Pharmaceutical
COMPLIANCE MONITOR

FDA Getting Tougher at the Border

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Increased Scrutiny of Imports

FDA regulated products offered for import are subject to significant scrutiny by U.S. Customs as well as the Food and Drug Administration ("FDA"). We have seen an increase in product detentions and refusals over the last year. FDA is more thoroughly evaluating the documentation submitted to support product entry. If the documentation is incomplete or raises questions over the marketing status of products – the FDA has not allowed the products to proceed into commerce. This detention or refusal can lead to interruption in the marketplace and loss of significant revenue. Companies must take notice of this trend in detaining or refusing product entry and take measures to ensure that import documentation is complete and acceptable so that products will not be held or refused at the border.

Under the Federal Food, Drug and Cosmetic Act ("FD&C Act"), FDA has broad authority over regulated products that are offered for import into the United States. If the products appear to be adulterated or misbranded, the products can be detained and refused entry into the U.S. See Section 801 FD&C Act, 21, U.S.C. §381. Based upon an examination of the documentation and paper work supplied to support the entry, among other items, if a product appears to have been manufactured, processed, or packed under insanitary conditions; manufactured in a facility that has not registered with FDA; manufactured under conditions that are not in compliance with current good manufacturing practices; or has improper labeling, the product can be detained and/or refused entry. Again, this can be based upon the appearance of a violation – the product may not necessarily be in violation of FDA requirements. However, once the product is detained or subject to further FDA review and evaluation, this can cause a significant interruption in product availability.

FDA implemented a new on line computerized system, the PREDICT system designed to improve import screening and targeting to prevent the entry into the US of adulterated, misbranded, or otherwise violative goods and expedite the entry of non-violative goods. This predictive risk-based evaluation for dynamic import compliance targeting replaced the electronic screening function of the FDA's OASIS system that was previously used by the Agency for import admissibility determinations. The PREDICT System evaluates the inherent risk to health of the proposed product, the admissibility history with respect to the manufacturer, exporter, importer, and consignee for the current product and provides a real-time, "may proceed" decisions for lower-risk products and provides FDA staff more time to evaluate higher- risk lines. The system now also provides FDA field staff with the ability to initiate automated queries of FDA databases where relevant (i.e., registration and listing, marketing approval status, low- acid canned food scheduled processes, etc.) The increased access to FDA automated databases has provided FDA field staff with more information on which to make admissibility decisions. As noted previously, there appears to be an increasing trend in product detentions and refusals over the last year which has likely resulted from FDA's increased scrutiny of products having a higher inherent risk as well as a review of FDA data bases. If the regulatory documentation for products offered for import raises questions or can not be verified, the products are not allowed to proceed and a detention and product refusal process is initiated.

Given the safety history of products offered for import, the FDA and Congress have taken other measures to enhance product safety of products manufactured abroad. FDA has implemented the Pathway to Global Product Safety and Quality initiative.

The initiative includes four key elements:

1. The FDA will partner with its counterparts worldwide to create global coalitions of regulators focused on ensuring and improving global product safety and quality;

2. The coalitions of regulators will develop international data information systems and networks and increase the regular and proactive sharing of data and regulatory resources across world markets;

3. The FDA will build in additional information gathering and analysis capabilities with an increased focus on risk analytics and information technology; and

4. The FDA increasingly will leverage the efforts of public and private third parties and industry and allocate FDA resources based on risk.

The FDA has established international offices in China, India, Europe, Latin America and the Middle East. FDA staff in these foreign offices are a resource for foreign companies; they act as a liaison with foreign regulatory officials and they coordinate and facilitate inspections of foreign companies.

Congress also enacted the FDA Food Safety Modernization Act ("FSMA"). FSMA charged FDA with inspecting foreign food processors and distributors, giving the Agency the power to form agreements with foreign governments to accomplish this mission. FSMA required the FDA to establish overseas offices (see above) to support inspections of foreign food facilities and to reject food imports from any foreign facilities that refuse to undergo U.S. inspections. FSMA gave FDA authority to require affirmative safety assurances for specific food types before allowing them into the U.S. FSMA also increased importers' responsibility for food safety by requiring them to implement preventive safety plans at their facilities and to provide records of those plans to the FDA. The FDA established a tracking system of the information obtained from importers. Under FSMA, there will be new inspection mandates, including one to inspect more than 19,000 foreign-food facilities by the year 2016.

All the programs identified above give FDA increased authority, resources and access to new information to evaluate risks associated with products offered for import. We have seen increased scrutiny concerning the regulatory status of products offered for import. Facilities that have not registered with FDA, products that have not undergone FDA approval or clearance where likely required, products with labeling claims or website claims that are possibly violative, i.e., for example, dietary supplements with treatment or cure claims have received much more scrutiny by FDA field staff. Once issues are raised by field staff, these issues are generally referred to complain staff in the respective Centers for further evaluation and determination for compliance with regulatory requirements. Our experience is that upon closer examination by FDA headquarters staff, more products are detained and ultimately refused entry.

Given these trends, we counsel companies to ensure that they have the appropriate documentation in place, well in advance of offering products for import. We also suggest that documentation of the regulatory status as well as establishment registration and product list where appropriate be provided with import document. This can help expedite review and release of the product. Once a product is detained, it is sometimes very difficult to ascertain the exact nature of the issue and/or the process to recondition it so that is may be permitted to enter the US. Currently, more often than not, products which are detained can not be reconditioned to come into compliance and these products must be re-exported or destroyed. With the heightened level of review and evaluation, companies must fully understand the regulatory and

compliance status of their products. They should take the necessary steps to ensure that facilities are registered and products have the necessary approvals and product listings before they are offered for import. By doing so, companies can prevent delays in obtaining release of products for import or more costly issues associated with the re-export or destruction of products.

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