of his colleagues, "We have met the enemy and they are us."

The second cost to consumers is in terms of consumer confusion, one of the very things the Act is designed to prevent. The prime example of this, of course, is in the dual declaration requirement. I simply can't believe that telling a consumer in two different ways how much a package contains is going to be helpful. And what about tray pack displays where the tray covers the bottom 30 per cent of the label where the quantity statement must appear? And is it going to help consumers to see as a signature "The Universal Hospital Supply Corporation" on a can of orange juice concentrate, or "The Tampa Cigar Company" on a package of aspirin?

The third cost to consumers is in a loss of freedom of choice. An inevitable result, sooner or later, is going to be a reduction in the number of package sizes available to consumers. There has been a lot of talk about the number of sizes of potato chip packages. But the complainers seem to forget that if consumers didn't want different package sizes they wouldn't buy them. It's the consumer who benefits by the various sizes of packages and if she doesn't want them they simply won't be on the market very long. So the consumer is going to pay in terms of fewer choices. We are heading for standardization.

The final cost I would like to mention is still problematical. I don't want to be melodramatic about it, but I think it is the most serious of all. It is the kind of thing which must make Patrick Henry twitch a little in his grave. FDA has denied a hearing on the regulations although approximately fifty objections and requests for a hearing were filed. And this is in the face of the specific requirement of both the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act that hearings be held on the filing of valid objections. I realize that the FDA, like industry, is highly desirous of getting on with the job of complying with congressional intent as expressed in the Fair Packaging and Labeling Act. But part of this intent is that hearings be held.

The reasons for denying the hearing as set forth in the final FDA order are in large measure unsound. Let me give you two or three examples. A hearing is denied on one issue on the ground that: "Since this was a matter which the Commissioner had to decide, it is not considered as one warranting a public hearing." This is a patent non

sequitur. On another issue, a hearing is denied "Since the statute provides that [the decision] should be made by the Commissioner and not by popular vote." The Commissioner has to make the final decision on all regulations. Indeed, this is the very reason a hearing is required—so that every American citizen has an opportunity to present his views, to question and oppose the views of others, and so that a full record can be prepared for a court to make a judicial determination if necessary.

A hearing is denied on another issue, and again I am going to quote, "since the objector did not suggest an alternative." There is no legal requirement that an objector suggest an alternative. If this is a valid ground for denying a hearing, no consumer, and no industry member, could ever get a hearing without suggesting an alternative, which is clearly unsound law.

I am greatly concerned, and a little disappointed and worried, that the final order deprives everyone, consumers and industry alike, of the right to be heard in an administrative tribunal. After all, in our modern society, administrative hearings are in many ways just as important as judicial hearings. Any impairment of the fundamental right to a hearing should be taken most seriously, not only because of the immediate effect, but also because of its ramifications for the future.

So the Packaging and Labeling Act isn't going to give consumers a free ride to anywhere. I imagine some Congressmen are having second thoughts about it. **[The End.]**

LACK OF PRIVITY BARS WARRANTY ACTION AGAINST DRUG MAKER

In the absence of privity of contract between a user and a drug manufacturer, the user could not maintain an action for breach of warranty against the manufacturer. Because the injured user's complaint did not allege privity, the user's complaint was dismissed by a federal district court in Maryland. *Blum v. Richardson-Merrell, Inc.* (DC Maryland) CCH PRODUCTS LIABILITY REPORTS ¶ 5839.

The Package Insert: Significance, Style, Synthesis

By PAUL V. BUDAY

Mr. Buday Is the Head of Drug Regulatory Affairs for Sandoz Pharmaceuticals. This Manuscript Was Read before the Plenary Session of the 1967 Annual Convention of the American Medical Writers' Association, on September 23, 1967 at the Palmer House, in Chicago, Illinois.

PACKAGE INSERTS ARE KNOWN commonly or alternatively as: "approved package brochures"; "product inserts"; "official drug brochures or leaflets"; "direction or package circulars"; and "drug package labeling." They have also been called "drug package stuffers."

Significance

By whatever name, package inserts or something similar have probably been with us for a long time—ever since nostrums were sold by the proverbial snake oil peddler. Inserts, however, did not legally become labeling (that is, descriptive matter accompanying a drug) until the passage of the Food, Drug and Cosmetic Act of 1938.[1] They are at times used today for non-NDA (new drug application) prescription, proprietary and ethical over-the-counter products, but primarily for NDA'd OTC (proprietary and ethical) and prescription drugs.

Inserts come in varied sizes, shapes, and modes of folding, and are enclosed within, or wrapped, glued, cellophane-taped, or elastic banded to the containers of drugs they describe (they really aren't used in cartons to prevent product rattling!).

With few exceptions inserts have been required since 1962 for prescription drugs wherever under the Food, Drug and Cosmetic Act full disclosure or adequate directions for use are needed, and where there is insufficient room on the label or carton for such information.

[1] Roe, R. S., "The Impact of the Food and Drug Administration on Our Society," edited by H. Welch and F. Martiibanez, *MD Publications*, N. Y., 1956, pp. 96-98.

They are a current summary or end-product of the extensive preclinical and clinical investigations required by law to substantially prove drugs safe and effective for the conditions of their intended use.

My subsequent remarks will apply exclusively to inserts prepared as labeling for NDA'd prescription drugs for human use.

The insert serves several publics:

(1) For the physician and para-medical professional—It is a condensate of periodically up-dated medical and technical information that permits the safe and intelligent use of drugs.[2] Not all physicians agree, however.[3] This disagreement is based on some fact—some mistaken opinion and some misinformation. An insert is not infallible. It is as accurate as the data upon which it is based. An insert may become outdated, but by and large it serves the pharmaceutical firm's best interests to keep the leaflet current.

(2) For the Food and Drug Administration (FDA)—It serves as a guide for determining proper therapeutic claims, the extent of information required to describe possible toxicity, and the adequacy of medical advertising and promotional copy.

(3) For the drug manufacturer—It serves as a basis for all promotional labeling and advertising, although it is reported[4] FDA plans to eliminate "built-in" promotional language from "official" labeling.

For example, the brief summary of an advertisement for a prescription drug must, under a proposed FDA regulation,[5] contain information found in the insert concerning adverse reactions and contraindications, including hazards, warnings, and precautions, and must reflect the substance of nothing other than the approved claims.

It also is a practical expedient, for if a label is too small to carry all the required information, then the carton or leaflet within the package must contain all the necessary information.[6] It also serves to some extent as a guide to 15-day reportable adverse reactions. That is, in most instances the listing of a reaction in the insert obviates the need of a report being filed with FDA within 15 days.

