American University

FDA and China Relations

Honors Capstone Spring 2009

Catherine E. Morgan

ABSTRACT

This project explains current issues, initiatives and recommendations for the FDA regarding Chinese relations. After discussing the background of the FDA and its entering into a "new era", the project delves into detail upon the Beyond Our Borders program. There are three recommendations given which are as follows: revamp inspection procedures and information systems, increase collaboration between countries to ensure preventative versus retroactive protection, and finally strategically maximizing the use of overseas offices. Also integrated is an extensive plan of implementation for strategic growth and effectiveness.

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EXECUTIVE SUMMARY

Approximately one-third of all imports to the United States fall under FDA regulation, which contributes to a growing concern regarding overseas regulation and cooperation.[1] These growing concerns are reason to reevaluate current strategies of overseas operations and revamp its inspection procedure, increase collaboration and make the most of its newly established Chinese offices.

BACKGROUND

The US Food and Drug Administration was formed by the passing of the Food and Drug Act of 1906. While the overall regulatory and scientific purposes of the FDA remain, the current goals of the administration are changing with the evolving marketplace. The main goals of the FDA are "to promote and protect the public health by helping safe and effective products reach the market in a timely way, monitor products for continued safety after they are in use, and to help the public get the accurate, science-based information needed to improve health."[2]

The FDA is "the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the

[1] "FDA Joins Pilot Program To Boost Foreign Checks - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 1 Apr. 2009 <http://online.wsj.com/article/SB121565064183841177.html>.
[2] "An Overview of FDA." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/oc/opacom/fda101/sld001.html>.

public."[3] While these are the official regulatory aims of the FDA, the administration also has current strategic goals that are intended to chart the course for future initiatives. The current strategic goals are as follows: strengthen the FDA for today and tomorrow, improve patient and consumer safety, increase access to new medical and food products, and improve the quality and safety of manufactured products and the supply chain.[4] This last strategic goal is especially important, which dedicates the administration to preventing safety problems instead of acting retroactively to recall unsafe products. This is especially important when considering the changing nature of the FDA and responds to this need.

Also important when understanding the FDA is the summary of the fiscal year 2009's budget request. The upcoming fiscal year's budgetary changes represent an overall 5.7% increase. Incorporated in these changes are initiatives that intended to promote and protect public health. Notably among these are Protecting America's Food (approx. $42 million) and Medical Product and Safety Development (approx. $17 million). There is also a savings in the budget of almost $9 million under Administrative Savings and Management Efficiencies.[5]

The regulatory nature of the FDA can be compared to a swinging pendulum, alternating from being extremely conservative to very liberal. In the past, they have fast tracked drugs that supposedly satisfied unmet medical needs or offered accelerated approval for drugs that were

[3] "What FDA Regulates." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/comments/regs.html>.
[4] " Consumer Update ." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/consumer/updates/strategicplan022908.html>.
[5] "Summary of FDA's FY 2009 Budget." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/oc/factsheets/budget2009.html>.

intended for life-threatening diseases.[6] However, the current environment is considered extremely conservative, having approved only 19 new medicines in 2007, the lowest number in 24 years. This conservative nature is not limited to the drug industry. In November 2008, the FDA blocked all products made with Chinese milk from entering the US until they were proven to be melamine-free. This move of blocking an entire country's food imports is unusual, and further shows the conservative current state of the FDA.[7]

CURRENT ISSUES

A number one issue concerning the FDA involves protecting Americans from tainted products, namely from China. Amid concerns over toys recalled containing lead paint, contaminated heparin, and the current debacle regarding melamine in milk and other products, the FDA is facing a new era of regulatory needs.[8] Currently China exports $3.8 billion in food and beverages exports to the United States. While this is not as much as is exported to other Asian countries, there is a sense of vulnerability to tainted products in America.[9] This sense of vulnerability will be later discussed regarding the country of origin effect and stereotypes. Therefore, a large issue facing the FDA right now is dealing with the quality of imports and making sure that they are safe for consumption.

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[6] "Drug Makers Say FDA Safety Focus Is Slowing New-Medicine Pipeline - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB121476772560213981.html>.

