UNITED STATES DEPARTMENT OF AGRICULTURE

CONTINUING CONSUMER PROTECTION AT FDA

Talk by Kate Stahl
Coordinator of Consumer Services, Food and Drug Administration
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We in the Food and Drug Administration are pleased to share in your 45th Agricultural Outlook Conference.

During this particular session, recent legislation and ongoing programs in consumer protection will be discussed. If you are interested in the "outlook" for more consumer protection legislation, you need only look for offending practices in your environment. When public sentiment mounts against a particular practice--and if the offenders do not do their own housecleaning--there is a good prospect that restraining laws will be enacted. For example, consider some of the measures to protect the consumer which the President has recommended--truth-in-lending and pre-marketing clearance of certain medical devices. Agencies such as FDA come into being because society knows how to protect its interests.

As for recent legislation and FDA: the 89th Congress in 1966 gave us new regulatory responsibilities for foods, drugs, devices, and cosmetics under the Fair Packaging and Labeling Act. The same Congress expanded our authority over household chemicals and other products which may endanger children by enacting the Child Protection Act of 1966. We have also just completed the first year of work resulting from the 1965 Drug Abuse Control Amendments to the Federal Food, Drug, and Cosmetic Act. These amendments give us added responsibility to control the misuse of such drugs as stimulants, depressants, and hallucinogens.

Many provisions of the Fair Packaging and Labeling Act, as assigned to FDA, parallel provisions of the Food, Drug, and Cosmetic Act. The laws are complementary and not contradictory. Thus we realized that regulations for the enforcement of each Act must not be contradictory either. We felt that an integrated body of regulations for packaging and labeling under both laws would be the surest way of avoiding contradiction, and would provide industry with the clearest guide to compliance. Because penalties for violating the Food, Drug, and Cosmetic Act may be more severe than those imposed under Fair Packaging, we spelled out which regulations were issued under the packaging act alone.

Labeling for a drug product, of course, must have different kinds of information than that for a cosmetic. Packaging practices are quite different too--compare a lipstick with a bottle of aspirin. So FDA has been writing separate regulations for each class of commodities--for foods, for cosmetics, and for over-the-counter drugs and devices.

We think the final regulations for food packaging and labeling, and those now proposed for cosmetics, drugs and devices make no unreasonable demands on industry, but at the same time are responsive to consumer needs. Assessment of their worth may have to wait until July 1968 when all food packages must comply with the regulations unless granted specific extensions.

The new food labeling regulations add to the definitions of terms appearing in the Food, Drug, and Cosmetic Act. For example, "label" means any display of written, printed, or graphic matter on the immediate container of any consumer commodity, affixed to any consumer commodity, or affixed to any package containing a consumer commodity.

We have now defined "package" to mean any container or wrapping in which a consumer commodity is enclosed for delivery to retail purchasers. Transparent wrappers which do not obscure the required label information appearing on an inner wrapper, and certain shipping or display containers, are excluded from this definition.

I think an important new definition is that of "principal display panel." The principal display panel of a food package means that part of a label that is most likely to be shown or examined under customary conditions of display for retail sale. The area of the principal display panel is also defined:

1. For rectangular packages, the area of the principal display panel is the product of the height times the width of the side most likely to be displayed.

2. For cylindrical or nearly cylindrical packages, the area is 40 percent of the product of the height times the circumference.

3. For packages of other shapes, the area is 40 percent of the total surface. However, when such containers present an obvious principal display panel, as does the top of a triangular or circular package of cheese, the area of the principal display panel is the entire top surface.

The law requires that the net quantity of contents must be separately and accurately stated at a uniform location on the principal display panel. Our regulations define the uniform location as the lower 30 percent of the principal display panel. The contents statement must be in boldface type in lines generally parallel to the base of the package; in a type size determined by the area of the principal display panel; and in distinct contrast to its background and separated from any other printed label information. So that the contents declaration will be of uniform size for packages of substantially the same size, regulations were established for five minimum type sizes.

For packages 5 square inches or less---------- 1/16 inch in height
Over 5 square inches but less than 25 ---------- 1/8 inch in height
Over 25 square inches but less than 100 ---------- 3/16 inch in height
Over 100 square inches but less than 400 ---------- 1/4 inch in height
Over 400 square inches ---------- 1/2 inch in height

The quantity statement is expressed in terms of fluid measure if the food is a liquid; in terms of dry weight if solid, or a mixture of solid and liquid.