(4) For others—It serves in legal proceedings as a guide to what the practitioner should know about a drug, and how to use it. If the

[2] Holland, A. H., Jr., "Drugs, Doctors and Directives," 7 *J. Amer. Geriat. Soc.*, 19, 1965.

[3] American Medical Association Department of Drugs, "Package Inserts of Drugs—Related Problems," (Letters), 194 *J. A. M. A.*, 207, 1965.

[4] *FDC*, 29: 38, 1967, F-D-C Reports, Inc.

[5] CCH Food Drug Cosmetic Law Reports ¶ 40,256, 32 *Federal Register* 7533.

[6] 21 CFR 1.104(i).

physician decides to ignore or deviate from the directions given, this decision may play a significant role in his ability to defend himself in a malpractice or liability suit.[7, 8] The ramifications of this problem are much beyond the scope of this paper, but they loom ominous.

Style

The FDA has unofficially recommended that certain paragraph headings be given in a package insert and in the following sequence (there are exceptions). I offer the following respective commentaries:

(1) Name of drug—Trade (proprietary or brand) name followed prominently by the established or generic name. The capital letters (caps) of the trade name must not be bigger in actual size than twice the measured height of the tallest letter of the established name. The established name is often in all lower case but small full caps are used too.

Although the courts have yet to decide if the established name must follow the trade name each and every time, many firms now follow this system routinely.

FDA has never issued any final regulation as to the minimum size of inserts' type, although 6 and 8-point sizes were proposed in late 1961 and early 1962. Insert typography varies from manufacturer to manufacturer but 14-point Franklin Gothic caps or 18-point Standard Bold caps for the trade name (depending on its length) and 8-point (News Gothic Condensed or Times Roman) for the body copy are legible, elegant fonts. Paragraph headings are routinely boldfaced (8-point News Gothic) and may run in with body copy or may be column centered. Smaller size type (6 or 7-point) is reserved at times when space is limited, or when footnotes or literature references are listed.

If the chemical name for a new drug is given, FDA prefers to have it cited according to the most recent cumulative list or edition of the United States Adopted Names.[9] There is no objection to designating the established name of a compound as "U. S. P." or "N. F.", but the drug must be currently official to be so designated. FDA considers it confusing and misleading to qualify an established name with the designation "N. D."[10]

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[7] Holland, A. H., Jr., See footnote 2, p. 148.

[8] Mills, D. H., "Physican Responsibility for Drug Prescription," 192 *J. A. M. A.*, 1965, 460.

[9] Published for the USAN Council by the United States Pharmacopoeial Convention, Inc., N. Y.

[10] *New Drugs,* American Medical Association, Chicago.

If an FDA-certified drug (for example, an antibiotic) is involved, the specified monograph (regulation) name becomes the generic (nonproprietary) name until an established name is selected.

(2) Description—This should briefly give the drug's chemical and physical properties and ideally the structural formula of each new drug in the product. For a multi-ingredient drug for oral use, the established name and quantity of each active ingredient (and inactive, if a parenteral product), must be listed at least once under the name of the product.

(3) Actions—This basically is a description of the pharmacology of the drug; it should specify whether the actions cited pertain to animals or man. A much neglected bit of information is a description of the onset, peak, and duration of action, when such information is pertinent and available.

(4) Indications—The approved therapeutic claims. This section may describe relative efficacy if substantiated. If the percent of patient cures or relief is mentioned, then the insert becomes outdated rather quickly as periodic NDA progress reports are submitted. If there are limitations to efficacy, for example, if an anti-bacterial drug is relatively inactive when urine pH is high, then this limitation should be mentioned here or under the Precautions section.

The Indications section is obviously a key section. It gives the limit or breadth of use. The language used must be precise. For example, to say that a certain phenothiazine tranquilizer is useful in alcoholism is not very precise: actually most phenothiazines potentiate the central nervous system depressant action of alcohol. What is really meant is that the phenothiazine benefits alcohol withdrawal anxiety or delirium tremens.

(5) Contraindications—These are the absolute prohibitions to use of the product in certain patients because of age, pregnancy, physiological impairment, etc.

(6) Warnings—Extraordinary hazards (potential dangers); the serious adverse reactions. Warnings generally involve the weighing of potential risk of treatment with potential benefit from use. Because of the uniqueness of toxicity of some drugs (for example, monoamine oxidase inhibitors), or their possible misuse by suicidal-prone patients, antidotal information for overdosage might be given in this section or in a paragraph immediately following Dosage and Administration.

(7) Precautions—Relative warnings and contraindications; any precautionary measure to improve the product's prospects of beneficial use.

(8) Adverse Reactions—The so-called "side effects" from a drug's use. FDA prefers the former term.

By and large an insert must mention all proven or suspect adverse reactions mentioned in the NDA or, when the situation requires it, as a result of periodic experience reports.

If a given reaction is not mentioned in the insert, reporting of a given situation would require submission of a 15-day report (21 CFR 130.13(d)(2)). Generally, the mentioning of a given number of reactions is not very practical, as it dates the labeling. For example, the statement "fatal hepatic necrosis has been reported in 8 patients" might conceivably require the revision of the leaflet should a ninth case be reported.

FDA by and large requires or recommends mentioning of adverse reactions particular to a class of drugs and recommends listing them either by affected body system, or in a decreasing order of occurrence, unless data are available to give an exemption.

(9) Dosage and Administration—The directions for safe and effective use by route, especially if the product is given parenterally, should be detailed. If any compatibilities or incompatibilities are known with masking agents, diluents, vehicles, etc. these should be mentioned.

(10) Drug Availability (How Supplied)—A description of the dose forms, strengths and package sizes, together with product characteristics, commonly available. If pertinent, drug dosage should be specified by age group.

(11) References—If listed, the articles cited must be part of the NDA. Standard abbreviations, for example the use of the conventions of *Index Medicus* or *Chemical Abstracts,* make for uniformity.

The insert must show the date of original issuance or date of latest revision, and the name and address of the manufacturer.

Some manufacturers identify their inserts by a specification number or code. This number may give all details concerning the supplier and the type, quality, cut size, etc. of the paper used for the insert; a change in specification number may signify that some change in color or format or the deletion or addition of text has occurred since printing of the last copy.

Synthesis

The preparation of an insert is a formidable task. Whether written by copywriter, medical writer, or physician, the insert requires a

thorough knowledge of the product, its preclinical actions, and the distillation of hundreds, perhaps thousands, of patient report forms; for example, a distinct understanding of the NDA. The recent development of electronic data processing, summary print-outs, and resultant graphic displays permits the writer to deal more easily with reams of data. The writer must have a scientific background and a sharp, crisp writing style to prepare a draft effectively.

