DISCUSSION

Over the past few years, pasteurized fluid milk and milk products have been demonstrated to contain pathogenic microorganisms and to have caused outbreaks of human illness. The most recent significant outbreaks have been Yersiniosis in Tennessee, Arkansas, and Mississippi in 1982; Listeriosis in Massachusetts in 1983 and California in 1985; Salmonellosis in Illinois in 1985; and staphylococcal enterotoxins in Kentucky in 1985. These incidents seemed to be occurring with greater frequency and affecting larger numbers of people. Deaths have been associated with some of these outbreaks.

The FDA has the responsibility under the Food, Drug and Cosmetic Act (FD&C Act) and the Public Health Service Act of assuring the public that nation's milk supply is uniformly safe and wholesome. The FDA fulfills its responsibilities for Grade A dairy plants through a signed Memorandum of Understanding with the National Conference on Interstate Milk Shipments, which comprises all 50 states. Under this program, responsibilities for assuring the wholesomeness of Grade A milk products are shared cooperatively between the states, and FDA responsibilities for non-Grade A products such as ice cream and cheese are undertaken separately by FDA and the states under the regulatory provisions of FD&C Act and state statutes.

As a result of the outbreaks mentioned, FDA increased surveillance for the nation's dairy industry to provide assurance that there were no generic public health control weaknesses in the industry and to prevent further disease outbreaks. The primary purposes of this regulatory response were to identify better faulty equipment and improper processing procedures in dairy plants and to assess concurrently the microbiological (pathogenic) quality of finished dairy products. In April 1986, FDA implemented Dairy Safety Initiatives with a special emphasis on the probable contributing factors identified in previous disease investigations: 1) postpasteurization contamination, 2) plant system reviews, 3) equipment review and evaluation, and 4) education and training of dairy industry personnel.

Under these initiatives, FDA requested each state to conduct meetings with industry to discuss problems and areas of concern. Additionally, FDA requested states to intensify their own surveillance efforts in dairy processing plants.

The major objectives of FDA's initiatives are as follows:

1) To conduct intensified check-ratings by focusing on a more thorough review of records, sampling data, and product sources; to evaluate piping flow more strictly; to search actively for cross-connections; to examine critical control points; to evaluate postpasteurization contamination possibilities; to stress cleaning and sanitizing procedures; and to concentrate on proper pasteurization equipment;

2) To conduct intensified inspections under the FD&C Act in non-Grade A dairy plants;

3) To implement a microbiological surveillance program designed to detect pathogenic contamination of finished products;

4) To intensify and upgrade training of federal, state, and dairy industry personnel;

5) To tabulate and analyze the results of the initiatives and prepare a national status report on the dairy industry.
The results of these Dairy Safety Initiatives as of September 18, 1987 are as follows: 1016 check-ratings and inspections have been conducted since April 1, 1986. Seventy (6.9%) plants had finished products with pathogenic or nonpathogenic organisms; 29 (2.9%) of these plants' finished products contained the *Listeria* species; 33 (3.2%) contained nonpathogenic *Yersinia*; and 8 (.8%) contained other organisms.

As a result of the intensive surveillance program, *Guidelines for the Prevention of Environmental Contamination of Dairy Plants* were developed in conjunction with Milk Industry Foundation and International Ice Cream Association (MIF/IICA) and issued in September 1986. They were revised and reissued in October 1987. Training programs and workshops were developed for educating regulatory and industry personnel; these focused on current problems and issues encountered in the initiatives. Numerous states and companies are conducting their own environmental sampling programs in dairy plants.

As a logical progression from the guidelines and information derived from this effort, a number of significant problems were submitted by FDA to the recent 1987 NCIMS Conference held in St. Louis, MO. The problems focused on changes in requirements for specific equipment such as fillers and packaging equipment that have led to postpasteurization contamination and focused on practices such as returned milk and reclaiming operations.

Elimination of potential public health hazards was emphasized by including language that would require immediate action on the part of the regulatory authority when conditions involving improper pasteurization, cross-connections between raw and pasteurized products, or evidence of finished product contamination were evident.

New information continues to be derived from these initiatives that will serve to prevent problems in the future. This continuing commitment is evident in Phase II of FDA's recently issued Commissioner's Action Plan, a number of significant dairy-related activities have been incorporated into the Commissioner's Action Plan to enhance public health support of preventive programs.

Specifically, Phase II contains the following dairy-related activities: 1) determine the adequacy of the Pasteurized Milk Ordinance regarding the pasteurization time and temperature relationship for *Listeria monocytogenes* and *Yersinia enterocolitica*, using commercial-scale pasteurization equipment; 2) determine the adequacy of the current phosphatase method to detect raw milk adulteration or underpasteurization in soft-ripened and blue veined cheese. Modify the method to overcome observed problems from microbial phosphatases, which give false positive results; 3) complete the surveillance of the total US dairy industry to remedy fully current contamination problems.

To help prevent future incidents, FDA's Commissioner's Action Plan "will conduct a cooperative program with the states and the dairy industry which will intensify surveillance of sanitary conditions in processing plants." The Agency will offer advice to states and industry on improving quality control and training, stating in the Action Plan that "These information education activities will be carried out in conjunction with an increased number of joint State-FDA evaluations of pasteurization plants and a sampling program for specific microorganisms."

The Action Plan also indicates that research on the dairy product problem illustrates the uniqueness of FDA science: "It is research unlikely to be done at other institutions; it is research directed toward solving public health emergencies; and it provided scientific information necessary for disease prevention."

Research by the Scientists at FDA's Center for Food Safety and Applied Nutrition scientists resulted in tests to differentiate pathogenic and nonpathogenic strains of *Listeria*. When the listeriosis outbreak in California required an immediate survey of domestic cheeses, FDA scientists developed a selective medium to enhance the detection of this organism among all the other microbes found in dairy products. This method has been adopted by industry and foreign governments to monitor dairy products and to prevent a recurrence of *Listeria* contamination. Continuing research is attempting to improve further detection of *Listeria* and other important pathogens with specific DNA probes.
In addition, FDA will continue to promote actively the dissemination of health protection information on dairy safety. The Center for Food Safety and Applied Nutrition has established a new technical assistance program to strengthen its efforts to provide technical assistance to the states, local governments, industry, foreign governments, international organizations, other federal agencies, and the public on matters concerning food safety. The unique expertise, experience, and information of FDA will be used in a highly leveraged way through cooperative arrangements, training, and other forms of oral and written communications. The dissemination of this information will aid other organizations and nations in effectively carrying out their responsibilities in ensuring dairy safety.

In summary, the regulatory response to the problem of pathogenic bacteria in the dairy industry has been a strategically developed plan of action. It started with a Dairy Safety Initiative Program, designed to detect problems and develop useful information. Dissemination of this information and special training efforts have been developed. Changes in present regulations were effected to address these problem areas. Finally, research activities for future consideration are being implemented. As the FDA Action Plan continues, the regulatory response will continue to play an important role in the dairy industry.