Triggering Factors for US Import Refusals

Ly Nguyen
Robert G. Nelson
Norbert L. Wilson

Department of Agricultural Economics and Rural Sociology
Auburn University
Comer Hall, Auburn, Alabama 36849
Email: ltn0002@auburn.edu; nelsorg@auburn.edu; wilsonl@auburn.edu

Department of Selected Paper prepared for presentation at the Southern Agricultural Economics Association's 2015 Annual Meeting, Atlanta, Georgia, January 31-February 3, 2015

Abstract

Antifreeze in toothpaste and melamine-tainted infant formula have raised concerns about the quality and safety of imports into the US to unprecedented levels. However, the Food and Drug Administration (FDA) cannot inspect all imports, so their inspections are path-dependent (Baylis et al., 2009) and targeted based on risk (Elder, 2013). This research investigates potential factors triggering FDA's import refusals within the three categories of food, drugs, and cosmetics during the period from 2002 to 2014. Triggering factors are differentiated by: 1) FDA's human resource and financial capacity; 2) product-specific characteristics; 3) economic and political pressures in the US and exporting countries; and 4) spillover effects among exporting countries. Number of refusals and ratio of refusals to import value are used as the dependent variable in a dynamic panel data model and in Negative Binominal model, respectively. The dummy variables for 20 countries classified into three regions (Asia, EU, and the Americas) are not statistically significant. Factors related to FDA's human resource and financial capacity, including FDA budget allocation, FDA foreign offices, the Food Safety Modernization Act of 2010 and historical compliance all have a significant influence on refusals. Determination of spillover effects indicates that lagged refusals and food scandal from China caused significant influence on rejections not only from the neighbor countries but also the EU members and American countries.

Key words: Import refusals, triggering factor, food, drug, cosmetics.

JEL code: F5

Introduction

Imports are becoming a more significant proportion of the US economy, which grew approximately 7% annually for the period from 2002 to 2013. During this period, imported food accounted for 17 percent of total consumption per capita, 40 percent of all drugs were imported, and 80 percent of the active pharmaceutical ingredients in drugs consumed in the United States were imported (FDA, 2014). However, the recent issues of antifreeze in toothpaste and melamine-tainted infant formula have raised concerns about the quality and safety of imports into the US to unprecedented levels. Considered as one of the world's most efficiently working systems in terms of imported-product safety and regulations, FDA is responsible for ensuring that merchandise entering the US market is wholesome, safe, and produced under sanitary conditions (FDA, 2012). Tasked with an enormous job, FDA is responsible for monitoring imports from over 300,000 facilities from more than 130,000 importers in 150 different countries whose products enter the United States through over 300 ports of entry. Because of the tremendous volume of imported products, limited time and human resources, and financial constraints, FDA can only physically examine less than 1% of all regulated products, although 100% of imported food products are electronically examined and 100% of drug products are reviewed at an additional level before reaching US borders. Therefore, FDA's inspections have become path dependent (Baylis, Martens, and Nogueira, 2009) and targeted based on risk (Elder, 2013). For example, frozen fish from Norway has never been a problem, so it would be considered low risk, while seafood from China, has been a persistent problem indicating high risk (Knox, 2007).

The FDA, the USDA Food Safety and Inspection Service (FSIS), and the Environmental Protection Agency are three agencies who take responsibility to ensure the safety of imported merchandise for domestic consumption. FDA regulates $2 trillion of imported goods including food (except meat, poultry, and processed eggs), animal feed, human and veterinary drugs, vaccines and other biological products, cosmetics, and medical devices. Although FDA frequently upgrades their regulations to keep Americans safe and healthy but the number of refusals didn't change much over the last decade. Refusals ranged 18,663 per year for the period from Jan. 2002 to Apr. 2014 except in 2011 when they rose to 85,000. The research question is the degree to which refusals change as a result of improvements or declines in imported

product's safety, industry compliance, and other factors. Thus this paper investigates potential factors triggering FDA's import refusals within the three categories of food, drugs, and cosmetics during the period from 2002 to 2014.