[7] " Banned by Washington: Chinese Food Imports - China Journal - WSJ." Blogs - WSJ.com. 1 Apr. 2009 <http://blogs.wsj.com/chinajournal/2008/11/14/banned-by-washington-chinese-food-imports/>.

[8] Rockoff, Jonathan D.. " How Do You Say FDA in Mandarin? - Health Blog - WSJ." Blogs - WSJ.com. 1 Apr. 2009 <http://blogs.wsj.com/health/2008/11/19/how-do-you-say-fda-in-mandarin/>.

[9] Canaves, Sky. "Firms Struggle With Varied Rules on Melamine - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 5 Apr. 2009 <http://online.wsj.com/article/SB122304181115402173.html>.

Another important issue facing the FDA currently is that of the budgetary problems. In June of 2008, the FDA asked for $275 million in order to facilitate drug inspections. This reflects FDA's aim to transition from being an agency that intervenes to one that prevents. With about a third of American imports regulated by the FDA, there are a large number of products to inspect.[10] This amount of money was to be used as follows: $125 million for food protection; $100 million for safer drugs, devices and biologics; $50 million for updating the FDA's science and workforce; and finally $20 million to create a presence overseas.[11]

Regarding budgets, the administrative savings in fiscal year 2009 redirects money previously spent on human resources to high priority activities.[12] Removing these funds from human resource activities, combined with the constant criticism leveled at the FDA, "has hurt employee morale and depleted staffing."[13] As is evident with many organizations, taking away money from human resources causes internal conflict, increases turnover, and finally decreases productivity. Also, matching the employee skills with the jobs needed is a continuous problem at the FDA. Suppose there were a position that required certain project management skills, locating an employee within the FDA system that possesses these skills is difficult. There is no formal way of matching skill sets to projects in terms of maximizing efficiency.

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[10] Favole, Jared. "FDA Joins Pilot Program To Boost Foreign Checks ." WSJ.com. 1 Apr. 2009 <online.wsj.com/article/SB121565064183841177.html>.

[11] "FDA Seeks Extra $275 Million To Beef Up Overseas Inspections - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 5 Apr. 2009 <http://online.wsj.com/article/SB121080510568593153.html>.

[12] "Summary of FDA's FY 2009 Budget." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/oc/factsheets/budget2009.html>.

[13] "Drug Makers Say FDA Safety Focus Is Slowing New-Medicine Pipeline - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 5 Apr. 2009 <http://online.wsj.com/article/SB121476772560213981.html>.

Yet another important issue is foreign inspections. Inspections overseas are not conducted in a way comparable to those in the United States, nor is it helpful as a preventative measure for safety purposes. These inspections are intended to evaluate the facilities' ability to manufacture safe goods.[14] The average amount of time between inspections of domestic companies is 2.7 years. In contrast, the average amount of time between inspections of foreign firms is approximately 13 years.[15] This long period of time is indicative of the intervening nature of the FDA, and how lack of foreign inspections can lead to unsafe products reaching the borders. This creates major issues because it hinders the progress of becoming more preventative in nature instead of simply reacting to problems as they occur.

Not only are these companies not being inspected, the agency is unsure of how many companies are even subject to inspection. While the FDA requires information such as addresses and names to be updated, they do not enforce this practice. Even if a firm is inspected, the translators are usually supplied by the company, and the company is given advanced warning of the visit. This lack of "surprise" is something unique to foreign firms, as in the US there surprise inspections.[16] This makes findings both true and honest, and therefore an important issue in the regulation of products by the FDA.

[14] Scott, Greg. "Article : FDA Seeks to Establish Branch Office in China Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business." Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business. 1 Apr. 2009 <http://www.genengnews.com/articles/chitem.aspx?aid=2573>.
[15] Mundy, Alicia. "FDA Is Faulted for Oversight of Foreign Drugs - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 1 Apr. 2009 <http://online.wsj.com/article/SB122463804562757099.html>.
[16] Ibid.

