cans that contain lead solder, because the ban on the use of lead solder in food cans renders the labeling issue moot.

II. Discussion of Comments

In response to the notice of proposed rulemaking to prohibit the use of lead solder in food cans, FDA received eight comments. The comments were from a labor union, a State Government, an individual, two nonprofit public interest organizations, and three trade associations representing the can manufacturing industry, the food industry, and the Danish meat-canning industry.

One comment agreed that documentation clearly supports FDA's finding that a prior sanction exists for lead solder used in metal food packaging. All eight comments supported FDA's proposal to prohibit the use of lead solder in cans that are used to hold food. One comment submitted economic data on the cost to Danish meat canners of switching to other canning technologies. This comment is discussed in section IV. of this document. Other issues raised by the comments, and the agency's responses to them, are set forth below.

1. One comment stated that lead solder is incorrectly described in the proposed regulation as being ''* * * used in the construction of the metal ends of food cans.'' The comment explained that, although lead solder was historically used to seal both the end and side seams of metal cans, current production of lead-soldered containers involves use of lead solder only to seal side seams of the container. The comment suggested that the regulation state that ''Lead solders * * * are used in the construction of the side seams of food cans.''

The agency agrees that the language in the regulation should be clarified. However, even though lead solder is currently used to seal only side seams of containers, FDA is prohibiting all uses of lead solder in food cans. Therefore, FDA is modifying the regulation to read: ''Lead solders are alloys of metals that include lead and are used in the construction of metal food cans.'' This language clarification does not affect the intent or scope of the regulation.

2. One comment disagreed with language in the June 21, 1993, proposed rule, characterizing the agency's proposed action to ban the use of lead solder in food cans as a proposal to ''revoke'' the prior sanction for this use of lead solder. The comment contended that although §§ 181.1(b) and 181.5(c) (21 CFR 181.1(b) and 181.5(c)) provide that the agency may prohibit the use of a prior-sanctioned ingredient if scientific data or information show that use of the ingredient may be injurious to health, the agency cannot ''revoke'' a prior sanction. The comment stated that a prior sanction for the use of a food ingredient is based solely on its recognized use prior to enactment of the Food Additives Amendment of 1958 (to the Federal Food, Drug, and Cosmetic Act (the act)), and that revocation of a prior sanction is inconsistent with the meaning and intent of the law.

FDA considers the comment to be making a semantic point that ultimately has no effect on the agency's action. As the comment recognizes, FDA's regulations in § 181.1(b) provide that if scientific data or information show that use of a prior-sanctioned food ingredient may be injurious to health, and thus is in violation of section 402 of the act (21 U.S.C. 342), FDA can prohibit use of the ingredient in food. If the agency prohibits use of a prior-sanctioned food ingredient, this action has the effect of revoking the prior sanction for that use of the ingredient.

Further, § 181.5(c) states that known prior sanctions for food ingredients shall be the subject of a regulation, and that this regulation may be revoked to prohibit use of the ingredient to prevent adulteration of food in violation of section 402 of the act. If a regulation for the prior-sanctioned use of a food ingredient is revoked to prevent such adulteration, the prior sanction for that use is in effect also revoked.

Thus, the agency believes that revocation of a prior-sanctioned use is consistent with the intent of the regulations and the act. To disagree with this conclusion is tantamount to saying that FDA does not have the authority to determine whether a food ingredient can be used safely. This is obviously not true.

3. One comment requested that the effective date for the ban on the introduction or delivery for introduction of lead-soldered canned foods into interstate commerce be extended to 24 months after publication of a final rule in the **Federal Register**. The comment requested the extension to allow conversion of the meat can soldering lines in Denmark to other canning technologies. The comment estimated that the conversion of the meat can lines would be completed by the end of 1995.

The effective date for banning the use of lead solder in food cans, that FDA proposed in the document published in the **Federal Register** of June 21, 1993 (58 FR 33860), was based on a recognition that it might take some time for the domestic and foreign food industries to convert their equipment. However, the agency's primary concern in establishing an effective date for this action is the protection of the public health. As stated in the June 21, 1993, proposed rule, FDA has determined that there is a need to control dietary lead intake, especially for fetuses, infants, and children, because exposure to very low lead levels has been associated with adverse health effects. The current daily dietary lead intakes of infants and children approach or may exceed the PTTIL that the agency has established for lead for these population groups. (Lead levels that exceed the PTTIL are likely to result in adverse health effects.) The use of lead solder in food cans adds lead to food, and available toxicological and exposure data establish that the lead may render the food injurious to health and, therefore, adulterated under section 402(a)(1) of the act. Further, lead solder is not required to manufacture food cans, and therefore, its use is avoidable.

Over the years, the agency has expressed its concern about dietary exposure to lead resulting from the use of lead-soldered cans for food. In the 1970's, the agency worked with the evaporated milk industry, the infant food industry, and manufacturers of juices for infants to establish voluntary quality assurance programs to reduce the levels of lead in their canned products. These efforts were discussed in an advanced notice of proposed rulemaking (ANPRM) published in the **Federal Register** of August 31, 1979 (44 FR 51233). In this ANPRM, FDA also announced its intent to establish action levels for food packaged in lead-soldered cans. The agency's goal was to reduce the dietary lead intake resulting from use of lead-soldered food cans by at least 50 percent within 5 years.

FDA has been in direct contact with foreign countries, including Denmark, that might export food in lead-soldered cans to the United States. Beginning in mid-1990, the agency sent letters to over 65 nations, reminding U.S. trading partners that FDA has made efforts over the past two decades to reduce the levels of lead in the U.S. food supply, and that U.S. food manufacturers were voluntarily discontinuing the use of lead solder in cans for packaging food. The agency also said that it was concerned about dietary lead exposure from lead-soldered canned foods imported from other countries. The agency has also held numerous discussions at world forums over the past few years regarding the need to reduce dietary exposures to lead, particularly that resulting from use of lead-soldered cans for food.