The net contents declaration must also be an accurate statement of the quantity of food contained in the package. For example, it should not include the weight of any packaging material. However, the amount of propellant in a food designed for use under pressure...instant whipped cream...may be included in the net contents. The regulations also spell out the appropriate temperatures at which frozen foods, refrigerated foods, and other foods are to be measured. Ice cream would be weighed at a frozen temperature; frozen vegetables or fruits at their thawed temperature.

Another new departure will be the dual declaration. For packages containing 1 pound, but less than 4 pounds, the net contents must be declared in total ounces followed by a separate declaration in parenthesis of pounds and ounces or pounds and common or decimal fractions of a pound. For example:

Net weight 24 ounces (1 lb. 8 oz.) or
Net weight 24 ounces (1 1/2 or 1.5 lbs.)

Packages which contain liquid contents of 1 pint but less than 1 gallon shall also carry a dual declaration. For example:

Net contents 56 fl. oz. (1 qt. 1 1/2 pts.) or
Net contents 56 fl. oz. (1 qt. 1 pt. 8 fl. oz.)

Exaggerated terms such as "full gallon," "jumbo pound," and "giant quart" are prohibited.

The law states that any label which says anything about servings must also say how much is in each serving. Our regulations define that the quantity of each serving must be shown in the same size type in immediate conjunction with the serving statement. For example:

2 servings ..... 2 oz. each

Identity of the product is also important. The common or usual name of the product (green beans, let's say, or chili con carne) must appear as a principal feature on the principal display panel and generally parallel to the base of the panel. If the product could be offered in more than one form--for example, sliced or whole--the particular form of the product must be part of the identity statement. It may be stated or shown by illustration, or it may be visible through the package.

The ingredients are to be listed on any single panel of the label in decreasing order of predominance by their usual or common name. When a particular expensive ingredient is significant to the consumer making value comparisons, a statement of the proportion of that ingredient may be required to avoid misleading the consumer.

The name and address of the manufacturer, packer, or distributor must be given. The regulations call for the actual corporate name although a subsidiary or division of the corporation may also be listed. We have been told about problems in test marketing and product identification that this provision may create, but we believe only the actual corporate name best meets the requirements of the law.

It was at FDA's discretion, however, and with a cooperative gesture to our fellow workers in the Post Office Department, that the ZIP code became a required part of the address. We try to assist other government agencies, but not without regard to possible increased costs to industry or the consumer, or a possible disruption of the orderly flow of goods into the marketplace. So, while the ZIP code ultimately will be included in every address, for now, if a label meets all the other regulations, the ZIP code need not be added until the label is redesigned and new plates must be ordered.

The law does not prohibit valid cents off on economy size packages, but does require that such practices represent real value to the consumer. Authority to issue regulations to preclude abuses in these areas is included in the Act.

Let's summarize some of the more important features of the required labeling for food products.

1. Identity of product

   By common or usual name
   Must appear on principal display panel
   Form of product (whole, sliced, etc.)

2. Name, address, and zip code of manufacturer, packer, or distributor

3. Contents Statement

   Lower 30 percent of principal display panel
   Easily read
   Boldface type
   Same size type for packages of the same size

4. If number of servings stated, quantity of each serving must be shown in the same size type in immediate conjunction with the serving statement

5. Ingredients

Should be listed in decreasing predominance by usual or common name

Optional ingredients in standardized foods must be listed

If necessary for value comparison, the proportion of the ingredients may be required

At this time FDA's regulation-writers are reviewing the comments of the drug, device, and cosmetic industries on our proposed regulations for them. We already require quite a lot of labeling information for drugs and devices, as the label on a bottle of aspirin shows. The final regulations for the packaging and labeling of over-the-counter drugs and devices will take into consideration the existing regulations and the special responsibilities of these industries.

Our proposal for the packaging and labeling of cosmetics was made too with consideration of that industry's unique practices. We know that many cosmetics are sold in small and decorative packages which may influence the sale as much as the contents. We think our final regulations will make adequate provisions for the unusual cosmetic packages and provide, at the same time, the useful information a consumer needs to make value judgments.

The Fair Packaging and Labeling Act does not include or cover labeling of meat, poultry, tobacco products, products under the Federal Insecticide, Fungicide, and Rodenticide Act, prescription and insulin-containing drugs, alcoholic beverages, or products subject to the Federal Seed Act.

Let's go on to another area of consumer protection under FDA as a result of recent legislation. The Drug Abuse Control Amendments of the Food, Drug, and Cosmetic Act were passed in 1965 and became effective as of February 1966. They were the result of national concern over the widespread abuse of three groups of dangerous drugs--depressants, stimulants, and hallucinogens.

