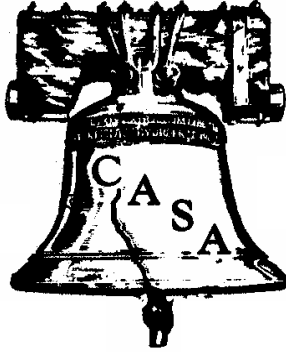


The Bell Ringer

THE NEWSLETTER OF THE PHILADELPHIA CONFERENCE OF THE
CENTRAL ATLANTIC STATES ASSOCIATION OF FOOD AND DRUG

SUMMER 2006



THE PRESIDENT'S MESSAGE

As I take over the office of President, the first thing I would like to do is thank Pat Taylor for the exceptional job she did as president and is still doing as the Past President Board Member. I would also like to commend all of the Board Members as well as the committee chairpersons and members for the excellent job they have done and continue to do.

The 90th Annual C.A.S.A. Conference occurred in Gettysburg, PA this year during May 16th through May 19th. The topics were wide-ranging including discussions on amusement park ride inspection, molecular epidemiology and internet posting of complete inspection records. George Zameska, the Philadelphia Conference C.A.S.A. Representative to the Executive Board received an achievement award from C.A.S.A. for all of the work he has done for the association. During the executive board meeting, one of the major discussions revolved around cost-cutting measures. It was decided that all communications will now be delivered electronically. Our local conference will also be instituting this measure due to escalating postage and printing expenses. Because of this, if you wish to receive any communications from the local or principal conference, it is critical that you register a current e-mail address at www.casafdo.org as well as at registration during one of the local meetings.

Our association could not and would not exist without our members. We need to know your concerns and interests. Therefore, if you have any ideas or suggestions that you feel would benefit the association please e-mail me at bernard.finkel@phila.gov. I can also be contacted by postal mail at 111 W. Hunting Park Avenue, Phila., PA 19140.

Our summer meeting was held on June 16th, 2006. At this meeting we will be awarding the Philadelphia Conference Scholarship Award. Congratulations to the recipient, Patrick T. Brown, son of longstanding member Patrick Brown. Hope to see you at the meeting. To those of you who can't make the meeting, have a safe wonderful summer.

*Sincerely,
Bernie Finkel*

Federal News

FDA's Accomplishments in 2005

Submitted By: Paulette Smith

In 2005, on the eve of its 100th anniversary, the Food and Drug Administration continued strengthening the performance of its core functions: ensuring the safety and effectiveness of drugs, biologics, and medical products; protecting the safety and security of 80 percent of the food supply; making certain that cosmetics and equipment that emits radiation do no harm; and ensuring the safety of animal drugs and feed. In addition, the agency took major steps to advance its forward-oriented agenda by implementing the FDA's strategic plan, a part of the Administration's blueprint for a healthier and more vigorous America.

During the year, all FDA's components -- Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM) and National Center for Toxicological Research (NCTR), ORA and various offices within the Office of the Commissioner -- achieved outstanding results. In addition, the agency continued to advance long-term strategic objectives.

The FDA made progress in implementing its Critical Path initiative, a pioneering project that seeks to apply the best available science to the medical product development process by creating novel tools -- such as proven biomarkers and simulation models -- for assessment of the safety and effectiveness of drugs and medical devices.

As part of this initiative, the FDA conducted a workshop with The Drug Information Association and The Biotechnology Industry Association to discuss ways of routinely using new imaging techniques in drug development. The agency

also created a non-regulatory pathway for discussions with sponsors about certain issues involving submission and use of pharmacogenomic data; concluded an agreement with BG Medicine, a biotechnology research company, to collaborate on discovering signs of liver toxicity in the initial stages of drug development; and published a final guidance on the development of pharmacogenomic data that could help predict the optimum treatment for each individual patient. The agency issued a final guidance on Exploratory Investigational New Drugs, setting forth recommendations regarding preclinical and clinical issues as well as chemistry, manufacturing and controls issues that sponsors should consider when planning exploratory studies, including studies on closely related molecules, early in drug development.