Frankly, the insert as finally written is a compromise between the desires of the company's marketing and medical departments, and the FDA. Under the present regulatory climate, it is more near the latter pole.

It has been said that inserts are costly, of limited value. Inserts probably cost a fraction of the total cost of pharmaceutical drug promotion. For example, the printing and other mechanical costs involved in producing them in commercial quantities rarely amount to more than two and one-half cents for each insert. Perhaps physicians don't read them enough; this is irrelevant. "The insert makes certain that no patient can be treated with a drug anywhere, at any time, without the information concerning it being available nearby."[11] Pharmacists and nurses do read them—these people advise and remind physicians. Alternatives to inserts have been suggested: a general reference book or a general or limited drug compendium containing edited versions of inserts. Any of these alternatives if adopted will involve a massive and much more expensive task and will probably raise as many problems as they solve.

Package inserts have been accused of being too promotional and failing to compare one drug's efficacy with another. The first charge may be true; it is being rectified through experience and maturity of medical writing. To the second charge, which is perhaps true, I can only retort that comparative drug efficacy is a relatively recent consideration in clinical evaluations.

According to the FDA,[12] "The package insert is not the most effective means for communicating drug-use information to physicians, but until more effective communication can be required or is voluntarily established as an alternative, the package insert requirement [of the regulations] must be retained." This is a fair statement!

[The End]

[11] Tice, L. F., "The Package Insert," (Editorial), 138 *Amer. J. Pharm.* 220, 1966.

[12] Hauser, J., "FDA Goals in Labeling and Advertising Regulations," 22 FOOD, DRUG AND COSMETIC LAW JOURNAL 300 (May 1967).

The Color Additive Amendments of 1960 Revisited— Seven Years of Feast or Famine

By ALAN H. KAPLAN

The Following Article Was Delivered as a Speech at the Thirteenth Annual Seminar Program of the Society of Cosmetic Chemists. Mr. Kaplan Is a Partner of the Law Firm of Kleinfeld and Kaplan of Washington, D. C.

SINCE ITS ENACTMENT IN 1938, there has been a multitude of amendatory statutes to the Federal Food, Drug and Cosmetic Act which have generally extended the scope of federal control over the commodities subject to the Act's jurisdiction. Some of these amendments were adopted in response to an immediate need for legislation to fill a gap in the law. An example was the enactment in 1953 of the "factory inspection" amendments which were made necessary by the Supreme Court decision in *United States v. Cardiff*.[1] The decision held the original provisions of the Act relating to factory inspections unconstitutional on the grounds of "vagueness." The vagueness existed as a result of the fact that the original provision in Section 704 of the Act relating to factory inspections seemingly conditioned the right to inspect upon the Agency's "first making a request and obtaining permission of the owner, operator, or custodian" to inspect the facilities, while under Section 301(f) of the Act, "the refusal to permit entry or inspection as authorized by Section 704" was made a criminal offense. The evident conflict between the standards of 704, which called for the "obtaining [of] permission" and 301(f), which negated the element of permission, produced the uncertainty which rendered the statutory provisions unconstitutionally vague.

[1] ('52) 344 U. S. 174, 73 S. Ct. 189.

As distinct from amendments to the Act which came about out of an immediate need for legislation, other amendments were adopted during the course of the years on the thesis that some of the processes and standards in the original enactment were unnecessary or wasteful. The Hale Amendments, which limited formal hearings in certain rulemaking proceedings to situations where factual issues existed are an example of this type of amendment.

Another example of amendatory legislation which had no immediate problems of an emergency nature to resolve is the Food Additives Amendment of 1958. This legislation, which was enacted only after several years of Congressional hearings, came about largely as a result of the view of some people that elements of the existing legislation were inadequate to protect the public health. In part, it was argued that the existing law permitted the marketing of foods made by certain processes or containing certain ingredients the safety of which had not been clearly established. In response to this situation the Food Additives Amendment was enacted. It required that unless a process or substance used in food was generally recognized by qualified experts to be safe in such use, it could not be used until data demonstrating safety had been provided to and evaluated by the Food and Drug Administration (FDA), and until a regulation had been issued which defined the conditions of appropriate use. Any use not in conformity with those conditions was of itself deemed illegal.

One amendatory statute which combined aspects of both an immediate need for legislation and an underlying desire to revamp existing procedures is provided by the Color Additive Amendments of 1960. The immediate impetus for legislation in this area was the Supreme Court's decision in *Flemming v. Florida Citrus Exchange*[2] in 1958 which held that the provisions of the Act relating to the certification of coal-tar colors "which are harmless and suitable for use in food" did not provide for the establishment of tolerances under which such colors might be safely used. The standard for certification as stated by the Supreme Court was that the colors must be harmless when applied at toxicologically significant levels. Unless this test could be met, the colors could not be certified, and unless the colors were certified, they could not be used.

It is of significance that the standard for coal-tar color certification enunciated by the Supreme Court in 1958 came about only be-

[2] ('58) 79 S. Ct. 160.

cause the FDA's position forced a court test of the issue. If the Agency had construed the color certification provisions of the Act in a more flexible, and perhaps more reasonable and realistic manner, there would have been no necessity for the initiation of the *Florida Citrus Exchange* case. That a more flexible position could reasonably have been taken by the Agency is indicated by the decision of the Court of Appeals for the Fifth Circuit in this same case, as well as by the decision of the Second Circuit in the related case of *Certified Color Industry v. Folsom.*[3] But a more flexible approach by the Agency in these two cases would not have enabled the FDA to broaden its scope of control over colors in general. And thus, an underlying cause of the enactment of the Color Additive Amendments becomes evident.

Underlying Cause

An underlying cause of the adoption of the Color Additive Amendments was that there was a broad range of non-coal-tar colors in use, in drugs and cosmetics particularly, for which no governmental preclearance as to safety was generally required. (In the case of foods, such colors were, since 1958, subject to the standards of the Food Additives Amendment and, in the case of new drugs, to the standards of safety called for by the new drug provisions of the Act.) In order, supposedly, to create more uniform regulation of the use of such coloring agents in general, and to establish more realistic standards governing the use of coal-tar colors in particular, and to permit the establishment of levels of tolerance for all colors, the Color Additive Amendments of 1960 were devised.

The Color Additive Amendments took a different tack from that which was followed in the food additives amendments two years earlier in that they did not utilize fully a concept bearing upon "general recognition of safety." Rather, under the Color Additive Amendments, a blanket requirement was imposed that only colors which were listed in regulations and used in accordance with the standards of such regulations were legitimate. Such a requirement had the supposedly incidental benefit of enabling a potential user of a color to check the list of regulations and ascertain if his contemplated use was permissible. In this manner, the Color Additive Amendments contained the potential benefit of eliminating the uncertainty of whether an unlisted item was or was not generally recognized as safe.

