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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

BEFORE THE

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Introduction

Good morning, Chairman Collins and Members of the Committee. I am Dr. Lester M. Crawford, Deputy Commissioner of the Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS or the Department). I am pleased to be here today with my colleagues from the U.S. Department of Agriculture (USDA) and the Department of Homeland Security (DHS). FDA appreciates the opportunity to discuss our food counterterrorism activities.

In my testimony today, I will first briefly describe FDA's overall role in counterterrorism activities. Then, I will discuss FDA's ten-point plan for ensuring the safety and security of the nation's food supply. Within the discussion of the ten-point plan, I will describe FDA's recent actions to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

FDA's Role in Counterterrorism Activities

FDA is the Federal agency that regulates 80 percent of the nation's food supply–everything we eat except for meat, poultry, and certain egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. FDA is also responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as veterinary drugs are safe and effective and that cosmetics are safe. In addition, FDA is responsible for assuring that the health consequences of foods and medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. While performing our mission, FDA plays a central role in the nation's defense against terrorism. First, terrorists could use an FDA-regulated product, such as food, as a vehicle for biological, chemical, or radiological agents. Second, FDA-regulated products, such as human drugs, vaccines, tissues, blood, and blood products as well as veterinary drugs, will play a central role in countering or preventing the effects of terrorism. It is FDA's responsibility, working closely within HHS and with other Federal agencies, state, and local governments, industry, and the public, to reduce the chance that an FDA-regulated product could be used to terrorize Americans. We also help ensure that the nation's public health system is prepared to deter a potential threat and is ready to respond to an act of terrorism.

Ten-Point Plan for Ensuring the Safety and Security of the Nation's Food Supply

Food safety and food security continue to be top priorities for this Administration. The events of September 11, the discovery of terrorist cells in Europe, the potential threat of a terrorist attack on the nation's critical infrastructure – all of these challenge us to sharpen our focus on protecting Americans from those who could harm us through our food supply. A terrorist attack on the food supply could have both severe public health and economic consequences, while damaging the public's confidence in the food we eat.

Therefore, today, FDA's food safety mission includes food security as well. The changes in food safety and security that we are implementing are the most fundamental enhancements in our food safety activities in many years.

On July 23, 2003, FDA Commissioner Mark B. McClellan issued a report to HHS Secretary Tommy G. Thompson entitled, "Ensuring the Safety and Security of the Nation's Food Supply." The report outlines a comprehensive ten-point program to protect the safety and security of our food supply. The ten-point program is based on four overall principles:

- Food security and safety are integrated goals. By building upon the Nation's core food safety/public health systems and expertise, FDA is enhancing food security and improving food safety in the process.
- The food safety and security system is comprehensive, addressing the full range of assessment, prevention, and response needs throughout the food production and distribution chain.
- The food safety and security system is built on a solid foundation of a national partnership with other entities involved in food safety and security that fully integrates the assets of state, local and tribal governments, other Federal agencies, and the private sector.
- Americans must have confidence that the government is taking all reasonable steps to protect the food supply and is providing Americans with timely and relevant information about threats.

Consistent with these principles, the Agency is employing the following overall strategies:

- Awareness: develop increased awareness among Federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge;
- Prevention: develop capacity to identify a specific threat or attack on the food supply;
- Preparedness: develop effective protection strategies to "shield" the food supply from terrorist threats;
- Response: develop capacity for a rapid, coordinated response to a foodborne terrorist attack; and
- Recovery: develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack.

In these efforts, FDA has many partners – Federal and state agencies, academia, and industry. We are working closely with our Federal partners such as USDA, DHS, the Homeland Security Council at the White House, the Department of State, and the U.S. Trade Representative, as well as with law enforcement and intelligence-gathering agencies. I also want to emphasize our close working relationships with our sister public health agency, the Centers for Disease Control and Prevention (CDC), Customs and Border Protection (CBP) in DHS, and USDA's Food Safety and Inspection Service (FSIS), our counterpart agency responsible for meat, poultry, and certain egg products. Some of our other Federal partners include USDA's Animal and Plant Health Inspection Service (APHIS), USDA's Foreign Agriculture Service, USDA's Agricultural

Research Service, USDA's Food and Nutrition Service, Department of the Army Veterinary Services Activity, Department of Commerce's (DOC) National Oceanic and Atmospheric Administration, the Environmental Protection Agency (EPA), the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), the Federal Bureau of Investigation, and the Central Intelligence Agency.

Now, I would like to describe the program areas in the ten-point plan.