The FDA launched several initiatives to reform and make more transparent the system that protects patients from adverse events associated with marketed drugs. The steps taken in 2005 included a contract with the Institute of Medicine to study the effectiveness of the U.S. drug safety system; the appointment of 31 top drug experts to a novel Drug Safety Oversight Board that oversees the management of important drug safety issues; and four contracts to improve FDA's access to databases that can help identify rare side effects of medicines. Other examples of patient and consumer safety-oriented projects included FDA's investigation of the mechanical strength of vertebrae following injections with bone glue, the most common treatment for compression fractures that affect a quarter of all women over the age of 50; and studies of the toxicity of acrylamide in food. FDA made important contributions to the nation's preparedness for the potential influenza pandemic. The agency provided guidance to speed vaccine manufacturing and

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availability; sought to increase the number of vaccine manufacturers and their capacity; and addressed such needs as the creation of pandemic strain libraries, for use in vaccine manufacturing and development, and improved assays and testing.

CFSAN launched a new comprehensive bi-lingual food safety education program for pregnant women which focuses on prevention of food borne illness. This program, Food Safety for Moms-to-Be, highlights food borne illness risks that pregnant women and their babies are particularly vulnerable to, such as illnesses due to *Listeria monocytogenes*, methylmercury, and *Toxoplasma*. FDA proposed to modify its animal feed regulations to prohibit from use in the food or feed of all animals certain high-risk cattle materials that can potentially carry and spread the agent of bovine spongiform encephalopathy (BSE or mad cow disease.) This proposed regulation builds on a series of previously established anti-BSE firewalls that include FDA's 1997 ruminant feed ban regulation. The removal of high-risk materials from all animal feed, including pet food, will protect against the transmission of the agent of BSE that could occur through cross-contamination during feed manufacture and transport, or intentional or unintentional misfeeding of non-ruminant feed to cows on the farm.

To help protect the nation against bioterrorism, Congress has charged the FDA with helping to secure the food supply and encouraging the development and availability of counter-terrorism medical products. As part of this program, the FDA last year strengthened the protection against the effects of inhaled anthrax by approving several generic versions of Cipro (ciprofloxacin). The agency also approved ThyroShield (potassium iodide oral solution) for use in radiation emergencies and developed draft guidance on studies of

products to eliminate inhaled, absorbed, or ingested radioactive contaminants.

CFSAN, along with the U.S. Department of Agriculture (USDA), the Federal Bureau of Investigation (FBI), and the Department of Homeland Security, announced a new collaborative effort with states and private industry to protect the nation's food supply from terrorist threats through the Strategic Partnership Program Agroterrorism (SPPA) Initiative. CFSAN has spearheaded this effort to identify sector-wide vulnerabilities, mitigation strategies and research needs to protect our nation's food supply.

Over the past three years, FDA has continued to implement the provisions of the Bioterrorism Act of 2002 designed to prevent the importation of intentionally contaminated regulated products. Last year, the agency finalized registration requirements for food and animal feed companies that sell products in the U.S., and processed approximately 167,000 prior notifications each week of intended regulated imports. These notifications were used to review, evaluate and assess the inspections of imported foods.

Another major FDA priority in 2005 was to ensure the proper manufacture of medications by strengthening compliance with the recently overhauled pharmaceutical standards Good Manufacturing Practices (GMPs). An example of this emphasis has been the agency's close cooperation with the United Kingdom's Medicines and Health Products Regulatory Agency (MHRA) in ensuring the correction of sterility failures that had caused the MHRA to suspend the license for Chiron, a major producer of influenza vaccine for the United States.

Both FDA and MHRA provided extensive input on Chiron's remediation plan for the firm's facility in Liverpool, and repeatedly inspected its implementation. The joint efforts resulted in the release and delivery of

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the Fluvirin influenza vaccine to the United States for the 2005-2006 influenza season.