CURRENT INITIATIVES

The first and most recent news item related to current initiatives at the FDA is the Beyond Our Borders program. This initiative focuses on several key factors that the FDA realized needed to be addressed. The first is that every year over $2 trillion worth of products enter the United States from more than 150 countries and territories all over the world. United States citizens need to be protected from many possible public health and national security issues. There are four keys areas to this initiative:

- increase collaboration with foreign counterparts,
- learn more about foreign exporters and their products,
- provide assistance to foreign regulators and industries, and finally
- establish overseas offices within some foreign countries.[17]

Of these key areas for the initiative, the one which responds most directly to market needs is that of establishing offices within some foreign countries, notably China. In November 2008 the FDA opened a main office in Beijing, China (北京, 中国) with other offices in Shanghai, China (上海, 中国), and Guangzhou, China (广州, 中国). These offices are designed to support a staff of eight FDA experts from the United States and will also employ five Chinese nationals. They will be able to work out of any of these three offices.[18] Murray M. Lumpkin, M.D., FDA's deputy commissioner of international and special programs states that “by promoting food and drug safety and quality, and helping to raise standards beyond our borders, we can better

[17] " FDA Beyond Our Borders ." U S Food and Drug Administration Home Page. 2 Apr. 2009 <http://www.fda.gov/consumer/updates/beyondborders120908.html>.
[18] Ibid.

protect Americans while they continue to enjoy the benefits of the global marketplace… and more importantly, contribute to the overall public health of our global community."[19]

In conjunction with the Beyond Our Borders Initiative, steps are being taken to encourage positive interactions between the United States and China on FDA regulated products. At the same time when the FDA was stopped all Chinese milk products at the border, the Department of Health and Human Services (parent to the FDA) in partnership with the FDA went to open the overseas office in Beijing, China. This was a tumultuous and tense time between the Chinese and Americans, however efforts were being made to improve cooperation. Mike Leavitt, the Health and Human Services (HHS) Secretary at the time (Current Acting Secretary: Charles Johnson),[20] as well as the FDA Commissioner at the time Andrew con Eschenbach (Current Acting Commissioner: Frank M. Torti, M.D., M.P.H.)[21] were present at the ribbon-cutting ceremony for the new office in Beijing, Shanghai and Guangzhou (北京，上海，广州). Also part of their trip was to interact with Chinese officials regarding food and drug policies in the United States as well as information regarding the latest information on melamine, which was the import scare at that time.[22]

The Beyond our Borders initiative has been receiving large amounts of requests for more formal information regarding this program. Currently the program is so small that it has no way to

[19] Ibid.
[20] "Biography of Charles E. Johnson." United States Department of Health and Human Services. 3 Apr. 2009 <http://www.hhs.gov/about/bios/asrtbio.html>.
[21] "Bio: Frank M. Torti, M.D., M.P.H., F.A.C.P.." U S Food and Drug Administration Home Page. 3 Apr. 2009 <http://www.fda.gov/oc/bios/torti.html>.
[22] Mundy, Alicia. " Feds Send Mixed Message to China - Health Blog - WSJ." Blogs - WSJ.com. 2 Apr. 2009 <http://blogs.wsj.com/health/2008/11/14/feds-send-mixed-message-to-china/>.

respond to the massive amount of requests for information. These requests are being made by academia, US and Chinese industry, as well as Chinese regulatory individuals. This interest is important to note because it shows that this small program that encompasses a small number of people is attracting attention from important individuals in all kinds of positions.[23]

A last initiative being implemented by the FDA involves working in conjunction with the European Union and Australia. As previously mentioned the FDA lacks controls in the arena of overseas inspections, and they are acknowledging this weakness and choosing to act on it. This pilot program is collaboration between the three governments in order to "plan, allocate, and conduct inspections of drug-manufacturing facilities."[24] This is going to initially be focused on the pharmaceutical industry and the active ingredients in drugs, however if this pilot program is successful it could be extended to other types of manufacturing facilities. This move is mainly in response to the approximately 80 deaths in the US alone associated with the drug heparin, which is a blood thinner. This drug was imported from China in early 2008, and is one of the contributing factors to the need for overseas offices in China. This lack of oversight is one that has caused intense criticism of the FDA.[25]

[23] Michael R. Kravchuk. Personal Email. 30 April 2009.

[24] "FDA Joins Pilot Program To Boost Foreign Checks - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB121565064183841177.html>.

[25] "FDA Joins Pilot Program To Boost Foreign Checks - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB121565064183841177.html>.