1. Stronger FDA

Thanks to bipartisan Congressional support, a Fiscal Year 2002 supplemental included counterterrorism funds for FDA. This enabled FDA to hire over 800 employees, 655 of whom were hired by FDA's Office of Regulatory Affairs (ORA) as additional field personnel. Of the 655 field personnel, 635 were hired to address food safety and security issues, primarily at the border. These staff have all been hired, trained, and deployed. Three hundred support consumer safety investigations at 90 U.S. ports of entry, 100 support laboratory analyses on imported products, 33 are for criminal investigations of import activities, and the remaining personnel support domestic efforts.

The continuous threat of terrorism requires FDA to remain vigilant in its effort to recruit and retain a competent, trained workforce if we are to maintain a high level of readiness. A key component of FDA's strategic plan is to assure a high-quality professional workforce. Capable personnel with the appropriate expertise are critical for the success of FDA and for the Agency's ability to maintain a high level of public trust in its activities. FDA's responsibilities require a

very special workforce, one that can keep up with rapid changes in the industries that it regulates and one that is capable of developing and implementing effective and innovative public health measures. Our workforce includes a solid cadre of experienced physicians, toxicologists, chemists, microbiologists, statisticians, mathematicians, biologists, pharmacologists, veterinarians, and other highly qualified and dedicated professionals.

FDA continues to find innovative ways to educate and train our staff and further develop the necessary scientific, technical, and investigational skills to integrate food safety and security activities. FDA has not only mobilized the new staff but also has redirected and trained current investigators and scientists to ensure that the Agency has the necessary expertise to respond to an event that could threaten the safety and security of the food supply. FDA has hired or re-trained scientific experts in biological, chemical, and radiological agent research, detection methodology, and preventive technologies. It has also acquired substantial knowledge of these agents. ORA has developed a succession plan to ensure that the Agency will continue to have highly trained and competent scientists, investigators, analysts, and managers to accomplish the Agency's overall mission of consumer protection. FDA has created many new human resources policies to attract and keep high-caliber employees. We realize that recruitment and retention of our highly skilled and often specialized workforce requires thoughtful planning so that we will be ready to effectively and efficiently meet future challenges.

2. Imports

The volume of imported food shipments has been rising steadily in recent years, and this trend is likely to continue. In Fiscal Year 2003, FDA has the challenge of assuring the safety and security of more than 5.4 million imported food entries. With the additional field employees that we mentioned earlier, we have expanded FDA's presence at ports of entry, increased surveillance of imported foods, increased domestic inspections, and enhanced our laboratory analysis capacity. More specifically, within the last two years, we have more than doubled the number of ports that have an FDA presence from 40 to 90 ports. We have increased by more than six-fold the number of food examinations at the border. This past fiscal year, we surpassed our goal of 48,000 import examinations, conducting 78,569 food import examinations compared to 12,000 just two years ago. This increase was so significant due, in large part, to increased surveillance of imported food products during Operation Liberty Shield when the nation was at a heightened security alert status.

3. Implementation of the Bioterrorism Act

Title III of the Bioterrorism Act provided the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these food safety and security provisions. These new authorities will improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies.

The Agency has been working hard to implement this law effectively and efficiently. On October 10, 2003, we published two interim final regulations to implement Section 305, Registration of Food Facilities, and Section 307, Prior Notice of Imported Food Shipments. We have also published proposed regulations to implement Section 303, Administrative Detention, and Section 306, Maintenance and Inspection of Records for Foods. We intend to publish final regulations on these two provisions by the end of the year.

The interim final rule on registration requires domestic and foreign facilities that manufacture or process, pack, or hold food for human or animal consumption in the U.S. to register with FDA. FDA will have, for the first time, a complete roster of foreign and domestic food facilities. In the event of a potential or actual terrorist incident or an outbreak of foodborne illness, the registration information will enable FDA to quickly identify and locate the facilities that may be affected. FDA expects up to 420,000 facilities to register under this requirement.

The Bioterrorism Act requires facilities to register by December 12, 2003. FDA's electronic registration system became operational on October 16, 2003, giving facilities time to register by the statutory deadline. The system is available 24 hours a day, seven days a week, to anyone with access to the internet. We are also providing technical assistance to persons who need help with the registration process. Facilities are strongly encouraged to use the electronic system to register. As of the morning of November 17th, 49,975 facilities have registered. This includes 22,708 domestic and 27,267 foreign facilities.