In 2005, the consolidation of the FDA's widely dispersed facilities moved close to reality with the completion of a new building for CDER on the agency's White Oak campus. Another significant achievement was the consolidation of administrative and IT services in all of FDA's locations, which improved administrative procedures and made possible non-stop IT helpdesk services. Working for a better future has been the key to the FDA's success story since the agency's founding in 1906. In 2006, this tradition is stronger than ever. During its centennial year, the agency will continue following its strategic plan by developing new tools and methods for speeding safe and effective medical products to patients, advancing medical and pharmaceutical sciences, and helping improve the public health and quality of life in the United States. To help protect patients from medication errors, to better inform practitioners about the information they need to use products most safely, and to better enable the use of electronic labeling of drug and biologic products, FDA finalized its new rules governing the format and content of the required information (labeling) that must accompany drug and biologic products when they are marketed in the United States. Recognizing that most of the food we eat and that many of the medical products we use are imported, FDA continued this year to foster special relationships with agencies with similar responsibilities in other key countries. These efforts have resulted in the completion of confidentiality and other agreements with these agencies in thirteen key countries around the world. Under these agreements, FDA is more quickly and efficiently able to share important information regarding product safety with and to leverage our scientific, human, and inspectional resources

with those of these key countries. These efforts are primarily aimed at helping to protect and promote the health of the USA and these countries and to reduce the burden of duplicative regulation of common products through timely exchange of important knowledge, data, and expertise and by increasing the internal capacity of foreign agencies to help oversee products destined for the United States before they leave their country of production.

FDA News FOR IMMEDIATE RELEASE Kimberly Rawlings,
301-827-6242, Consumer Inquiries: 888-INFO-FDA



FDA Issues Draft Guidance for the Safe Production of Fresh-Cut Fruits and Vegetables

To minimize microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers in a ready-to-eat form, The Food and Drug Administration (FDA) today published a draft guidance document for producers of fresh-cut produce entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables."

"Fresh cut produce is the fastest growing sector of the fresh produce industry. This document should help to improve safety by providing clearer guidance on how to reduce health hazards that are potentially introduced during the production process," said Acting FDA Commissioner Dr. Andrew von Eschenbach.

Processing produce into fresh-cut produce increases the risk of bacterial contamination and growth by breaking the natural exterior

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barrier of the produce by peeling, slicing, coring, trimming, or mashing with or without washing or other treatment before being packaged for consumption. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melons, sliced pineapple, and sectioned grapefruit.

This draft guidance discusses the production and harvesting of fresh produce and provides recommendations for fresh-cut processing in several areas-- (1) personnel health and hygiene, (2) training, (3) building and equipment, (4) sanitation operations, and (5) fresh-cut produce production and processing controls from product specification to packaging, storage and transport. The final chapters provide recommendations on recordkeeping and on recalls and tracebacks. The guide complements FDA's Current Good Manufacturing Practices regulations by providing specific guidance on the processing of fresh-cut produce.

In the draft guidance, FDA recommends that processors encourage the adoption of safe practices by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers, to ensure that the processor's efforts will be enhanced. These practices include:

- Establishing a company policy that employees report any active case of illness to supervisors before beginning work and training;
- Training supervisors to recognize typical signs/symptoms of infectious disease; maintain the proper first aid to protect and cover any wound; and not allow an employee to work with any

aspect of fresh or fresh-cut produce, processing equipment or tools until the wound has healed and/or the infectious disease has been treated.

The guidance also recommends that fresh-cut processors consider a preventive control program such as the Hazard Analysis and Critical Control Points (HACCP) system to build safety into the processing operations for fresh-cut fruits and vegetables. HACCP is a prevention-based food safety system designed to prevent, eliminate, or reduce to acceptable levels the microbial, chemical, and physical hazards associated with food production. FDA believes awareness of the common risk factors discussed in this guidance and implementation of preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of fresh-cut fruits and vegetables.

Consumers can reduce their risk of illness from fresh-cut produce by following safe handling practices such as refrigerating the product after purchase; using only clean hands, utensils or dishes in preparing the product; and discarding the product when the "use by" date has expired. More information on safe handling practices of produce can be found at <http://portal.fightbac.org/pfse/toolsyoucanuse/phec/>.