RECOMMENDATIONS

Taking into account these issues and initiatives currently facing and facilitating change within the FDA, there are several strategic courses the FDA needs to pursue to maintain pace with the marketplace so it can fulfill its mission of protecting public health. These recommendations are as follows:

1. Revamp the inspection procedures in place in order to reduce the time between inspection of foreign companies

2. Increase collaboration by joining forces with other countries to offer more preventative rather than retroactive protection

3. Make the opening of overseas offices more than political by making strategic use of resources to ensure the greatest protection of American public health. This can be done by creating a standard approach to Chinese imports through training and providing information to foreign regulators and industries.

Restructuring of Inspection Procedures

Considering the amount of time between foreign inspections is approximately 13 years as opposed to domestically 2.7 years average time,[26] this disparity is something that needs to be addressed. However, an overarching theme of these recommendations is to use resources strategically instead of merely throwing money at a problem that won't solve itself. While

[26] Mundy, Alicia. "FDA Is Faulted for Oversight of Foreign Drugs - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 1 Apr. 2009 <http://online.wsj.com/article/SB122463804562757099.html>.

simply increasing inspections will not solve the problem of lax oversight of imports, it cannot be ignored as a method of protecting public health. Therefore, there needs to be a careful balance between increasing the number of foreign inspections and creating a better system and database of foreign manufacturers to identify where inspection can offer the most benefit and greatest protection.

Also in regards to the inspection procedures, databases should be revamped and continually updated as to have better records as to foreign companies importing into the United States that fall under FDA regulation. Whereas previously a good may be stopped at the border and looking into the previous database there were no references to contact points, building addresses or factory names, revamping this system would create increased communication. This increasing of information is vital to the success of the aim of having a more preventative FDA.

Increased Collaboration Between Countries

Since a main strategic goal of the FDA is to prevent problems rather than blocking imports at the border,[27] increasing collaboration between countries is a primary way of ensuring this is accomplished. Due to a lack of resources to conduct more inspections of foreign companies, the FDA joined the European Union and Australia in a pilot program to respond to this need.[28] With a constantly expanding global marketplace that is becoming more impossible to monitor

[27] Scott, Greg. "Article : FDA Seeks to Establish Branch Office in China Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business." Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business. 1 Apr. 2009 <http://www.genengnews.com/articles/chitem.aspx?aid=2573>.
[28] Favole, Jared. "FDA Joins Pilot Program To Boost Foreign Checks ." WSJ.com. 1 Apr. 2009 <online.wsj.com/article/SB121565064183841177.html>.

alone, combining forces with other countries is a viable option to monitor the safety of manufacturers. By encouraging higher standards and ensuring products are produced at acceptable levels of quality, this will assist FDA achieve its goal of operating in a more preventative manner.

Strategic Use of Resources in Overseas Offices

The main focus of efforts currently in the FDA is related to Chinese relations, and more importantly, the recent opening of overseas offices in Beijing, Shanghai and Guangzhou, China. Since the FDA is in fact a government agency and therefore responds to political and public pressure, it is of utmost importance that the FDA use this opportunity of overseas expansion as more than a merely political move. Getting the most out of the offices in China can also be seen as a challenge, since although there are FDA experts and Chinese nationals working in these offices, they technically have "no enforcement authority on foreign soil."[29] Therefore, in order to make the most of these offices, it is important to look at the opportunity from a strategic point of view. There is a heightened sense of vulnerability to Chinese goods due to several recent negative stories, such as animal deaths due to melamine in pet food in March 2007, Mattel recalling over 20 million toys made in China due to lead paint and magnets, approximately 80 deaths due to contaminated heparin, and most recently melamine used as a

[29] Scott, Greg. "Article : FDA Seeks to Establish Branch Office in China Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business." Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business. 1 Apr. 2009 <http://www.genengnews.com/articles/chitem.aspx?aid=2573>.