The interim final regulation on prior notice requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the U.S. This advance information will allow FDA, working closely with CBP, to more effectively target inspections to ensure the safety of imported foods. CBP represents the Administration's attempt to build a single lead border authority, which was part of the rationale for establishing the DHS. FDA expects to receive about 25,000 notifications about incoming shipments each day. The timeframes for submitting prior notice are the least amount of time that FDA needs to meet our statutory responsibility to receive, review, and respond to the prior notice submission. They take into account different modes of transportation. The regulations allow two hours for arrival by land by road, four hours for arrival by air or land by rail, and eight hours for arrival by water.

The HHS and DHS co-signed the regulations. FDA and CBP worked collaboratively to ensure the new regulations promote a coordinated strategy for border protection. Thanks to this collaboration, most of the current imported food shipments can comply with the prior notice requirement by using CBP's Automated Commercial System (ACS). Prior notice can be submitted either through ACS or FDA's Prior Notice System Interface beginning December 12, 2003, when the requirement takes effect. FDA and CBP are committed to the joint implementation of an automated approach that will: (1) reduce submission of redundant data to the extent possible; (2) build on current operational procedures; and (3) implement the law with minimal disruption to current entry practices.

In addition, FDA and CBP intend to sign a Memorandum of Understanding to commission CBP employees to serve on FDA's behalf at ports where FDA may not currently have staff or to

augment FDA staff in the enforcement of FDA's prior notice. This ability to utilize CBP staff was a key factor in our ability to shorten the amounts of time required for prior notice.

In developing these interim final regulations, FDA conducted extensive outreach, both domestically and abroad, to ensure that affected parties were aware of the proposed requirements and could have the opportunity to provide meaningful comment for the Agency to consider before finalizing the regulations. FDA listened carefully to stakeholders' comments to develop rules that are workable. We believe these rules will enhance food safety and security without hindering trade.

FDA also held a worldwide satellite downlink on October 28 to discuss the implementation of the registration and prior notice regulations. FDA's outreach plan includes foreign country visits to Canada, Mexico, and the European Commission; videoconferences with more than 20 countries in partnership with the World Bank's Global Long Distance Learning Network; domestic grassroots meetings and satellite telecasts; industry association meetings; and numerous educational materials and technical assistance.

While these rules take effect December 12, 2003, we are receiving comments until December 24, 2003. To increase security while ensuring that the regulations are implemented efficiently and with minimal disruption, FDA intends to initially emphasize education over enforcement. During this time, FDA and CBP will educate those involved in importing food about how they can comply with the regulations and will work with trade associations and

foreign governments to make sure all parties are well informed of the new requirements. We will continue our outreach efforts on both rules both domestically and abroad.

4. Industry Guidance and Preventive Measures

FDA has issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. We have issued such guidance, "Security Preventive Measures Guidance Documents," for food producers, processors, and transporters, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. In addition, we have issued specific security guidance for the milk industry. During domestic inspections and import examinations, FDA's field personnel continue to hand out and discuss these guidance documents to firms that have not previously received it. Three of the guidance documents are final – producers, processors, and transports; importers and filers; and milk industry. The other two guidance documents for retail food stores and food service establishments and cosmetic processors and transporters are in draft status. We anticipate publishing these documents in final format in the near future.

5. Vulnerability and Threat Assessments

As part of our efforts to anticipate threats to the food supply, we have conducted extensive scientific vulnerability assessments of different categories of food, determining the most serious risks of intentional contamination with different biological or chemical agents during

various stages of food production and distribution. FDA's initial assessment utilized an analytical framework called Operational Risk Management (ORM) that considers both the severity of the public health impact and the likelihood of such an event taking place. FDA has incorporated threat information received from the intelligence community.

To validate our findings, FDA contracted with the Institute of Food Technologists to conduct an in-depth review of ORM and provide a critique of its application to food security. This review validated FDA's vulnerability assessment and provided additional information on the public health consequences of a range of scenarios involving various products, agents, and processes.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment." The assessment also affirmed the findings of FDA's ORM assessment. In addition, it provided another decision-making tool for performing risk assessments. Further, the Battelle assessment made a number of recommendations that addressed research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between Federal, state, and local governments to ensure food security. FDA is addressing each of these recommendations.

FDA is continuing to update and refine these assessments regarding the vulnerability of

FDA-regulated foods to intentional contamination from biological, chemical, and radiological agents. These refinements use processes adapted from techniques developed by the U.S. Department of Defense (DOD) for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments will be used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector.

