COMPTROLLER GENERAL OF THE UNITED STATES
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The Honorable Harrison A. Williams, Jr.
Chairman, Committee on Human Resources
United States Senate

Dear Mr. Chairman:

As requested in your letter dated February 20, 1978, we have the following comments on S. 2540, 95th Congress, which if enacted will be known as the "Food Amendments Act of 1978." The bill contains a number of provisions that should (1) provide greater protection to the public from adulterated foods, (2) provide better information to consumers, and (3) result in more efficient and effective enforcement of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 301) by the Food and Drug Administration (FDA).

Many of the bill's proposed amendments to the FD&C Act are consistent with conclusions and recommendations contained in General Accounting Office reports issued to the Congress. Pertinent sections of these reports are briefly discussed below.

1. In our report entitled "Dimensions of Insanitary Conditions in the Food Manufacturing Industry" (B-164031(2), April 18, 1972), we pointed out that FDA needed to take more aggressive regulatory action when the reinspection of a plant historically shows a disregard for sanitation standards. Enforcement alternatives provided by the FD&C Act include criminal penalties, injunctions, and letters of warning. In our opinion, the difference between the rather severe consequences of criminal penalties or injunctions, which FDA stated it was reluctant to initiate, and the relatively inconsequential letters of warning indicated that intermediate enforcement powers, such as civil penalties, would provide an effective means to obtain timely corrective action. Accordingly, we suggested that the Congress amend the law to provide for civil penalties. Section 6 of the bill would add to the FD&C Act section 308 to provide for civil penalties which would allow FDA greater flexibility in enforcing the act.

Also, we pointed out that FDA needed a complete and accurate inventory of food manufacturing plants to (1) know

which plants it is responsibe for inspecting, particularly those which may not have been included in the inventory, (2) better plan its selection of plants to be inspected, and (3) provide appropriate congressional committees with meaningful statistics to relate to the need for resources to carry out the FDA mission. About 35 percent of the plants in FDA's inventory at the time of our review were either out of business, misclassified as food manufacturers, or not an FDA inspection responsibility. Section 11 of the bill would add to the FD&C Act section 414 to require food processors to register with the Secretary of Health, Education, and Welfare. This would assist FDA in maintaining an accurate inventory of food plants.

2. Our report entitled "Lack of Authority Limits Consumer Protection: Problems in Identifying and Removing from the Market Products Which Violate the Law" (B-164031(2), September 14, 1972) pointed out that FDA needed sufficient authority to review manufacturers' records where there were questions about violative products. We found that many firms were unwilling to cooperate with FDA in making records available and that FDA was sometimes unable to obtain information essential to identifying and removing violative products from the market. Section 11 of the bill would add section 412(c) to the FD&C Act and Section 14 would amend section 704(a) to give FDA access to a firm's records. This would assist FDA in identifying and removing violative products from the market.

We also pointed out that FDA needed authority to temporarily detain products believed to be violative because FDA's seizure authority to prevent suspected products from reaching the market usually involved review by several authorities and resulted in delays in preventing products suspected or known to be violative from reaching the public. To improve FDA's ability to protect the consumer, we recommended that the Congress amend the law to provide FDA with detention authority. Section 5 of the bill would add section 304(g) to the FD&C Act to give FDA authority to detain products that it finds or has reason to believe are adulterated.

We also found that firms that voluntarily initiated a recall of any products suspected or known to be violative from the market often did so without notifying FDA of the recall. According to FDA, to make certain that violative products are removed from the market, manufacturers should be required to notify FDA when they discover such products so that FDA would

be in a position to determine the nature and extent of any hazard to consumers and to monitor the recall. Section 11 of the bill would add to the FD&C Act section 412(d) to require a manufacturer to notify FDA when it initiates a recall of food.