Rendell Administration Launches Pennsylvania's New Pandemic Preparedness Web Site

HARRISBURG – At the direction of Governor Edward G. Rendell, the commonwealth unveiled a new pandemic preparedness Web site today to provide people with timely, accurate and reliable

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information about influenza pandemic. Officials also updated the public on the state's ongoing efforts to prepare should a flu pandemic hit the U.S.

"With this new Web site, people in Pennsylvania will have access to a state-of-the-art, informative tool to get quick, accurate answers about flu pandemics," Governor Rendell said. "If this health problem should hit the commonwealth, we will be ready to act because of the hard work of the people who are dedicated to protecting the public's health."

Governor Rendell's deputy chief of staff Art Stephens, state Health Secretary Dr. Calvin B. Johnson and state Agriculture Secretary Dennis Wolff announced the Official launch of www.pandemicflu.state.pa.us. "Pennsylvania hasn't faced an influenza pandemic in nearly 40 years and at this point, there is no immediate threat of one," said Stephens. "But the outbreak of a new strain of avian flu – called the H5N1 virus – in Asia, has reminded the world of the need to be prepared in case a pandemic strikes at home. That's what we're doing in Pennsylvania – both for animals and humans.

"The success of our planning relies on making sure that the proper information is getting out to individuals and organizations about steps they can take to educate and prepare themselves for the possibility of a pandemic. The state's new pandemic preparedness Web site builds on the strong foundation of resources already in place to ensure that our ability to respond to this potential public health threat is efficient and effective." The Web site features specific resources and directions for various groups – including local governments, individuals, businesses, schools, healthcare providers, communities and agriculture; frequently asked questions; and the latest information on what Pennsylvania is doing to prepare. Pennsylvania-specific planning documents,

articles and fact sheets are available for download and up-to-date news and information from other health care and government resources as well.

In addition to a walkthrough of the Web site during today's news conference, Dr. Johnson addressed the upcoming made-for-television movie, "Fatal Contact: Bird Flu In America," and the potential that it may have to cause confusion among its viewers. "It is important for viewers to accept this movie for what it is – entertainment," Dr. Johnson said. "It is our hope that this movie will draw people to more reliable sources for information such as the Department of Health's 1-877-PA-HEALTH line and the Web site we've launched today."

Secretary Wolff said the state Agriculture Department is also working to monitor the poultry and wild bird populations for avian influenza "For more than 20 years, Pennsylvania has had an aggressive avian influenza surveillance program for both wild and domestic birds," Wolff said. "Today, we lead the nation in testing, performing more than 240,000 tests last year alone. As a result, the state's poultry industry is among the safest in the world." Stephens also announced the specifics on three of six regional meetings being held to follow-up on the state's recent Pandemic Preparedness Summit. "Pennsylvania is committed to meeting the pandemic issue head-on by taking deliberate and detailed steps to ensure that every individual and organization is aware of the role they play in preparedness and response efforts," Stephens said. "After a successful statewide pandemic planning summit in March, Governor Rendell made a commitment to hold six regional planning summits so we intensify our local planning efforts. Three of those meetings are scheduled and the other three will be soon – you can find information about them on the pandemic Web site."



From the Editor

Well we are in the midst of the summer already. As you know we are continuing our efforts to encourage participation in the Bell Ringer, so if you have a story idea, an announcement, or information, please email it to me at palak.raval-nelson@phila.gov. Also, feel free to provide feedback on the articles in the issues or write a letter to the Editor. Lastly, space is available for advertising in the Bell Ringer, just send me the information in an email and I will contact you. I look forward to your feedback and participation. Enjoy the summer before the temperature changes.

Tentative Schedule of Meetings

Fall: September 29, 2006

Winter: December 1, 2006

**Make sure to
register your email
on the CASA
website:
[http://www.casafdo.
org/](http://www.casafdo.org/)**

**Hey, do you know some
one that would make a
great CASA member?**

**Bring them to a meeting!
Tell them about CASA!
Get them to join!**