6. Operation Liberty Shield

In March 2003, the Federal government launched Operation Liberty Shield to increase security and readiness at a time of elevated risk for terrorist attack. Operation Liberty Shield was a comprehensive national plan designed to increase protections for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of life. FDA's efforts during Operation Liberty Shield were targeted towards increasing the Agency's surveillance activities in the food and cosmetic areas in an effort to enhance security of these products. This targeted approach was based on the vulnerability assessments described above and included domestic inspections and import examinations, sample collections of targeted commodities, and import reconciliation examinations. Domestic and import reconciliation examinations were conducted to ensure that: the targeted food/cosmetic was what it purported to be; there were no unexplained differences in the quantity of products ordered and what was subsequently received; that there were no visible signs of tampering or counterfeiting; and that sampled products were not adulterated with contaminants of concern. During each and every domestic inspection or import examination,

FDA personnel handed out and discussed FDA's "Security Preventive Measures Guidance Documents."

7. Emergency Preparedness and Response

FDA has established an Office of Crisis Management to coordinate the preparedness and emergency response activities within FDA and with our Federal, state, and local counterparts. Over the past two years, FDA has participated in and conducted multiple emergency response activities including exercises coordinated with other Federal and state agencies. For example, FDA and USDA's FSIS have focused on strengthening our working relationships through joint testing of several response plans in an exercise environment. FDA has also reviewed food security and rapid response and recovery procedures with industry groups and trade associations.

In May of this year, FDA participated in the government-wide TOPOFF2 counterterrorism exercise led by the DHS and the Department of Justice. This was a national, full-scale, fully functional exercise intended to simulate two separate terrorist attacks: detonation of a "dirty bomb" in Seattle and aerosol release of plague in Chicago. The ensuing response involved participation from 17 Federal departments and agencies, the state governments of Washington and Illinois, the local governments of the affected cities, and the Canadian Government. FDA's response was coordinated from our Emergency Operations Center on an around-the-clock basis throughout the exercise, working together with all of FDA's Centers.

From September 8 – 10, 2003, FDA participated in Exercise Global Mercury. Global Mercury involved the G-7 countries plus Mexico and was designed to test international communications during a public health emergency in the international community. Coordination of HHS participation was done through the Secretary's Command Center. Other U.S. players in the exercise were CDC and the Department of State. Throughout the exercise, FDA's experts from our Center for Drug Evaluation and Research and our Center for Biologics Evaluation and Research provided assistance on issues relating to a hypothetical smallpox outbreak occurring in several different countries.

On October 7, 2003, FDA hosted the first trilateral food terrorism tabletop exercise via videoconference with Mexico and Canada. The exercise was conducted from FDA's Office of Crisis Management/Emergency Operations Center. Participants included FDA's Center for Food Safety and Applied Nutrition (CFSAN), ORA, Office of International Programs, Southwest Import District, New York District, Mexico's Federal Commission for Health Risk Protection (COFEPRIS), Health Canada, and the Canadian Food Inspection Agency. The objectives of the exercise were to elicit discussion of emergency preparedness and response activities, to ensure that all players have a common understanding of the communications plans and systems that could be utilized in response to an international terrorism event, and to use videoconferencing to practice international response communications. The players were pleased with the opportunity to participate in the exercise and found it to be a valuable learning experience. At the Trilateral Meeting on October 29, 2003, in Baltimore, Maryland, a discussion was held on the lessons learned including the challenges related to notification, sharing of data including classified

information, and sharing of intelligence information between and among the three countries. Another trilateral exercise will be conducted in 2004.

FDA's Office of Crisis Management/Emergency Operations Center will also coordinate FDA participation in other interagency exercises being conducted in 2003 and 2004 and will conduct two additional exercises to test updated response plans for chemical/biological and radiological emergencies.

8. Laboratory Enhancements

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with CDC and USDA/FSIS to expand the Laboratory Response Network by establishing the Food Emergency Response Network (FERN) to include a substantial number of counterterrorism laboratories capable of analyzing foods for agents of concern. We are seeking to expand our capacity through agreements with other Federal and state laboratories. As of November 2003, there are 63 laboratories representing 27 states which have expressed interest in participating in FERN, including five Federal agencies, thus providing a framework to build upon. Participation continues to grow. By working together with our Federal and state partners, we would have the ability to test a much higher than normal volume of samples. With CDC, we recently announced grants that states can use to buy special laboratory equipment and reagents and to develop the skills of those working in the laboratory.

This is one small step towards the development of a national network of laboratories that are ready to assess and respond to a food security emergency.