Although exporters are interested in the reasons for FDA's import refusals, the literature in this area is still limited and has only been studied in recent years. Because of limited and biased data, previous researchers could only investigate particular aspects. Most of these authors focused on product-specific refusals such as seafood (Anders and Westra, 2011), fish and seafood (Grant and Anders, 2010), different kinds of food (Baylis, Martens, and Nogueira, 2009; Jouanjean, Maur, and Shepherd, 2012; Nakuja, 2012), or food in general (Buzby and Regmi, 2009).

In general, most papers were based on historical data to describe simple trends in FDA's refusals in specific food sectors such as vegetables and vegetable products, fishery and seafood products, and fruits and fruit products. Buzby, Unnevehr, and Roberts (2008) used FDA's Import Refusal Reports from 1998 through 2004 to examine FDA's refusals of food offered for importation into the United States. The authors created tabulations of refusals by industry group and violation code, in which they particularly focused on "adulteration" violations. They determined that import refusals highlight food safety problem that appear to occur in trade where the FDA has focused on alerts, examinations, and other monitoring efforts. Moreover, the data showed that some food industries and types of violations are consistent sources of problems both over time and in comparison with previous studies.

Using the same dataset and method, Buzby and Regmi (2009) classified import refusals by food industry group, type of violation, and country from 1998 to 2004. Their study found that low-income countries share the highest number of violations and the most refusals per billion dollars of US food imports. The implication from this study is that low-income countries may not have as effective food safety standards, practices, and regulations as the middle-income and high-income countries. Therefore, in order to approve more food exported to the US from these countries, it is necessary for them to improve their food safety procedures and techniques. In addition, if relying on the data for a short period only (Sep. 2006 to Oct. 2007), India, China, and Mexico were the leading violators in terms of FDA's refusals, with fishery/seafood products, vegetables/vegetable products, and spices/flavorings having the largest share of refused

shipments because the products were filthy (Allen et al., 2008). From these descriptive/analysis studies, with the exception of food quality, the factors which influenced the number of food import refusals to the US depended on the food industry groups, country development status, and refusal history.

Because of the complexity and limitation of the refusal data from the FDA for all products imported from different countries, some earlier studies targeted only a particular product or specific country. Emphasizing the most highly-traded commodities with the most violations, Anders and Westra (2011) investigated trends and patterns in U.S import detentions and refusals of seafood products from 2000 to 2010. Their research was also conducted via tabulations of the FDA's refusal data. Their results are consistent with the statement by Buzby and Regmi (2009), that lower-middle income seafood exporting countries account for higher levels of shipment detentions and refusals. As an important source of food imports into the United States, China accounts for the highest number of import refusals from FDA. Therefore, analyzing the FDA refusals of food shipments from China is a typical case for other countries (Gale and Buzby, 2009). These two authors have tabulated the number of refusals of food shipments from China by year, product category, and type of violation in order to characterize potential safety problems in food imports. The result of their statistical description shows that FDA refusals of food shipments from China peaked in early 2007, including mostly fish and shellfish, fruit, and vegetable products.

With more comprehensive investigations, quantitative methods are applied in order to determine the relative importance of factors that influence import refusals. Grant and Anders (2010) also focused on US import refusals and detections in fishery and seafood. Instead of just tabulating historical data, these authors went further by applying the standard gravity equation to analyze the potential reorientation of fishery and seafood trade conditional on the refusals imposed by FDA for the time period 1996-2006. Therefore, the new variable added to the traditional gravity model is frequency of FDA refusals. This allows for testing as to whether FDA refusals occurring in the US impact fishery and seafood trade patterns throughout the rest-of-world market. Their results showed that FDA import refusals are significantly correlated with higher exports to markets other than the United States. However, this study had some limitations, such as, it did not consider the spurious relationship of countries exporting both to the US and rest-of-world markets simultaneously. In addition, the authors did not incorporate other

information contained in the FDA database such as the value of the refused shipments, the reason for the adulteration, and a shipment originated from a developed or developing country.