[3] ('56) 236 F. 2d 866.

In point of fact, however, the well known "gras" concept was not included in the Color Additive Amendments because the impact of the *Florida Citrus Exchange* decision compelled industry to support any legislation that would permit the continued use of coal-tar colors.

It was on July 12th of this year that the seventh anniversary of the enactment of the Color Additive Amendments took place. While there was no ceremony commemorating this date, it may be a lesson for the future to look back upon these past seven years in order to ascertain how the provisions of this legislation have functioned and whether they have served both the public interest and the needs of industry. Were these seven years of feast or were they ones of famine?

In order to assist in providing a smooth period of transition for producers of products containing coloring components, the Color Additive Amendments provided for "provisional listings" for colors that were in commercial use on the day preceding the enactment date of the legislation; that is, colors used on July 11, 1960. For all of such items, a period of two and one-half years was allotted which was intended for the purpose of obtaining and submitting data to the FDA on particular color additives which would enable the FDA to issue regulations concerning their continued use. Thus, it was anticipated that by January 1963 data would have been compiled and evaluated which would either justify the continued use of specific colors or restrict or prohibit such usage at particular levels in particular commodities. For any colors which might not have been listed in final regulations at the expiration of this two and one-half year period, authority was conferred upon the Secretary of Health, Education and Welfare to continue the provisional listings for an indefinite period, so long as such action was "consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to [the final] listing [of] such additive. . . ."

What is the status of the regulations, both provisional and final, today—seven years later?

Seven Years Later

In the case of foods, as of July 12, 1967, a total of 25 color additive regulations had been finally promulgated. Of these, 3 relate to the so-called "coal tar" colors for which batch certification had been previously required and is still required. Two of these three coal-

tar colors are restricted to uses in specified food items. Thus, Citrus Red No. 2 may be used only for "coloring the skins of [certain] oranges." The color "Orange B" may be used only "for coloring the casings or surfaces of frankfurters and sausages." It is only with respect to FD&C Yellow No. 5 that the coloring of foods generally was to have been permitted. But, because of the filing of objections to this regulation, its effectiveness was stayed on June 15, 1966, "pending a decision in this matter." No decision has yet been rendered. Consequently, the provisional listings for FD&C Yellow No. 5 still apply.

The remaining 22 food colors which have been finally listed in the regulations (one of which deals with "diluents" only), are exempt from the requirements of certification and include such exotic items as "fruit juice," "vegetable juice," "dehydrated beets (beet powder)," "caramel," "paprika," "turmeric" and "saffron," all of which themselves are foods. While general food coloring use has been authorized for each of the previously named colors, others, such as "dried algae meal," "tagetes" and "corn endosperm oil" have been cleared only for use in coloring chicken feed to "enhance the yellow color of chicken skins and egg yolks"; "grape skin extract" has been cleared for the "coloring of still and carbonated ades, beverage bases, and alcoholic beverages"; "ultramarine blue" has been cleared for "coloring salt intended for animal feed"; while "ferrous gluconate" has been cleared for "coloring ripe olives." Thus, in the final regulations relating to food coloring, there are but 15 colors for which general use is permitted, and of these, 3 have specified quantitative limitations imposed upon their levels of use.

In the case of drugs, where the concept of a "color additive" is a somewhat different one from that which applies to "foods" and "cosmetics," a total of 14 final regulations has been issued. Three of these pertain to coal-tar colors for which batch certification is required. Of these three, two are restricted to uses of a specified type. Thus, D&C Green 6 is limited to the coloring of certain surgical sutures only; D&C Red 39 is limited to the coloring of various germicidal solutions intended for external application only. The third, FD&C Yellow 5 was to have been authorized for use "for coloring ingested drugs generally, provided that not more than 30 mgs. of the color additive is consumed per day if the recommended dosage is followed." But, as stated previously, this regulation has been stayed due to the filing of objections.

The 11 other color additives which have been finally listed in regulations for drug use (one of which regulations covers only diluents) are all exempt from certification requirements. These regulations cover "synthetic iron oxide," "caramel," "annatto extract," "beta carotene," "titanium dioxide," "pyrophyllite," "carmine," "alumina," "calcium carbonate" and "talc." Of these, three (calcium carbonate, alumina, talc) are permitted to be used in drugs "generally." This presumably means that they may be used in both ingested an externally applied drugs, but not in drugs applied in the area of the eye, or in injectables. Five of the listed color additives (synthetic iron oxide, caramel, titanium dioxide, pyrophyllite and carmine) may be used in externally applied drugs, six may be used in ingested drugs (synthetic iron oxide, caramel, annatto, B-carotene, titanium dioxide and carmine), and one, titanium dioxide, may be used in drugs applied in the area of the eyes. No color additive whatever has been finally listed for use in injectable drugs. It is important to note, however, that, in the case of drugs, a substance is a "color additive" only if it is used solely for the purpose of coloring, whereas, in the case of foods and cosmetics, unless specifically exempted by regulation, a substance is a color additive if it imparts color, regardless of the fact that it may serve another function as well.

With respect to cosmetics, only a single color additive regulation has been issued in final form. This regulation applies to "henna," which has been exempted from the certification requirement, but is permitted in use "for coloring hair only." The limited application of this regulation of itself has some uncertain aspects from a legal point of view, since the concept of color additive clearance for cosmetics, under the relevant statutory provisions, does not apply to hair dyes. (See Sections 601(e) and 602(e).) Consequently, this regulation may be not only unnecessary but also unauthorized. Certainly, there is a marked difference in the number of final regulations which have been issued for color additives in foods and drugs and the single one (possibly of dubious validity) that has been issued for cosmetics. There is an explanation, which I will come to shortly, of why this difference exists.

With reference to provisional listings of color additives, most of the coal-tar colors which were certified under the original provision of the Act continue to be available for cosmetic use, albeit some are now restricted to specific usages, such as in lipsticks, mouth washes or dentifrices.

Paucity of Final Regulations

Now, why has there been such a paucity of final regulations for cosmetics? Perhaps the most important single element is that, when the basic definitional, procedural, and interpretative regulations relating to color additives were published in June 1963, they contained a provision which classified as color additives "lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body. . . ." This provision created a furor, which has not yet abated or been finally resolved, because throughout the substantial period of time during which the amendments had been considered in Congress, there was no indication whatever that finished cosmetic products would of themselves be subject to classification as color additives. Rather, the commonly shared thought was that only the ingredients used in such products for the purpose of giving color were to be subjected. Because of the construction which the Food and Drug Administration imposed upon the concept of "color additives," so as to have it include finished cosmetic products, the Toilet Goods Association, together with many individual members of the cosmetic industry, instituted an action in the federal courts seeking to declare those portions of the regulations applicable to finished cosmetics illlegal because they exceeded the statutory authority.

