RELATIONS WITH OTHER AGENCIES

Working Agreement Between FTC and Food and Drug Administration

[¶ 9850]

(Prepared by the Secretary of the Department of Health, Education, and Welfare and the Chairman of the Federal Trade Commission, approved June 9, 1954.)

[¶ 9850.01] [FTC's Jurisdiction Compared with Food and Drug Administration's Jurisdiction]

The Food and Drug Administration of the Department of Health, Education, and Welfare is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act. This Act makes illegal any article of food, drug, device or cosmetic that is adulterated or misbranded while introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce. When the surveillance and investigative work of the Food and Drug Administration discloses a violation of the statute the facts are reported to the Department of Justice with a recommendation for seizure, criminal prosecution, or injunction actions in the Federal courts. Under the provisions of the statute each of the four commodities dealt with is deemed to be misbranded "if its labeling is false or misleading in any particular." In addition to this general misbranding provision, the Federal Food, Drug, and Cosmetic Act also defines a number of other circumstances under which a food, drug, device or cosmetic shall be deemed to be misbranded—some of these definitions of misbranding being applicable solely to foods, drugs, devices or cosmetics as the case may be. Among the definitions of misbranding specific to drugs or devices is the requirement that the labeling of these articles bear (1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

The Federal Trade Commission enforces the Federal Trade Commission Act which prohibits unfair competition and unfair or deceptive acts and practices in commerce. The Wheeler-Lea Amendment to the Federal Trade Commission Act specifically declared the false advertisement of food, drugs, devices or cosmetics to be an unfair or deceptive act or practice. This amendment defined the term "false advertisement" as applied to food, drugs, devices and cosmetics as meaning an advertisement, other than labeling, which is misleading in a material respect and provides that in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity.

The two agencies have a common objective of preventing deception of the public through the misrepresentation of food, drugs, devices or cosmetics. The Food and Drug Administration strives to prevent misrepresentation of these commodities by means of false or misleading statements made in labeling or by the omission of certain required information from the labeling.

The Federal Trade Commission strives to prevent the misrepresentation of these four commodities through the use of false or misleading statements in advertisements or the omission of certain necessary statements from advertising. The definition of a false advertisement of a food, drug, device or cosmetic contained in Section 15 of the Federal Trade Commission Act specifically excludes labeling. The definition of labeling in the Federal Food, Drug, and Cosmetic Act includes written, printed or graphic matter which accompanies a food, drug, device or cosmetic and by regulation this includes such matter accompanying an article while it is in interstate commerce or while held for sale after shipment or delivery in interstate commerce. Written, printed or graphic matter descriptive of a food, drug, device or cosmetic may at one time be used as advertising and at another time accompany the article and thereby become labeling.

The requirement of the Federal Food, Drug, and Cosmetic Act that drugs or devices bear adequate directions for use has been judicially interpreted as including directions for the use of the drug or device for the purposes for which it is prescribed, recommended or suggested in advertising.

[¶ 9850.02] [Liaison Between FTC and Food and Drug Administration]

While the responsibilities of the two agencies thus are closely related in many respects, significant differences in procedure and in nature and effect of sanctions are inherent in the statutes and regulations governing the two agencies. The close relationship of the objectives of the two agencies in the respects outlined herein, however, is now recognized as requiring a more effective liaison for the purpose of eliminating any duplication of effort and resulting waste.

In order to provide for exchange of complete information so that both agencies will be utilized to the maximum effectiveness in the public interest, each agency will designate a liaison officer to serve as the primary source of contact. These liaison officers will be responsible for currently informing each other of proposed proceedings within the below-described area to effectuate the purposes of this agreement.

At all times and to every extent possible each agency will furnish information to the other prior to the expenditure of time and effort for investigation or other steps preliminary to specific regulatory action. The liaison will be directed to correlating the work of the two agencies, the elimination of duplication of effort in individual cases, promoting uniformity and consistency in handling matters throughout those areas which are of mutual interest and recommending to higher authority the adoption of policies which will further promote uniformity of actions and enforcement of law in the public interest.

[¶ 9850.03] [Primary Responsibilities; Sole Jurisdiction; Duplication of Proceedings]

It is agreed that

(1) The Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise sole jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs, devices, and cosmetics;

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(2) The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise sole jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics;

(3) The initiation of proceedings involving the same parties by both agencies simultaneously shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings. For the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other, it is recognized that such liaison activity is required,

In instances where:

(a) The same or similar claims are found in both labeling and advertising;

(b) written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution;

(c) the article is a drug or device and appears to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

Updated FTC-FDA Liaison Agreement—Advertising of Over-the-Counter Drugs

[¶ 9851]

(Issued September 9, 1971; approved by the Commissioner of Food and Drugs, April 27, 1971 and the Chairman of the Federal Trade Commission, May 14, 1971.)

I. Purpose:

a. It is agreed that the common objective of preventing injury and deception of the consumer requires that the statutory authorities and procedures, and the manpower and other resources available to each agency are so employed as to afford maximum protection to the consumer. This means joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law, by the staffs of both agencies in appropriate undertakings and the careful selection of the procedure of either agency (or simultaneously by both) promising greatest benefit to the public.

b. In order to provide for exchange of complete information so that both agencies will be utilized to the maximum effectiveness in the public interest, each agency will designate a liaison officer to serve as the primary source of contact. These liaison officers will be responsible for currently informing each other of proposed proceedings and of internal developments in areas of joint concern to the extent that such information is not privileged.

II. Designated liaison officers.

a. *Federal Trade Commission.* The Assistant to the General Counsel of the Federal Trade Commission.

b. *Food and Drug Administration.* The Associate Commissioner for Compliance of the Food and Drug Administration.