We also are expanding Federal, state, and local involvement in our eLEXNET system by increasing the number of laboratories around the country that participate in this electronic data system. eLEXNET is a seamless, integrated, web-based data exchange system for food testing information that allows multiple agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. It enables health officials to assess risks and analyze trends, and it provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. At present, there are 101 laboratories representing 50 states that are part of the eLEXNET system. We are continuing to increase the number of participating laboratories. Moreover, during the U.S./Canada/Mexico Trilateral Cooperation Meeting held in Baltimore, Maryland, at the end of October, the three governments agreed to establish a pilot to use eLEXNET to share food sample data among the three countries' laboratories.

In addition, FDA's ORA has signed an Interagency Agreement with the U.S. Department of the Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to enhance our ability to provide timely and efficient analyses of imported food. The mobile laboratories are expected to be ready for deployment in 2004.

9. Research

To prioritize research needs and avoid duplication, FDA coordinates with its sister agencies within HHS, such as CDC, and with other Federal partners such as USDA, DHS, DOD, and the Department of Energy. Within FDA, we have embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. To enhance food security, FDA has significantly redirected existing research staff to ensure that appropriate resources are focused on priority food safety and security issues. For example, research sponsored by FDA's CFSAN is aimed at developing the tools essential for testing a broad array of food products for a multiple number of biological and chemical agents. We are actively working with our partners in government, industry, and academia to develop such methods. FDA's work with AOAC International, an association of analytical chemists, on validating analytical methods for the detection of biological, chemical, and radiological agents in foods is considered the "gold standard" against which other validations programs are judged. Likewise, FDA's research on microbial genomics and analytical chemistry is widely recognized for its importance to other Federal agencies charged with forensic investigations of terrorism events.

In July 2003, FDA received $5 million in one-time funding to support a new research program to develop technologies and strategies to prevent and minimize potential threats to the safety and security of the nation's food supply. The White House Office of Management and Budget allocated these funds from the 2002 supplemental appropriations to FDA for food security research, including efforts to develop new prevention and mitigation technologies and to improve the ability to assess foods for contamination with chemical, biological, and radiological agents.

In compliance with Section 302 of the Bioterrorism Act, on October 16, 2003, we submitted a report to Congress, "Testing for Rapid Detection of Adulteration of Food," about the research that is underway. FDA has commenced more than 90 different research projects to develop tests and sampling methodologies to increase the detection of adulteration of food. A number of the research projects are designed specifically to develop tests suitable for inspections of foods at ports of entry. For example, commercially available test kits are currently being analyzed for a variety of food matrices to evaluate their suitability for use in the field at ports of entry. This is a good start – a small down payment – in the overall research agenda needed to fully protect the security of the U.S. food supply.

10. Interagency and International Communication and Collaboration

Food security requires effective and enhanced coordination across many government agencies at the Federal, state, and local level. FDA's activities in public health security are coordinated through the HHS Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, the Department, and other Federal agencies and departments, including DHS. FDA has also worked closely with the Interagency Food Working Group of the White House Homeland Security Council on three initiatives – development of a national network of food laboratories, identification of vulnerabilities and subsequent mitigations for commodities of concern, and the development of a national incident management system.

FDA holds regularly scheduled interagency conference calls with representatives from USDA's APHIS and FSIS, CDC, EPA, DOD, DOC, TTB, and CBP. On February 4, 2003, FDA, in conjunction with the National Association of State Departments of Agriculture, the Association

of State and Territorial Health Officials, USDA, and CDC sponsored a one-day executive level meeting with the Secretaries of State Departments of Agriculture and the State Departments of Health titled "Homeland Security – Protecting Agriculture, the Food Supply and Public Health – the Role of the States." FDA is also working closely with Canada and Mexico in an effort to assess and strengthen our public health and food security systems and infrastructures at our mutual borders.

In addition, ORA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies to receive and act on any information regarding product tampering. OCI is FDA's liaison with the intelligence community (the Central Intelligence Agency, National Security Agency, and others). OCI agents serve on several interagency committees including the FBI's Joint Terrorism Task Forces, the U.S. Attorney's Office Anti-Terrorism Task Forces, and DHS' Bureau of Immigration and Customs Enforcement Task Forces around the country. OCI has a specialized staff with the capability and background to analyze information from law enforcement and intelligence community sources to assist in terrorism-related threat assessments pertaining to FDA-regulated products.

Conclusion

FDA plays a critical role in the nation's defense against terrorism. Although we are better prepared than ever before, we are continuously working to improve our ability to detect and respond to terrorist threats. Through the new authorities in the Bioterrorism Act and the measures outlined in the ten-point plan, we are making tremendous progress in our ability to

ensure the safety and security of the nation's food supply. There is a lot to do, but we have a plan to get there.

Thank you for this opportunity to discuss FDA's food safety and security activities. I would be pleased to respond to any questions.