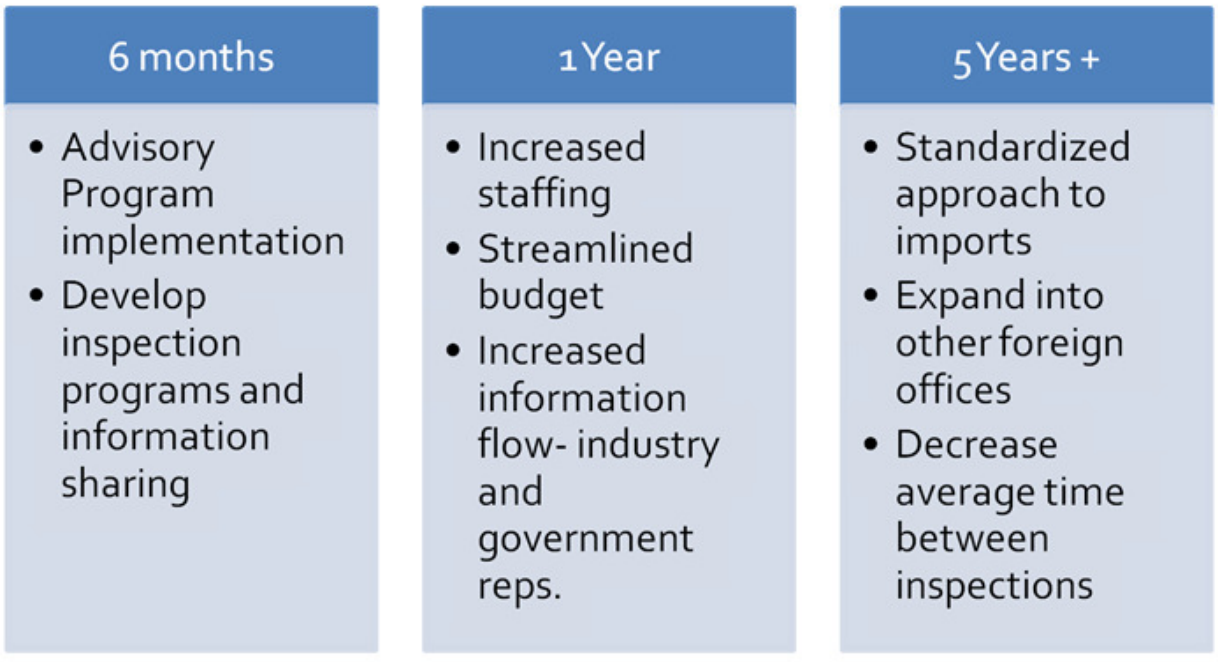
protein substitute in testing in infant formula.[30] While not all of these products made it to the United States, there is still huge debate and criticism toward the FDA for these events.

As previously mentioned, Mike Leavitt, the former Health and Human Services (HHS) Secretary (Current Acting Secretary: Charles Johnson)[31] and the FDA Commissioner at the time, Andrew con Eschenbach (Current Acting Commissioner: Frank M. Torti, M.D., M.P.H.),[32] engaged Chinese regulatory leaders in seminars discussing import standards. This is imperative for improving relations and creating a more preventative FDA. Therefore, the FDA should create a more open forum and education program for foreign companies looking to export to the United States. It is questionable whether the United States and the FDA should require certain standards of imports without showing and educating the companies of the standards before they reach the border. Especially considering that before last year China did not have recall regulation in place for foods and toys,[33] it is important to encourage and foster growth in appropriate regulation so that products are not stopped at the U.S. border.

In a more specific nature, it is important to establish general guidelines for measuring the success of these foreign offices. The three most important ways to measure the success of

[30] "Infant Illnesses Force Major Chinese Baby-Formula Recall - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB122122542993527897.html>.
[31] "Biography of Charles E. Johnson." United States Department of Health and Human Services. 3 Apr. 2009 <http://www.hhs.gov/about/bios/asrtbio.html>.
[32] "Bio: Frank M. Torti, M.D., M.P.H., F.A.C.P.." U S Food and Drug Administration Home Page. 3 Apr. 2009 <http://www.fda.gov/oc/bios/torti.html>.
[33] "Infant Illnesses Force Major Chinese Baby-Formula Recall - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB122122542993527897.html>.

these offices are through increased inspections, increased information flow, and decreased violations at that US border. Using these three points of measure for success, one can then use these to formulate a flexible timeline of implementation. This flexible plan can be divided into three areas: within 6 months, within one year, and finally 5 years and beyond. During this time, the organizational chart, comprised of FDA Experts, ex-patriots and Chinese nationals, should strive toward having a three-pronged structure. The employees will be divided between three business functions, which are as follows: inspection staff, Advisory Program staff, and administrative staff.



