The United States Food and Drug Administration (“FDA”) recently published a list of every foreign manufacturer that has had a shipment refused entry to the U.S. since October 2001. In the past, FDA listed Import Refusals monthly on its website. The ‘Import Refusals’ page of FDA’s site was ‘out of commission’ due to technical problems for several months – until recently. Now that FDA’s Import Refusal Report is once again operating, Benjamin England, founder of FDAImports.com, LLC, a food and drug regulatory consulting firm, says that “Many foreign manufacturers will soon be facing potential enforcement action from their domestic regulatory bodies, as well as public and competitor scrutiny, concerning their products.”

FDA’s new publication of its FDA Refusals data is functioning more efficiently than ever before. Now the Import Refusal Report publicizes cumulative refusal data since October 2001. The purpose for publishing FDA Refusal of Admission data is to “provide the public with information on products that have been found to appear in violation of the Act,” according to FDA. “While these manufacturers’ initial concern may be the extent to which the FDA Refusal Report affects their consumers’ image of their company,” notes Mr. England, “there is a far greater concern to address and that’s the foreign manufacturer’s local government.”

For example, the China Inspection and Quarantine (“CIQ”) agency, which regulates and reviews the safety of food imports and issues inspection certificates and export permits, has already started sending letters to several Chinese manufacturers recently listed on FDA’s Import Refusal website page. In these letters, CIQ has been asking for an explanation about FDA Refusals of Admission of their products. Documenting what occurred can take some time and definitely money.

“The problem here,” Mr. England explains, “is that CIQ, or the food-regulatory body of any other foreign government often believes FDA actually tested the refused food and found it was contaminated or unsafe and therefore FDA refused admission to the product.” The Food, Drug and Cosmetic Act (“FDCA”) grants FDA the authority to enforce food safety and labeling laws against manufacturers, producers, importers and distributors. It is not uncommon for FDA to refuse imported food for a technical labeling violation (i.e., a misbranding charge) which may not pose a food safety risk. Therefore, when CIQ makes enforcement decisions out of concern for public safety, merely because a company appears on FDA’s Import Refusal Report, this subjects manufacturers to additional (local) scrutiny which may not promote public health.

CIQ governs all Chinese exports with authority to grant export licenses. When CIQ recognizes a Chinese manufacturer on FDA’s Import Refusal page, its immediate reaction may be to assume the manufacturer’s products are in violation of U.S. law or worse, are unsafe. If the manufacturer cannot provide a satisfactory explanation to CIQ, that agency has been known to revoke a manufacturer’s export license.
“If a manufacturer is unable to provide sufficient explanation for their publication on the FDA Refusal Report page,” says Benjamin England, “the consequences may be severe.” Understanding the laws and regulations that govern FDA’s authority is no small task – and explaining them proves to be even more challenging.

FDA may refuse entry of a product to the U.S. for reasons as miniscule print size or location of a quantity statement on a food label. However, if a foreign manufacturer does not understand all of the laws that govern product labeling, they can hardly be expected to explain the reason for the refusal and propose the necessary corrections.

“Whatever the reason for the refusal,” adds Mr. England, “being published on the published FDA Refusal of Admission report means greater enforcement action on several levels.” First, once a product is refused admission and published on the refusal page, FDA may refuse admission to future importations of that product to the U.S. Second, the foreign manufacturer’s government may go as far as to refuse export of that product; as seen by recent CIQ enforcement in China. Resolving these issues requires experts knowledgeable of both FDA and CIQ regulatory procedures. Now that the FDA Import Refusal Report page is being published again, with a 10-year history of import enforcement actions, regulatory overreaching by non-U.S. governmental bodies, such as CIQ, will likely increase.

FDAImports.com, LLC specializes in communicating with FDA on behalf of manufacturers, producers and importers all over the globe. FDAImports.com, LLC is a regulatory consulting firm that concentrates its practice at engaging and managing FDA and Customs laws, regulations, requirements and enforcement actions. Let FDAImports.com, LLC show you ‘the way through.’