Overview

Shanghai Municipal Food and Drug Administration (hereinafter referred to as SHFDA) is an organization directly under Shanghai Municipal Government, performing integrated supervision over the safety management of food, health product and cosmetics, and taking charge of the drug supervision and administration in the whole city. According to the Decision of Shanghai Municipal People’s Government on Adjusting the Functions of the Relevant Food Safety Supervision Departments in Shanghai (HFF[2004] No.51 Document), the supervisory duty in the food circulation link and consumption link has been added.

Facing the current grave situation in food and drug safety, we always adhere to the scientific outlook on development as the guide, seriously summarize the experiences and lessons of the food and drug supervision work in both positive and negative aspects, establish and put into practice the concept of scientific supervision, adhere to placing the people’s interest above all else, make sure that the aim and outcome of supervision is to guarantee the food and drug safety of the general public, correctly deal with the relationship between rigorous supervision and development facilitation, and public interest and commercial interest, constantly strengthen the routine supervision and dynamic supervision over food and drug enterprises, and promote the development of food and drug industry. In the process of putting into practice the concept of scientific supervision, we insist on resolving the outstanding problems affecting the food and drug safety by applying the reform ideas, innovative methods, and long-term measures. The establishment and practice of the concept of scientific supervision has enabled us to achieve a better defined direction of supervision, much clearer thoughts of supervision, and more remarkable supervision results.

(1) Strictly Perform Administrative Approval, and Standardize the Development of Food and Pharmaceutical Industry. In 2007, there are over 141,500 food hygiene license holders in Shanghai. SHFDA handled 5,373 pieces of drug registration, 1,076 pieces of administrative examination and approval for drug safety, and 838 pieces of administrative examination and approval for drug circulation, and completed check-up on the registration certificates of 5,615 drug products and 4,530 medical devices. SHFDA audited 481 Class II and III medical device producers for quality system certification, and conducted field verification on 150 pharmaceutical enterprises and 1,082 medical device enterprises. SHFDA handled the record-filing of 4,033 copies of packages, labels and instructions for use of drug and medical device products, approved 1,747 drug advertisements, rejected 47 ads, made public notice of 136 illegal ads, and transferred 164 ads to the department of Shanghai Administration of Industry and Commerce(SHAIC). SHFDA approved 604 medical device advertisements, rejected 5 ads, and transferred 55 ads to the SHAIC. By enhancing administrative approval and field verification, SHFDA has gradually raised the threshold for industrial access, and requested the food and drug trading companies to take safety management measures by law, and construct the relevant hardware facilities, thus standardizing the development of the food and drug industry.

(2) Strengthen Supervision and Inspection, and Eliminate the Potential Safety Hazards in Food and Drug. In 2007, SHFDA conducted supervision and inspection on food, drug, medical device, health product and cosmetics enterprises in Shanghai for over 289,000 times, and placed 12,000 administrative penalty cases on file, with the amount of penalty of nearly RMB 39.698 million. SHFDA conducted supervision and random inspection on nearly 41,000 foods, with the overall conformity rate of
91.16%, and performed rapid test for over 160,000 times. SHFDA conducted supervision and inspection over nearly 19,000 samples of drugs, medical devices and drug packaging materials, with the conformity rate of over 95%. SHFDA undertook the food safety guarantee tasks for the various major events including the FIFA Women’s World Cup and the Special Olympics World Summer Games for 244 times. As required by the State Council for conducting special rectification on product quality and food safety, SHFDA carried out special rectification from September 2007 to December 2007. By Strengthening supervision & inspection and random inspection, SHFDA investigated and prosecuted the companies in violation of the relevant laws or rules by law, and eliminated the potential safety hazards, and achieved the established performance goals.

(3) Construct the Long-term Mechanism, and Consolidate the Basis for Food and Drug Supervision. Under the support of Shanghai Municipal and District Government and the relevant departments, the strength of guarantee for financial appropriation has been further raised, so that the basic work including the supervision network construction, informatization construction, and technical capacity building have been further improved. The 11th Five-Year Plan of Shanghai for Food and Drug Safety was listed as the city-level plan, and was officially promulgated and implemented through the General Office of Shanghai Municipal People’s Government. SHFDA established the Complaint Center, and opened the hotline “962727” for food and drug supervision, and thus cleared up the channel for citizens to lodge reports and complaints. SHFDA established an institute for food and drug safety (named Shanghai Institute for Food and Drug Safety), and strengthened scientific research and international exchange. The defective food recall system has gradually been promoted and implemented, the real-time supervision system for drug circulation has been put into operation, and the training for legal representatives and employees of enterprises has been widely conducted. The news publicity work has been further enhanced, the roles of various media have been brought into full play, and social impact has been constantly expanded.

In 2007, the overall trend for the food and drug market in Shanghai is safe and controllable. 13 cases of collective food poisoning were reported in Shanghai, with 326 people poisoned, which were controlled at a fairly low level, a decrease of 60.61% and 64.45% respectively over 2006. The contaminant monitoring was conducted on 6,021 foods in 21 categories randomly sampled on the market, totaling 157 items and nearly 62,000 item-times, among which the overall conformity rate for the evaluable item-times is about 99.1%, indicating that the overall safety of the foods sold in Shanghai was good. 15,263 reports of adverse drug reactions and 351 reports of adverse events of medical devices were collected, and the report quality has been further improved, and the monitoring on drug safety has been more sensitive. In 2007, SHFDA received complaints, reports and consultations from citizens for over 30,000 times, achieving the level of satisfaction of over 92%. The food safety survey among citizens indicates that the overall satisfaction score given by Shanghai citizens for food safety work is 72.148, an increase of 4.241 over the score of 67.907 in 2006. 82.4% of the citizens have confidence in the current safety status of foods in Shanghai, and 85.5% of the citizens feel that the safety status of foods in Shanghai has turned better. By joining hands with the relevant departments, SHFDA severely combated, and investigated & prosecuted by law the major drug violation cases such as the “March 20” illegal collection and sale of drugs, and illegal production of Tamiflu, conducted in-depth investigation and properly handled the adverse drug event of Shanghai Hualian Pharmaceutical Co., Ltd, and formed the integrated emergency response mechanism, and effectively removed the adverse impact of the international and domestic food and drug safety events on the Shanghai market.