Baylis, Martens, and Nogueira (2009) econometrically analyzed the determinants of US import refusals. In their study, imported-food refusals are subject to experience in trade with the US and political or economic pressure. Specifically, the number of refusals is explained by a set of variables including whether the product was refused by EU, perishable product, high-risk product (meat and seafood), new exporter, WTO member, lobbying expenditures, percentage change in price, change in employment, and domestic trade protection (antidumping). The authors determined that six of these nine factors were highly correlated with the number of import refusals. Generally, domestic interests may be influencing the direction and stringency of import food inspections but newer exporters get fewer refusals than established ones. However, their paper did not mention any statistical techniques to test the results. In addition, the risk variable represented by meat and seafood was not consistent because seafood refusals come from FDA, whereas FSIS is responsible for the safety of all other imported meat (except game and exotic meats), poultry, and processed egg products. On the other hand, Jouanjean, Maur, and Shepherd (2012) investigated spillover effects on probability and number of refusals under owner reputation, sector reputation, and neighbor reputation. In fact, in their paper they developed the intuition in Baylis, Martens, and Nogueira (2009) via extending reputation of food itself, related-food products, and sectors. The authors determined that history of compliance of a product itself, related products, and a neighbor country's products have significant effects on both probability and number of refusals. In addition, import quantity, tariff rate, and per capita income are associated with refusals and refusal probability. Although the paper did not mention use of statistical tests for results' accuracy, the conditional fixed effects logit and fixed effect negative binomial models are not the best choice for a panel database. One recent study on this topic investigated political influence of the US Food Safety Modernization Act (FSMA) on fruit and vegetable trade (Nakuja, 2012). In this study, the cause-effect relationship between political influence and import refusals was tested for three major exporters to the US: Mexico, Canada, and China. Unemployment rate and antidumping activity were used as proxy variables for political influence, and country-specific exports and alerts are control variables. The author identified that the domestic political influence and sector unemployment rate motivated import refusals only from the major exporters of fruits and vegetables into the US market (Mexico and

Canada). Conversely, these variables are not statistically significant with respect to the import refusals from China because China is a relatively smaller exporter of fruit and vegetables in comparison to Mexico, Canada, and Peru. Although Nakuja reviewed significant literature, his result is not convincing since the model eliminated major variable controlling product quality and safety affect refusals. In addition, the endogeneity of import value could affect the model because exchange rate, import price, distance, and trade agreements play a role in import quantity between countries.

Overall, the previous researchers have investigated the domestic political and economic pressure on FDA's import refusals. However, beside the technical issues related to choosing a model, these researches did not consider variables for product quality and safety as FDA's target as well as capacity of system inspection. Therefore, together with updating the new data, our paper investigates triggering factors for FDA's refusals under four groups: 1) FDA's human resource and financial capacity; 2) product-specific characteristics; 3) economic and political pressures in the US and exporting countries; and 4) spillover effects among exporting countries. Moreover, it contributes a major part to the general literature of all categories of FDA refusals including food, drugs, and cosmetics. Accounting for approximately 60% of FDA refusals, the violations of drugs and cosmetics examined in this paper will provide an overall picture of a cause-effect relationship. Because of typical features of panel data, a dynamic panel data model is a more accurate choice for analyzing the data used in this study. The ratio of refusals to import value is used as the dependent variable in order to reduce endogeneity in the model. However, this paper also covers analyses using the number of refusals as a dependent variable in order to compare the results to those of former studies and to help choose the more consistent model.

Model and data

In this paper, we focused on investigating the trigger factors of FDA import refusals from the top-twenty countries which accounted for the major proportion of refusals (approximately 81% of total refusal) for the period 2002 to 2013. Because the collected dataset is panel data (combined cross-sectional of 20 countries and time series of 12 years) with potential issues of autocorrelation, fixed effects/random effects, heteroskedasticity, and endogenous regressors, the linear dynamic panel data (DPD) and negative binomial estimators are more preferable.

