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Life Sciences Health Industry Alert

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Client Alert 09-218

July 2009

reedsmith.com

A New Focus at FDA: Supply Chain and Import Challenges

Dr. Margaret A. Hamburg, the recently appointed Commissioner of the Food and Drug Administration ("FDA"), made an important statement during her first round of interviews since becoming Commissioner: "Under my new leadership, the industry can expect to see a more aggressive posture with respect to enforcement." This remark follows numerous signals by FDA over the past few weeks that the agency intends to toughen enforcement in several areas. These signals should be taken seriously. An "awakened" FDA will be funded with additional monies promised for FDA's budget and with funding proposed through legislation such as The Drug and Device Accountability Act of 2009 (S. 882). As a result, firms that manufacture, import, and distribute FDA-regulated products can anticipate being visited more often, and probably more critically, than in the past. This, in turn, will force a company to handle additional Inspectional Observations (FDA 483s), Warning Letters, and reinforcement actions.

Discussed below are two areas – supply chains and imports – in which FDA has begun to focus. Included in the discussion are suggestions firms may wish to consider in preparing for increased regulatory scrutiny.

Increased Focus on Supply Chain Management and Import-Related Inspections

Dr. Hamburg and Dr. Joshua Sharfstein, FDA's Principal Deputy Commissioner, signaled in a recent editorial in *The New England Journal of Medicine* that supply chain management is a priority at FDA. "Safety must be the shared responsibility of not only the producer but the country of origin, the importer, the importing country, and the final company in the supply chain." Supply chain management is not easy. As the number of entities involved in product development, manufacture, and distribution increases, the harder it is for a company to monitor the lifecycle of an FDA-regulated product.

A company's ability to manage successfully increased regulatory scrutiny will depend largely on the integrity of its supply chain management system. Companies should, therefore, review their supply chains now, before a regulatory agency identifies a problem. Not only does an effective supply chain management system reduce the likelihood of enforcement actions taken by a regulatory body (the system will reduce errors by protecting the supply chain), but it is also a signal to FDA that a company understands FDA's concerns about supply chain safety, and takes supply chain management seriously. The challenges presented by an increasingly complex global economy and a significant rise in imports has caused a paradigm shift in the way that FDA ensures that a product meets U.S. safety standards. Rather than continuing to use a traditional intervention, port-of-entry focused strategy (e.g., inspection and sampling) to protect the safety of imported products, FDA is transitioning to a risk-based, life-cycle approach that will hold all segments of a supply chain accountable. This approach will use both traditional and innovative mechanisms (e.g., third-party certifications and coordination with foreign regulatory agencies) to identify high-risk segments of a product life cycle, and to verify the safety of products at critical phases. Firms that acknowledge and adapt a risk-based supply chain management system will be in a more compliant posture when interacting with FDA.

Industry should act now. Firms can anticipate a doubling of the number of import field examinations in the next fiscal year (beginning Oct. 1, 2010) to an estimated 6,197, up from the FDA's projection of 2,870 for fiscal year 2009. For fiscal year 2009, the number of import samples collected, similarly, is projected to reach 586, up from 346 in fiscal year 2008. FDA also estimates it will double (from 1 percent to 2 percent) the number of import entries to be examined in fiscal year 2010.

FDA Supply Chain Safety and Import Initiatives

- **FDA Pilot Program:** A company should evaluate and consider participating in FDA's new two-year Secure Supply Chain ("SCC") pilot program. The SCC program, one of several agency initiatives to enhance drug product safety, will be jointly administered by FDA's Office of Compliance in the Center for Drug Evaluation and Research ("CDER") and FDA's Office of

Regulatory Affairs. The program is part of FDA's new risk-based approach to regulating drug imports, and is expected to increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States. Each applicant may designate up to five drugs for selection in the program. To qualify, applicants must meet the program's criteria, including a requirement that they maintain control over the drugs from the time of manufacture through entry into the United States. FDA is expected to announce the opening of the program in late 2009 or early 2010. The *Federal Register* announcement will include information about the application, the application process, and program criteria. Critics of the program (as described in the January 2009 *Federal Register* notice[1]) are concerned that it may not significantly reduce import clearance times because FDA, rather than adopting a system for random inspections, will conduct full electronic reviews of all participating products, with some entries receiving further FDA review or examination after the electronic review. Many also are concerned about FDA's ability to exclude a participant from the program if certain entities in the supply chain (e.g., applicant, foreign manufacturer, or consignee) receive a warning letter from FDA. This may occur regardless of whether the warning letter relates to a product that has been selected for inclusion in the SCC pilot program. These concerns and others that were submitted to FDA in January will likely impact the structure of the final program.