The first of this checklist is that of 6 months from beginning of implementation to effectively and strategically use the foreign offices currently in place. Within 6 months, the Advisory Program should begin to bring to full swing. This Program should be developed to increase

information, provide assistance and most importantly provide an advisory role to government and industry officials. This will be done through mentorship programs as well as lectures, workshops and informative information releases.

Also within the 6 month mark, the processes associated with inspection programs and information sharing and archiving should be more established. Through careful review of current procedures and utilizing the foreign offices as posts, establishing a new process of inspection should be normalized. Most important in this should be the enforcement of requirements to maintain information and company data of companies who are exporting to the United States. This information includes not only company official names and addresses, but also should be kept as detailed as possible.

Upon reaching the one year mark, the administrative end of the foreign offices should become more fully utilized. With a current staff of 8 FDA experts and 5 Chinese nationals, it is important to increase these numbers to fully take advantage of the opportunities presented. Also at this time, budgetary concerns should be ironed out; especially those concerning start-up costs should be eliminated from the budget. Over time, the budget should be used to maximize strategic effectiveness while achieving maximum impact. Lastly, within one year the Advisory Program should be reevaluated and constantly checked to maintain usefulness in achieving the goals previously set forth.

Therefore, when considering the long term goals of the foreign offices and maximizing their potential (5 years and beyond), it is important to have reached a standardized approach to the Chinese market. Using this effective model that has been adjusted over the 5 year implementation to account for inefficiencies, the FDA can use this knowledge to consider founding other foreign offices. While this may be done prior to the five year mark, it is important to note that the approach will vary from country to country.

When considering this five year and beyond point of implementation, the success should be evaluated of the foreign offices in China's value. Have the inspection rates increased, is more information flowing, and finally are there less violations at the border.

Also, as previously mentioned, these activities should be appropriately divided beneath the Office of International Programs. By dividing the organizational chart into three areas (Inspection Staff, Advisory Program, and Administrative), the work can be effectively divided and implemented.

The inspection staff would consist of the staff members associated with the inspections of the foreign plants and also with the maintaining and updating of the databases. This effort will increase communication and information flow. This provides use to the overall objective of decreasing time between inspections. The advisory program staff would consist of individuals who not only assist in the promotion of material regarding standards and so forth, but toward developing the eventual mentorship program between industry and foreign counterparts to maximize efficiency and teach best business practices. These functions would all be supported by the administrative staff.

Appropriate Use of Recommendations for Strategic Growth

By using these aforementioned recommendations in careful balance, it is feasible for the FDA to respond quickly to the changing marketplace and continually fulfill its mission of protecting public health.

RELATED ISSUES

Country of Origin Effect

This related issues section will seek to define, provide meaning behind, and show the management implications on the topic of country of origin effect. By providing a definition of the term and what it means in application, one can then outline why this applies to China, the FDA, and how this applies to general management principles.

The country of origin stereotypes (COO) is those that influence consumer product assessments. These perceptions change over time, and are more influential on certain times of consumers-

elderly, less educated and the politically conservative.[34] When taking this into account, the meaning behind this is that a consumer will associate or not associate a negative connotation to a good from a certain country.

This is important to consider when regarding consumer goods coming into the country and the reaction of the consumer to seeing a "Made in China" label. This is especially important when considering goods of high importance such as pharmaceuticals. Currently 80% of the active ingredients in US drugs now originate from overseas facilities. As previously mentioned, the FDA does not possess the resources alone to inspect all of these facilities more than once every 13 years. When considering the deaths related to the drug thinner heparin, more and more consumers are concerned about drugs from overseas- namely from China.[35]

Regardless of place of origin of the active ingredients in the drugs, they are required to meet the same standards. Therefore, it doesn't matter where the raw materials have originated from, they will still be the same quality.

The FDA currently only requires that the drug company disclose only the name, place of business of the manufacturer, packer or distributor of medications. Listing these places of origins can be considered excessive information and useless to the consumer. Especially

[34] Helsen, Kristiaan, and Masaaki Kotabe. Global Marketing Management. New York, NY: Wiley, 2007.