While litigation relating to these regulations has already been before the Supreme Court and the Court has handed down a decision, there has not yet been a determination concerning the legality of the regulations. Rather, that which has been resolved thus far deals only with whether the regulations are subject to judicial review. With respect to all but one portion of the regulations for which review was sought, the Supreme Court has stated that judicial review may be obtained without awaiting FDA action based upon noncompliance with the regulations. In other words, the Supreme Court has stated that, with respect to most of the regulations, a cosmetic manufacturer need not wait until the government has seized his products, sought to enjoin him, or instituted a criminal prosecution against him before he can challenge the validity of the regulations. While such a pronouncement by the court helps mark previously uncertain pathways in administrative law, it does not at all pass upon the validity of the underlying regulations. Such a determination is now in the process of being made, although there are prospects that no clear conclusion will be reached because of new legislation.

Notwithstanding the fact that only one final color additive regulation has been issued for cosmetics in the seven years since enactment of the Color Additive Amendments, there has been no paucity in the availability of cosmetic preparations. At the same time, no episode has occurred which has in any manner indicated that the public safety is in any jeopardy whatever as a result of the presence of color additives, or any other ingredients, used in cosmetics.

A critical review of the history of the Color Additive Amendments during the seven year period since they were enacted shows, however, little positive accomplishment. Several coal-tar colors that were certifiable prior to the passage of the Amendments, when a supposedly absolute standard of safety applied, have been withdrawn from eligibility for use or have had restrictive regulations applied to their continued use. However, with reference to non-coal-tar colors, which had never been subject to any governmental preclearance program whatever, no problems with respect to their safety in use have come to the attention of the FDA. Thus, there is a somewhat anomalous situation in that, insofar as cosmetics are concerned, safety questions have arisen only for coloring agents which have previously passed muster under the certification provisions of the original Act.

Is Governmental Clearance Necessary?

Does not this fact of itself raise a question as to the real necessity for and value of governmental preclearance of color additives in cosmetics? Does not this fact disclose, in effect, that cosmetic manufacturers have exercised care and good judgment in their selection of coloring agents and cosmetic ingredients in general and have, through their own sense of responsibility, taken adequate precautions to assure that their products are in fact safe for their intended uses? Does this not raise the question "Was this broad expansion of the prior legislation really necessary?"

While the history of the Color Additive Amendments, particularly as they apply to coloring agents used in cosmetics, does raise, in my opinion, serious questions with respect to the need for this legislation it would be foolish for anyone to consider seriously a move to repeal the Amendments. Once legislation of a stringent nature has been adopted, particularly in areas where the enhancement of "public safety" has been used as a main argument in its favor, it is an almost impossible task to change that legislation so as to make it

less restrictive. There is no need to detail the type of hue and cry that would be raised were such an attempt to be made.

But there is another aspect to the question which may warrant genuine consideration. While the repeal of existing legislation may be nigh impossible to obtain, may it not be possible to avoid the enactment of additional legislation which may, by act of Congress rather than administrative fiat, seek to subject cosmetics to further control by way of governmental preclearance? Is such prospective legislation necessary? Is it desirable? Would the enactment and, more importantly, the administration of such legislation truly enhance the public safety? On the basis of the record as it has been established over the course of the past seven years and more, I submit that the answer is "No."

Let us examine the record, to ascertain what safety problems, if any, have arisen over the course of the past several years for cosmetics generally, so as to indicate whether any additional federal control over these commodities is necessary. While my investigation into this record has not been exhaustive, it appears that there have been but two events involving cosmetic preparations which have raised a question of "safety." The first of these involved the marketing of a "press on" nail polish which, when worn for a significant period of time caused damage to, and sometimes loss of, fingernails. The second involved a neutralizer used in a hair wave preparation. This agent apparently had some anesthetizing effect and, if it accidentally entered the eyes, it caused a severe burning sensation which, though of a reversible nature, was not what the consumer sought. Both of these problems, it appears, could have been readily ascertained and avoided if appropriate pre-testing had utilized the conditions under which the products were intended to be used. Certainly, there is no question but that, if government preclearance of cosmetics had been required, such tests would have had to be conducted and the problems would probably have been avoided. But is that fact of itself sufficient reason to urge that all cosmetics must be subjected to a governmental preclearance program? Considering the thousands of cosmetics on the market today and the extremely low incidence of safety problems associated with them, even taking into consideration "allergic reactions," it appears fair to say that the incidence of problems associated with cosmetics has been less than those associated with drugs and food additives which have cleared the government's preclearance procedures. Thus, there have been several "new drugs" which, having undergone governmental pre-

clearance initially, have been subsequently found to be wanting with respect to the standards of safety imposed upon them. In the case of food additives, there has been at least one group of substances for which final clearance was issued but later revoked because "questions have been raised concerning the safety of the compounds." (Cobaltous salts, 21 CFR 121.1142, 31 F.R. 9008, 10744.)

From this brief comparison of the record between the safety of governmentally non-cleared cosmetics on the one hand and that of precleared new drugs and food additives on the other, it appears that no real distinction exists. That is, the record of the safety of cosmetics is at least as good as the record of the safety of approved new drugs and authorized food additives. Does this not of itself indicate that there is really no demonstrable need for additional legislation which would subject cosmetics generally to a governmental preclearance program? Has not the cosmetic industry itself performed as satisfactorily as can be expected without further extending the role of government in its activities? Perhaps if governmental surveillance of itself were synonymous with the attainment of perfection, valid-sounding arguments could be made for advocating preclearance legislation for cosmetics. But the fact that governmental participation in activities exists, of itself provides no assurance that greater protection will be accomplished than has taken place without such participation. Sometimes, it appears to provide even less protection.

Conclusion

If there is a lesson to be learned from the seven year history of the Color Additive Amendments, it might be that the naked letter of the law guarantees nothing. The law is merely an instrumentality which takes meaning from its implementation and administration. In the case of the Color Additive Amendments, it is questionable at best as to whether their enactment and past administration have enhanced the public safety to any degree. Neither feast nor famine has prevailed. Rather, but for one event, there may very well have been a period of waste. That event is that industry members and their trade association had sufficient fortitude to face up to and oppose what they regarded as an unreasonable and unjustified construction of the concept of a "color additive." Perhaps this event of itself is of sufficient importance to conclude that some public good has come about as a result of the enactment of the Color Additive Amendments of 1960. **[The End]**

FDA's Obligations Under the 1966 Public Information Act

By JOSEPH M. MAMANA

The Following Article Is Reprinted from the *FDA Papers* (September 1967, p. 16). Mr. Mamana Is With the Office of Policy Management.