While FDA has 17 District Offices and 1 national drug testing center, our Bureau of Drug Abuse Control was organized with 9 field offices. To carry out the provision of the law, some 300 trained agents are now empowered to seize illegal supplies of the controlled drugs, serve warrants and arrest persons engaged in the illegal manufacture or distribution of dangerous drugs. These agents have the right to carry firearms while engaged in their duties.

The law requires all legal handlers of drugs designated as dangerous to keep records of their supplies and sales. No prescription for the controlled drugs older than six months can be refilled. Nor can refills be made more than five times without a new prescription from a doctor.

The law carries criminal sanctions against those engaged in illegal drug traffic. It does not provide criminal penalties for the user. It has a two-sided approach--enforcement and education.

The Child Protection Act of 1966 amended a 1960 statute known as the Federal Hazardous Substances Labeling Act. The emphasis of that earlier piece of legislation was on labeling. The new hazardous substances law includes--but is not restricted to--labeling.

There are hundreds of thousands of household-sized products of potentially dangerous substances covered by the law. These include such labor-saving aids as cleaning agents, rust and stain removers, certain laundry supplies, drain cleaners, waxes, polishes, strong ammonia, bleaches, and paint thinners. Other substances that come under the law include many do-it-yourself home repair or hobby kits and such products as lime, adhesives of one kind or another, paint, chemicals for the photo laboratory, soldering agents, certain automotive fluids, antifreezes, and fuels for motor boats and motor bikes and similar vehicles.

Household-size containers of these substances must carry a conspicuous label to warn the user of the potential danger and to provide necessary safety information.

If a product is highly toxic, corrosive, or extremely flammable, the word "DANGER" must appear on the label. Substances so toxic that a small amount would cause death must have both DANGER and POISON conspicuously printed on the label. In some instances the skull and crossbones symbol (inherited from our Caustic Poison Act of 1926) is also required. All other products covered by the Federal Hazardous Substances Act have to display the word WARNING or CAUTION. The hazard has to be described. For example, FLAMMABLE, VAPOR HARMFUL, CAN BE ABSORBED THROUGH THE SKIN, CAUSES BURNS. The label must also list the hazardous substance or ingredients of the product for the consumer or physician in case of injury. The label must also tell what to do or not to do in case of injury. There must be directions for use of the product. The label must also include first aid directions, and if necessary, the phrase, CALL A PHYSICIAN IMMEDIATELY.

Finally, there must be the warning, KEEP OUT OF THE REACH OF CHILDREN, or an equivalent statement. The name of the manufacturer, packer, or distributor is very important if necessary to obtain antidote information in case of emergency.

It was not long after the 1960 Act that we discovered loopholes. Too many products were hazardous beyond the adequacy of label warnings. For example, in 1962 a product known as X-33 appeared on the market. It was sold as a water-proofing treatment for basement walls and other types of masonry around the home. As then manufactured, it had a flash point--the lowest temperature at which the fumes or vapors from the substance will ignite--of 40 degrees below zero F. Before removed from the market, three people had died and over 30 more were injured.

Clearly this kind of situation could not be tolerated. There were other instances of danger as well. For example, jequirity beans, so toxic that if one bean were chewed and swallowed it could cause death, were imported into this

country and sold on strings as jewelry. Certain kinds of fireworks or small explosives were also detected in the market place as being extremely hazardous to children. These fireworks were very small and round and looked like colored candy, gum drops or certain cereal products. In 1965 when the FDA warned parents and retail dealers to be on the lookout for them, the agency investigated over 30 cases where children suffered such injuries as loosened teeth, burns and cuts of the gums, tongue, and cheeks. A nationwide seizure campaign was required to round up the estimated 60 million "cracker balls" on the market.

In 1966 Congress enacted the Child Protection Act and thus amended the Federal Hazardous Substances Labeling Act by withdrawing the word "labeling." Obviously words on a label were not sufficient to protect the consumer.

We can now recall, ban, or seize items that are considered too hazardous for common use.

I would like to conclude these remarks on consumer protection by noting the complexity and interaction of the elements of our total environment.

That complexity involves the chemistry of air and water (note the interest in air and water pollution) and the chemistry of our food and drugs and household products. That complexity also involves our modern living in which open spaces between people are diminished and our emotional and psychological reactions are keener and quicker. No single consumer product can be evaluated in a total vacuum. Professionals in the fields of medicine, industrial technology, biochemistry, safety, government, and education all have a role to play. Nor can consumer protection be examined in bits and pieces. Essentially the problem is to gain some unity of concept. Consumer protection must be studied and aided within the context of our total modern environment. We have to know this environment; we have to face all of its positive and negative aspects, and see it whole. Interaction and interdependence are signal words to those of us interested in consumer protection today.