[35] Beck, Melinda. "Disclosing Drug Sources - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 15 Apr. 2009 <http://online.wsj.com/article/SB120759560791495641.html?mod=home_health_right>.

considering the massively diverse global supply chain involved in the manufacturing of pharmaceuticals, this level of detail would not necessarily helpful to the consumer.[36]

Therefore, the managerial implications of this to the FDA is in regards to creating a situation where they can strategically inform foreign companies of the standards required for entrance into the United States. While creating preventative measures for all to follow, less mishaps will happen and this will promote public health.

Justification for Suggestions

It is understood that there are many issues facing the FDA at the current time. However, the aforementioned recommendations are given as a first look into the importance of these issues and what can be done to further their development. With the recent opening of the offices in China and beginning of the Beyond our Borders program, it is important to strategically use the resources given to assist in the overall strategic goals of the FDA.

[36] Beck, Melinda. "Disclosing Drug Sources - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 15 Apr. 2009 <http://online.wsj.com/article/SB120759560791495641.html?mod=home_health_right>.

Appendix A

Summary of FDA's FY 2009 Budget

Total Budget: For FY 2009, the FDA requests a total budget of $2.4 billion. This amount is $129.7 million more than FY 2008 and represents a 5.7 percent increase.

Budget Authority: The FY 2009 budget requests $1.77 billion in budget authority and contains a net increase of $50.7 million over FY 2008 for high priority initiatives. This represents a 2.9 percent increase.

User Fees: Finally, the FDA's budget proposes $628 million in industry user fees, an increase of $79.0 million over FY 2008. This represents a 14.4 percent increase.

Specifics on FY 2009 Initiatives: The FDA's FY 2009 budget advances the agency's core mission: promoting and protecting public health. The budget funds initiatives above FY 2008 in priority areas:

- +$42.2 million for a total investment of $662 million to implement the Food Protection Plan. The FY 2009 investments in the Food Protection Plan will strengthen food safety by preventing foodborne illness outbreaks, intervening when food defense or food safety vulnerabilities emerge, and rapidly responding to food defense and food safety threats.
- +$17.4 million for a total investment of $887 million for medical product safety and development. This initiative allows the FDA to improve the safety of medical products, including human tissues, blood and blood products, human drugs, medical devices, and animal drugs.
- A savings of -$8.9 million due to administrative and management efficiencies, generated by productivity gains.
- $25.0 million is included in the initiatives listed above to fund cost of living increases for the FDA's world-class workforce.

The full details of the FY 2009 FDA budget request appear at:
http://www.fda.gov/oc/oms/ofm/budget/documentation.htm

Overview of FY 2009 Initiatives

Initiative	Amount	FTE	Synopsis
Budget Authority			
Protecting America's Food	+$42,232,000	94	This initiative supports the FDA's shift to a comprehensive, preventative, and risk-based approach to safeguard the food supply and the American homeland. The investment allows the FDA to implement major components of the Food Protection

			Plan, Import Safety Action Plan, the December 2007 agreements with China, and a possible FDA office in China. Includes a pay increase for agency personnel to sustain current services and conduct the FDA mission.
Medical Product Safety and Development	+$17,395,000	8	This initiative provides targeted resources to improve the safety of human and animal drugs, blood, human tissues, and medical devices. The investment will strengthen the FDA's ability to effectively monitor the safety of medical products, including imported products. The FDA will also assist medical product manufacturers to develop new products to treat life-threatening diseases and conditions. Includes a pay increase for agency personnel to sustain current services and conduct the FDA mission.
Administrative Savings and Management Efficiencies	- $8,918,000	- 11	In FY 2009 the FDA will redirect savings and management efficiencies to high priority activities.
Current Law & Proposed User Fees			
Current Law User Fees	+$57,534,000	239	The budget request includes inflationary increases for FDA user fee programs as well as other increases authorized by law under the prescription drug and medical device user fee programs. Three FDA user fee programs facilitate premarket review for human and animal drugs and human devices. Three other user fee programs support the mammography facilities inspection program and provide certification services for color additives and for drug and device products exported from the United States.
Proposed Generic Drug User Fee	+$16,628,000	34	The proposed user fee for Generic Drug Review will provide additional resources to improve the generic drug review process and to respond to the growing number of Abbreviated New Drug Applications.
Proposed Animal	+$4,831,000	22	The proposed user fee for Animal Generic