Knowledge will forever govern ignorance and a people who mean to be their own governors must arm themselves with the power knowledge gives. A popular government without popular information or the means of acquiring it, is but a prologue to a farce or a tragedy or perhaps both. James Madison

THE "FREEDOM OF INFORMATION ACT," PUBLIC LAW 89-487, was signed by President Johnson on July 4, 1966, and became effective July 4, 1967. It amended Section 3 of the Administrative Procedure Act and is known as the Public Information Act of 1966. Under this legislation, executive agencies are required to adopt new guidelines for publication and disclosure of information under their dominion and control. Public Law 89-487 has precipitated in the Food and Drug Administration (FDA) a critical and searching examination of its past disclosure policies and practices.

The report of the Senate Committee on the Judiciary found the following deficiencies in the Administrative Procedure Act before amendment:

> Section 3 of the Administrative Procedure Act, that section which this bill would amend, is full of loopholes which allow agencies to deny legitimate information to the public. Innumerable times it appears that information is withheld only to cover up embarrassing mistakes or irregularities and the withholding justified by such phrases in Section 3 of the Administrative Procedure Act as "requiring secrecy in the public interest," or "required for good cause to be held confidential."

The Senate report goes on to state that it is the purpose of this amendment "to establish a general policy of full agency disclosure" to be tempered by exemptions stated in "clearly delineated statutory

language." Specifically, subsection (e) of Public Law 89-487 sets out nine exemptions to the "full agency disclosure" concept of the amendment. These exemptions cover a wide variety of records and situations common to the daily activities of most regulatory agencies.

Regulations published in the *Federal Register* on June 30, 1967, attempted to accomplish two FDA goals: an informed public through "full agency disclosure," and the protection of private and individual interests through proper application of the exemptions contained in Public Law 89-487. When President Johnson signed the bill on July 4, 1966, he said,

> I know that the sponsors of this bill recognize these important interests and intend to provide for both the need of the public for access to information and the need of Government to protect certain categories of information. Both are vital to the welfare of our people.

Much has been written by the press in recent months about the implementation of the "Freedom of Information" law. Some writers expressed concern that the exemptions would be used and interpreted in such a way as to avoid "full agency disclosure." One writer feared "that the nine exemptions might be turned into sweepingly rigid new excuses for the same old practices."

On the other hand, representatives of regulated industry have also voiced concern. Some feared that FDA would modify its long-established policy "of maintaining the confidentiality of most of the materials contained in New Drug Applications as well as similar data obtained from other sources."

With these opposing positions in mind, FDA has attempted to satisfy all interests concerned, and, at the same time, fulfill the intent of the statute.

To a large extent, the disclosure of industry information and data under FDA's control is restricted by the exemptions in subsection (e). Of the nine exemptions, (2) through (7) are most pertinent to FDA.

Exemptions (2) Through (7) Under Subsection (e)

Exemption (2) applies primarily to FDA's internal operations. It exempts from disclosure matters "related solely to the internal personnel rules and practices of any agency." The House report of the Committee on Government Operations included in this category "operating rules, guidelines, and manuals of procedure for Government investigators or examiners. . . ."

Department Regulation 5.72 includes guidelines and instructions relating to tolerances, selection of cases, and quantums of proof. In FDA's situation, this would include internal documents, such as regu-

latory procedures, program guidelines to District Directors, Bureau guidelines, work plans, and any other internal instructions which cannot be disclosed to the public without prejudicing regulatory functions.

Personnel instructions for an administrative management nature, such as work hours, leave rules, and promotion plans, are being disclosed.

Exemption (3) exempts from disclosure matters which are "specifically exempted from disclosure by statute." This exemption includes Sec. 301 (j) of the Federal Food, Drug and Cosmetic Act. This section prohibits:

> The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of sections 404, 409, 505, 506, 507, 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

The restriction against disclosure of trade secret information to the public or for personal gain under 301 (j) still prevails. Therefore, any method or process which is a trade secret submitted in a New Drug Application under section 505 cannot be disclosed under Public Law 89-487. The same applies to a trade secret obtained during the course of an inspection under section 704.

The House report indicates that exemption (3) was intended to continue such statutory restrictions: "There are nearly 100 statutes or parts of statutes which restrict public access to specific Government records. These would not be modified by the public records provisions of S. 1160."

Closely related to exemption (3) is exemption (4). It exempts from disclosure "trade secrets and commercial or financial information obtained from any person and privileged or confidential." Exemption (4) would include any trade secrets obtained by FDA through other means and for other purposes than those cited in 301 (j). The House report states:

> This exemption would assure the confidentiality of information obtained by the Government through questionnaires or through material submitted and disclosures made in procedures such as the mediation of labor-management controversies. It exempts such material if it would not customarily be made public by the person from whom it was obtained by the Government.

The House report also includes under exemption (4), "information customarily subject to the doctor-patient, lawyer-client, or lender-borrower privileges. . . ."

One example of the doctor-patient privilege, which has been honored in the past by FDA, is the nondisclosure of reports of adverse drug reactions received from the medical profession, hospitals, and drug

manufacturers. The raw data sometimes include the names of patients, physicians, and personal information about the patient which is not disclosed. However, the analysis and conclusions from such data can be of public health importance and are published by FDA when the need arises.

Department Regulation 5.74 recognizes under exemption (4) that information "obtained from any person under an explicit or implicit pledge of confidentiality" is also exempt from disclosure. It also recognizes the "Government-informer" privilege which is an important aspect of investigations by the Bureau of Drug Abuse Control (BDAC).

Exemption (5) exempts from disclosure matters in "inter-agency or intra-agency memorandums or letters which would not be available by law to a private party in litigation with the agency."

The purpose of this exemption is to permit the internal exchange of ideas and communications within FDA, without fear of criticism before an official position is adopted. Such premature criticism or pressure can have an inhibiting effect on the decision-making processes of the Agency. The House report contains the following comments in reference to this exemption:

> Agency witnesses argued that a full and frank exchange of opinions would be impossible if all internal communications were made public. They contended, and with merit, that advice from staff assistants and the exchange of ideas among agency personnel would not be completely frank if they were forced to "operate in a fishbowl."

This exemption is most important in instances where FDA enforcement officials differ on the course of legal action to be taken in a given case. Other areas of possible internal disagreement are governed by exemption (5), such as the need for a new regulation, or the recommendation that a present enforcement policy be changed because circumstances in industry have changed. Staff papers and recommendations prepared by outside consultants for the purpose of supporting FDA regulatory activities would also come under this exemption.