However, because recalls are voluntary FDA cannot enforce them and, therefore, they do not provide FDA with a means to effectively remove products from the market. To improve FDA's ability to remove violative products from the market, we recommended that the Congress consider amending the law to provide FDA with authority to require manufacturers to recall violative products. The Committee, in its deliberation of the bill, should consider the need to provide FDA with such authority.

Moreover, since issuance of our report, we have become aware of instances where food manufacturers have not allowed FDA to photograph sanitary and other conditions during inspection. Although the FD&C Act does not specifically provide FDA authority to take photographs, FDA believes that the broad inspection authority given to it under the act includes photograph taking of plant conditions which, in some cases, are necessary to better document inspection findings. Since FDA's authority regarding photographs is not clear, the Committee should clarify the FD&C Act in this regard.

3. Our report entitled "Food Labeling: Goals, Shortcomings, and Proposed Changes" (MWD-75-19, January 29, 1975) discussed a number of improvements needed in the labeling of food products so that consumers could tell what they needed to know to compare and select those products best suited to their needs or preferences. Presently, some products are exempt from listing their ingredients and some ingredients are disclosed in general terms. Certain ingredients in "standardized" foods are exempt from any labeling requirement and spices, flavorings, and colorings in all products are allowed to be listed in general terms.

Section 9(a) of the bill would amend section 403(g) of the FD&C Act to require the label to bear the names of the ingredients of foods with standards of identity. Section 403(i) of the act would be amended by Section 9 (b) of the bill to permit the Secretary to issue regulations requiring that any particular spice or flavoring be named on the food product label if he finds that such disclosure is necessary for public health. Section 21 of the bill would require a study to be

made on the need for a label declaration of the common or usual name of every spice and flavoring used in the fabrication of a food for human consumption.

While knowledge of food ingredients in food products, including standardized products, is important to all consumers, it is especially important to those consumers on special diets because of illness, allergy, or other reasons. The bill would improve consumers' ability to identify ingredients used in foods they eat and to better enable them to make informed decisions of products best suited to their specific needs.

Section 9(b) of the bill would also amend section 403(i) of the FD&C Act to require a declaration of the percentage of any specified ingredient on the label if the Secretary determines, by regulation, that such ingredient is a characterizing part of such food. Our report points out that most food labels did not provide consumers data on the percentages of such ingredients that have a material bearing on the price or consumer acceptance of a product. Manufacturers can and do vary the percentage of characterizing ingredients and thus vary the value or acceptability of their product without consumers' knowledge. Percentage labeling would give consumers a useful basis for making a value comparison between competing products.

Section 9(d) of the bill would add section 403(p) to the FD&C Act to require the Secretary to promulgate regulations that would clarify the meaning of dates on foods for human consumption. In this regard, we found that many food chains have recognized consumer interest by voluntarily providing "open dating" on many of their perishable and semiperishable products; but the consumers' use and understanding of open dating was limited. Consumers were confused because they did not know what the dates on the products represented (pull date, packed date, expiration date, etc.). The bill would help consumers to better understand and use open dating information.

4. Our report entitled "Food and Drug Administration's Program for Regulating Imported Products Needs Improving" (HRD-77-72, July 5, 1977) discusses the need for FDA to require importers to certify that imported products meet the provisions of the FD&C Act because FDA's limited inspection resources may not be sufficient to adequately insure that substandard products are not being imported.

Section 17 of the bill would add to the FD&C Act section 801(e)(1) which requires importers of food products to file a certificate with the Secretary that establishes that the food has been produced in accordance with safety assurance procedures and applicable standards. This should be helpful in providing FDA some assurance, which it does not have now, that imported products are manufactured, processed, or packed under sanitary conditions.

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Copies of the reports mentioned above are enclosed for your information. Because the bill was also referred to the Senate Committee on Commerce, Science, and Transportation we are sending a copy of these comments to Senator Cannon, Chairman of that Committee.

Sincerely yours,

R.F.KELLER

Deputy Comptroller General
of the United States

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