- **Good Importer Practices Guidance:** Issued by several federal agencies, including FDA, in January 2009, the Draft Good Importer Practices Guidance[2] ("Guidance") is a response to the Interagency Working Group on Import Safety's *Action Plan for Import Safety: A Roadmap for Continual Improvement (Action Plan)*[3]. The Guidance recommends that importers institute certain practices to identify and to minimize risks associated with imported products. Although directed at importers, the Guidance states that manufacturers also should "carefully consider" the Guidance. The safety concerns that gave rise to the need to issue the Guidance are evident when one considers U.S. food imports from China, which more than tripled in value between 2001 and 2008. FDA refusals of food shipments from China suggest recurring problems with filth, unsafe additives, labeling, and drug residues in fish and shellfish. Addressing these safety risks and others is extremely difficult, given the scope and array of complex issues. Now, rather than relying primarily on random import inspections and foreign governments, FDA is working to place the onus on companies to comply with good importer practices.

  The Good Importer Practices are broadly organized under four guiding principles:

  Establishing a Product Safety Management Program: Starting at the very top of an organization, an importer should have an organizational structure that fosters corporate responsibility for product safety. An effective product safety management program should have a defined management structure; have clearly defined employee roles and responsibilities; provide adequate training for employees; have documented policies, specifications, and procedures; have a process to analyze and evaluate risks in a product life cycle; encourage effective communication between interested parties; and have a formal quality assurance program.

  Knowing the Product and Applicable U.S. Requirements: To enhance their ability to identify and minimize potential hazards to customers, importers should have a good understanding of the products they import, the applicable regulatory requirements, and the compliance history of the products and firms involved in the products' design, production, and handling.

  Verifying Product and Company Compliance Throughout the Supply Chain and Product Life Cycle: Importers should ensure that the appropriate preventive controls have been implemented throughout the supply chain and life cycle of the product, and that the product and companies down the supply chain comply with all applicable U.S. requirements. An importer should take responsibility for evaluating problems that develop with its imported products prior to importation while under its control, or while under the control of domestic parties with which it conducts business, and for working closely with all parties in the supply chain when issues arise.

  Taking Corrective and Preventive Action: After detecting a problem, an importer should take corrective and preventive action to ensure similar problems do not recur, such as developing corrective action plans, identifying root causes of problems, and taking steps to remediate and prevent them from current and future shipments. Corrective action may involve terminating business relationships with non-compliant firms.

- **Qualified Trusted Importer Program ("QTIP"):** A company may find it useful to obtain QTIP certification when it becomes available. FDA is considering endorsing QTIP as a voluntary certification program for certain importers. The QTIP program would certify the integrity of an importer's internal processes and controls with respect to product quality, supply chain security

and trade compliance. As a certified QTIP importer, a company will be afforded interagency green lane status for imports and certain other benefits.

Increased Foreign and Domestic Inspections

FDA will increase its foreign and domestic inspections over the next few years. According to FDA's Center for Drug Evaluation and Research, Office of Compliance (CDER/OC), since 2001, the number of foreign manufactured drug products has more than doubled. Similarly, foreign manufacturing sites also have more than doubled. China and India have had the largest increases. During this time, FDA's inspection rate decreased by more than 41 percent. As the number of foreign manufacturers exporting FDA-regulated products to the United States continues to increase over the next few years, FDA's role in collaborating with foreign governments and sending FDA inspectors from its new foreign offices to non-U.S. sites is anticipated to increase. Domestic inspections also are expected to increase significantly, countering the previous trend.

In sum, companies may anticipate increased numbers of and more aggressive inspections. Deborah Autor, Director, CDER/OC, at the April 2009 Food and Drug Law Institute annual conference, stated that companies can expect "swift, aggressive action" by FDA after it identifies an inspection problem. Her remarks may foreshadow how little time a firm could have from inspection to an enforcement action. Company management should consider having response teams in place to handle these increased inspections and enforcement actions.

Subsequent installments will address what companies can do when confronted with an FDA inspection and enforcement action.

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1 74 *Fed. Reg.* 2604 (January 15, 2009).

2 Guidance: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125805.htm.

3 Action Plan: http://www.importsafety.gov/report/actionplan.pdf.

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