Exemption (6) exempts from disclosure "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

This exemption includes such data as clinical information submitted by investigators of Investigational New Drugs (INDs), including the details of the patients' personal histories; the training, experience, and qualifications of the IND investigators; and, in the case of prescription drug establishment inspections, the qualifications of technical and professional personnel.

The House report indicates that this exemption provides

> a proper balance between the protection of an individual's right of privacy and the preservation of the public's right to Government information by excluding those kinds of files the disclosure of which might harm the individual.

Exemption (7) provides for nondisclosure of "investigatory files compiled for law enforcement purposes except to the extent available by law to a private party." Most of FDA's enforcement files and records are exempt from public disclosure under this subsection. These include records and files pertaining to factory inspections, sample collections, sample analyses, surveillance reports, warning letters, notices of hearing issued under 21 U. S. C. 335 and the responses thereto, BDAC investigations and audit reports, and all other investigatory records developed prior to termination of actions in court. The Senate report explains exemption (7) as follows:

> These are the files prepared by Government agencies to prosecute law violators. Their disclosure of such files, except to the extent they are available by law to a private party, could harm the Government's case in court.

It is also reasonable to conclude that the indiscriminate distribution of FDA investigative files to the public would result in a carte blanche interpretation of the facts contained in such files. This would not be in keeping with the principles of fair play and justice to those regulated.

When considering the nature of the information in many agency files in conjunction with the information and records included under the exemptions, FDA concluded that much of the information obtained from industry and private sources is still restricted as to disclosure. In this respect, Public Law 89-487 reaffirms FDA's previous practice of restricting the disclosure of privileged information.

FDA Information Center

Prior to the passage of Public Law 89-487, FDA sought to establish an information distribution capability. The purpose of this capability was the dissemination of information which was not available to the public only because FDA manpower was lacking to gather it together. FDA now has this capability

The FDA Information Center was estblished in Department Regulation 5.31. The Information Center facilities are located on the first floor of Federal Office Building No. 8, 200 C Street, S.W., Washington, D.C. 20204. Phone: 963-7161. Miss Dorothy H. Koegler, on the staff of the Office of the Assistant Commissioner for Education and Information, has been designated Information Center Officer. Miss Koegler is responsible for determining the propriety of requests for FDA information.

The FDA Information Center is open to the public on regular workdays between the hours of 9 a.m. and 5:30 p.m. Those materials which are readily available may be reviewed and copied at the Center. Some of the materials available include the *Federal Register, Code of Federal Regulations*, precedent opinions and orders subsequent to July 4, 1967, staff manuals, program manuals, statements of policy and interpretations issued or adopted after July 4, 1967, which have not been otherwise published, and current indices of the foregoing materials.

Requests for information or records can be made on Request For Records Form, FD-2138. These forms are available at all District offices and the Washington Information Center. Completed forms should be submitted to the FDA Information Center in Washington, D.C. Instructions on how to complete the Request For Records Form and fee schedules for photocopying reproduction and search services are included on the form itself.

In the past, FDA maintained, whenever possible, an open-door policy in relation to the press, the public, and industry. As a regulatory agency, FDA has a responsibility for the public health. The public has a right to know what FDA is doing on their behalf. At the same time, FDA recognizes its obligation to be responsive to the needs of the industries we regulate. One of these needs is the protection of valuable information, such as trade secrets.

Accordingly, the policy of the FDA will continue to be directed toward the satisfaction of both these interests. **[The End]**

RALPH BERNSTEIN APPOINTED A REGIONAL ASSISTANT COMMISSIONER

Ralph Bernstein, President of the Association of Food and Drug Officials of the United States, has been appointed a Regional Assistant Commissioner of the Food and Drug Administration. Mr. Bernstein, an employee of the New York State Department of Agriculture and Markets for more than 30 years, will serve in the New York City Regional Office of the Department of Health, Education and Welfare.

BOOK REVIEW

Use of Human Subjects in Safety Evaluation of Food Chemicals: Proceedings of a Conference. NAS/NRC Publication 1491: 1967(vii). 273 pages. NAS Printing & Publishing Office, 2101 Constitution Avenue, Washington, D. C. 20418. $5.00. Reviewed by Franklin M. Depew.

This new NAS publication is a report of a conference jointly sponsored by the National Academy of Sciences — National Research Council Food Protection Committee and The Food and Drug Law Institute held on November 29-30, 1966. The conference was called because it was felt that while there is a great deal of information about the use of humans in drug testing, there is at present little published material on the use of humans in evaluating the safety of food chemicals.

The participants were selected, and the general outline of the conference was defined, by a planning committee comprised of Dr. William J. Darby, Chairman, and Dr. R. Keith Cannon, Franklin M. Depew, Esq., Dr. Richard L. Hall, Kenneth E. Mulford, Esq., Dr. Maxwell Finland and Dr. W. H. Sebrell, Jr.

The problems inherent in and arising from such testing were discussed in depth in their varying aspects by physicians, medical scientists, lawyers, administrators, chemical and drug manufacturers, philosophers and theologians. The scope of the ground covered by the conference is apparent from the general areas that were discussed, namely, the benefits and usefulness of food chemicals, the usefulness of studies in man to evaluate the safety of food chemicals and the legal, ethical, moral and philosophical aspects of using humans in tests of this nature.

This conference made a valuable contribution to the field of knowledge in this area in that it has set the stage for further and more specific discussion out of which may come a set of guidelines for future experiments in this field.

This compilation of the conference papers and discussions should prove most useful to everyone engaged in the production and distribution of food products. The speakers, whether moral philosophers, theologians or experimental scientists, were unanimous in their views that there was a need for experimenting with humans in order to properly evaluate the safety of food chemicals and that such experiments were morally justified. However, the moral and legal difficulties involved in such testing were not overlooked.

Drs. Arthur J. Dyck and Herbert W. Richardson, of Harvard University, pointed out that the use of human

subjects in research that involves some risk is not only morally justifiable, but, in certain instances, morally required. Two kinds of consideration led to this conclusion: the limitation of research with animals, and the stringent moral demand to alleviate or eradicate human suffering. They pointed out that until much more about species differences and similarities is known, clinical research that establishes sound medical practice will have to rely upon the knowledge gleaned from the reactions of human subjects. In addition, whenever the use of certain food additives and environmental toxins is considered to be morally desirable, it will be necessary to establish safety levels for their use. In certain cases, these safety levels can only be established by using human subjects under carefully controlled test conditions.

Rabbi Abraham Shusterman pointed out that it would be folly to let all other types of investigation, such as space probes, continue, while condemning the one type of investigation which is for the purpose of feeding the hungry and relieving the distressed.