Generic Drug User Fee			Drug Review will provide additional resources to improve the animal generic drug review process and to respond to the growing number of Abbreviated New Animal Drug Applications.
Total Program Level Increase over FY 2008	***+ $129,702,000***		
Proposed Mandatory User Fees (Non-Add)			
Reinspection User Fee	+$23,276,000 (Non-Add)	118	Re-proposed new user fees to reimburse for reinspection of FDA-regulated facilities.
Food and Animal Feed Export Certification User Fee	+$3,741,000 (Non-Add)	23	Re-proposed new user fees to reimburse for issuing food and feed export certificates.
Mandatory User Fees	***+$27,017,000***		

Source: http://www.fda.gov/oc/factsheets/budget2009.html

Works Referenced

"An Overview of FDA." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/oc/opacom/fda101/sld001.html>.

" Banned by Washington: Chinese Food Imports - China Journal - WSJ." Blogs - WSJ.com. 1 Apr. 2009 <http://blogs.wsj.com/chinajournal/2008/11/14/banned-by-washington-chinese-food-imports/>.

Beck, Melinda. "Disclosing Drug Sources - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 15 Apr. 2009 <http://online.wsj.com/article/SB120759560791495641.html?mod=home_health_right>.

"Biography of Charles E. Johnson." United States Department of Health and Human Services. 3 Apr. 2009 <http://www.hhs.gov/about/bios/asrtbio.html>.

"Bio: Frank M. Torti, M.D., M.P.H., F.A.C.P.." U S Food and Drug Administration Home Page. 3 Apr. 2009 <http://www.fda.gov/oc/bios/torti.html>.

Canaves, Sky. "Firms Struggle With Varied Rules on Melamine - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 5 Apr. 2009 <http://online.wsj.com/article/SB122304181115402173.html>.

" Consumer Update ." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/consumer/updates/strategicplan022908.html>.

"Drug Makers Say FDA Safety Focus Is Slowing New-Medicine Pipeline - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB121476772560213981.html>.

Favole, Jared. "FDA Joins Pilot Program To Boost Foreign Checks ." WSJ.com. 1 Apr. 2009 <online.wsj.com/article/SB121565064183841177.html>.

" FDA Beyond Our Borders ." U S Food and Drug Administration Home Page. 2 Apr. 2009 <http://www.fda.gov/consumer/updates/beyondborders120908.html>.

"FDA Joins Pilot Program To Boost Foreign Checks - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 1 Apr. 2009 <http://online.wsj.com/article/SB121565064183841177.html>.

"FDA Seeks Extra $275 Million To Beef Up Overseas Inspections - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 5 Apr. 2009 <http://online.wsj.com/article/SB121080510568593153.html>.

Helsen, Kristiaan, and Masaaki Kotabe. Global Marketing Management. New York, NY: Wiley, 2007.

"Infant Illnesses Force Major Chinese Baby-Formula Recall - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 2 Apr. 2009 <http://online.wsj.com/article/SB122122542993527897.html>.

Michael R. Kravchuk. Personal Email. 30 April 2009.

Mundy, Alicia. "FDA Is Faulted for Oversight of Foreign Drugs - WSJ.com." Business News & Financial News - The Wall Street Journal - WSJ.com. 1 Apr. 2009 <http://online.wsj.com/article/SB122463804562757099.html>.

Rockoff, Jonathan D.. " How Do You Say FDA in Mandarin? - Health Blog - WSJ." Blogs - WSJ.com. 1 Apr. 2009 <http://blogs.wsj.com/health/2008/11/19/how-do-you-say-fda-in-mandarin/>.

Scott, Greg. "Article : FDA Seeks to Establish Branch Office in China Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business." Genetic Engineering & Biotechnology News - Biotechnology from Bench to Business. 1 Apr. 2009 <http://www.genengnews.com/articles/chitem.aspx?aid=2573>.

"Summary of FDA's FY 2009 Budget." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/oc/factsheets/budget2009.html>.

"What FDA Regulates." U S Food and Drug Administration Home Page. 1 Apr. 2009 <http://www.fda.gov/comments/regs.html>.