Dr. James L. Goddard, Commissioner of Food and Drugs, pointed out that the laws and regulations governing the introduction of new drugs into the American marketplace follow the logic of, first, animal work, and next, human work, when warranted. However, the testing process for food additives is not that clear. He said that currently the Food and Drug Administration's decisions on food additives and pesticides are based almost entirely upon animal data. From this he concluded that the decision-making process is not fully adequate to the objective: safety for use in man.

Alvin L. Gottlieb, Esq., of the Legal Division of the Department of Health, Education and Welfare, pointed out that to permit a chemical to enter our nation's food supply in the face of uncertainty concerning its effects on man is an invitation to disaster. Once it is entrenched in our diet, the prospect of isolating it from the many other factors in our environment and identifying it as the culprit doing damage is extremely difficult. He concluded that if the use of a chemical is important enough, and if it becomes necessary to resolve equivocating tests on other animals, carefully controlled and supervised tests on the human animal must be considered appropriate.

Dr. Alastair C. Frazer of the University of Birmingham, England, proposed certain criteria to be met before studies on human subjects should be permitted. These criteria are:

1. The information sought should be needed in the interests of the community or for the benefit of the individual receiving the substance or those with similar medical problems.

2. The information should not be readily obtainable by any other means.

3. The potential risks arising from the administration of the substance, or from the methods used for investigating the effects of the substance, should have been adequately defined by previous animal studies.

4. The potential risks should have been fully explained and adequately understood by the human subjects taking part in the investigation and, where appropriate, by legal guardians or dependents.

5. The effects to be studied should be clearly defined, whether they be wanted or unwanted effects, and appropriate methods for the assessment of these effects should be available.

6. Only those effects that have been shown to be reversible in animal studies and that would give rise to no serious permanent damage should be studied.

7. The human subject under investigation should retain a continued power of veto throughout the study, and a similar power of veto should be accorded to an objective supervisory body.

Dr. Irving Ladimer expanded on the understanding which must be reached under item 4 of Dr. Frazer's criteria. Dr. Ladimer called this an informed consent, which is not a different, but simply the intensive expression of the concept of an understanding freely and intelligently shared which is required when a person is engaged for research purposes. He said:

> Where novelty and investigation are paramount, benefit is minimal or incidental, and certainly where these are coupled with risk and possible injury, both law and morality insist upon clear and express discussion with the right to choose specifically understood by all concerned.

Crawford Morris, Esq. had this to say about consent:

> The rationale of the law is simple. Be fair to the patient. It is his body. He is the one who undergoes the pain and suffering if a bad result occurs. Give him the sporting chance to choose his own risks. Do not play God with his body. Let him choose for himself.

Dr. Frederick Coulston of Albany Medical College thought that the prospective subjects must be as fully informed about the dangers and discomforts possibly inherent in the experiment as is possible without compromising the results of the experiment. Each subject must be informed at the start of the experiment and from time to time thereafter that he is perfectly free to discontinue his participation at any time, and no reward or compensation should be given which would be sufficient to influence him to continue the experiment despite other reasons to the contrary.

Dr. Robert M. Kark of Chicago's Presbyterian-St. Luke's Hospital spoke of the value of and need for surveillance committees. They are needed for two reasons beyond protecting the patient: to encourage the investigator and the investigations, and to educate not only the investigator and the subjects, but the public.

Dr. Samuel E. Stumpf of Vanderbilt University, in his Critique and Summary, pointed out the limitations inherent in securing a truly informed consent to carry out investigations on a human when he said:

> There are a great many problems with this. One logical problem is this: an experiment is an experiment because you do not know what is going to happen. You cannot ask somebody to consent to something that you do not know will happen.

He summarized the remarks at the meeting in the following words:

> There has been great agreement on the fact that in the last analysis our best safeguards are not specific codes and a great deal of red tape, but a careful extrapolation of the basic convictions that men should be ends in themselves, persons and not things, that we should test our acts by the law of reciprocity, and that there should be an appropriate relation between individual and collective values.

Appended to Mr. Morris' remarks are citations to the cases in this field, together with a bibliography of codes and principles. **[The End]**

FDA's New Computer

By E. R. LANNON

The Following Article Is Reprinted from the *FDA Papers* (October 1967, p. 4). Mr. Lannon Is Assistant Commissioner for Administration.

IN AUGUST, DEPUTY COMMISSIONER WINTON B. RANKIN cut the white ribbon dedicating a new computer system which will help the Food and Drug Administration (FDA) untangle a lot of red tape.

Since 1962, when the Office of the Secretary obtained a computer, FDA has been competing for data processing time with sister agencies of the Department of Health, Education, and Welfare (HEW). While the FDA's needs were the major justification for the departmental computer installation in 1962, over the years other demands —such as the HEW payroll—left insufficient time for FDA programs.

The problem was compounded because of the many new responsibilities given to FDA through legislation enacted during this 5-year period. Fundamental to most of this legislation was the implied need for gathering, storing, and retrieving information.

In September 1966, the Secretary authorized FDA to issue specifications for a data processing system to meet the Agency's needs. The specifications called for the processing speed and memory capacity of a third generation computer. Through the competitive bidding process, an IBM 360-30 system was selected and installed in a special facility at 200 C Street, S.W.

While the site was prepared and the equipment installed, FDA programmers were making the adjustments necessary to move on-going programs from the Department's and other computers. The switch has been made and FDA is now processing the following programs:

NDA Status—Semiweekly, or on request, status report of every New Drug Application in progress.

Clinical Investigators—Periodic reports listing name, address of investigators, and the IND's and/or NDA's associated with them.

Adverse Reactions—Data accumulating and analyzing information from the drug experience reporting system.

Kaiser Permanente—Data on patient history, diagnosis, and treatment, including drug therapy, under contract program with Kaiser Permanente.

Pharmacology—Toxicological data from FDA's research programs evaluating animal reactions to compounds.

Established Intelligence — Accountability information from firms and individuals producing and handling controlled drugs.

Drug Firm Registration—Name, address, classification, and principal products of firms required to register with FDA. Program can be used to check compliance history.

Recall Monitoring—A history of each recall action.

Pesticide Samples—History of food samples examined and residue level.

PPBS—Accumulation of FDA's data base to operate the Agency's Planning-Programming-Budgeting System.

Other programs are in development, and the Agency's plans contemplate far greater utilization of data processing. In fact, the work-load anticipated by February 1968 requires an additional printer. The present site is designed to accommodate additional modifications to the system at minimum cost.

FDA is also planning to link the 17 District Offices to the computer through a telecommunications net-work. This system would permit a District to transmit data over telephone lines directly to storage or tape, and to receive a printed report of the information requested. Such a system would replace the present procedure requiring the District to mail magnetic or punched paper tape at monthly intervals. **[The End]**

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