The DPD model contains one or more lagged dependent variables as explanatory variables.

A number of DPD estimators are proposed and reviewed to implement with different characteristics. Overall, these estimators are divided into two groups; (1) instrumental estimators, and (2) direct bias correcting estimators (Behr, 2003), in which, the class of instrumental estimators use the lag levels or lag differences as instruments to prevent the bias resulting from correlation between explanatory variables and the error term or endogeneity of dependent and independent variables. These estimators were initially mentioned by Anderson-Hsiao (1981) based on a variation form of the original equation. In 1991, Arellano and Bond exploited additional moment restrictions, based on the Anderson-Hsiao estimator, to enlarge the set of instruments called least square dummy variable (LSDV) estimator and generalized method of moments (GMM) estimator. In addition, the Blundell and Bond (2000) estimator used the information contained in differences instead of instruments to improve the estimation, which was fundamentally based on the instrumental variable (IV) estimation once it uses all available lags at each period as instruments for the equation in the first difference. Recently, the system GMM estimator has been proposed as more effective since both the lags of the level and first difference are instruments.

Bias correction in the DPD model is developed to correct the bias on original estimators related to weakly exogenous regressors and time-dominant data of the LSDV estimator. This approach is initially mentioned by Nickell (1981) to show the inconsistence for first order autoregressive within a fixed time period and infinitive individual dataset. In 1995, Kiviet derived an approximation formula for the bias of the ordinary LSDV estimator in the first-order stable dynamic panel data model with normal disturbances and a scalar covariance matrix. Other methods to correct the bias or inconsistence of dynamic panel data estimators have been investigated by Hansen (2001) and Hahn, Kuersteiner, and Hyeon (2004). Bun and Carree (2005) derived the bias-corrected estimator for finite number of time periods and larger number of cross-section units under the assumption of homoscedasticity or to extend the framework of both time-series and cross-section heteroscedasticity disturbances. Because all LSDV, IV, and GMM estimators are dealing with bias and inconsistence, Everaert and Pozzi (2007) corrected the LSDV estimator using an iterative bootstrap algorithm.

Suppose the dynamic refusals of a country *n* for year *t* (R_{nt}) is characterized by the presence of a lagged dependent variable among the explanatory variables as:

$$R_{nt} = \mathcal{E} + \alpha R_{n,t-1} + X'_{nt}\beta + \mu_{nt} \qquad n = 1,\cdots 20 \quad t = 1, \cdots, 12 \qquad (1)$$

where, $\mathcal{E}$ is a constant, $R_{n,t-1}$ is the lag value of refusal ratio, X'_{nt} is explanatory variables, μ_{nt} is a two-way error component model in which $\mu_{nt} = \eta_n + \lambda_t + v_{nt}$; η_n is individual effects and λ_t is time effects, both are constant for given *n* over *t* and for given *t* over *i*, respectively; v_{nt} represents the unobserved random shocks over *n* and *t*; and both η_i and λ_t are assumed to follow either the fixed effects (FE) model or the random effects (RE) model.

The assumptions in this model are (1) the model is full rank in regression analysis: $rank\left(E\left(X_{n,t}X'_{n,t}\right)\right) = K$, (2) explanatory variables are strictly exogenous: $E\left(\varepsilon_{n,t}/X_{\iota,\tau}\right) = 0\ for\ all\ (n,t,\iota,\tau)$, and (3) there is no serial correlation in the error terms: $E\left(\varepsilon_{n,t}\varepsilon_{\iota,\tau}/X\right) = 0$ for $(n,t) \neq$ all (ι,τ)

In order to make comparisons of this paper to the previous papers and for the extension of this paper, two models are utilized with different independent variables. Number of refusals and ratio of number of refusals to import value are considered respectively in each model. The explanatory variables are composed of four groups: (1) FDA's human resource and financial capacity; 2) product-specific characteristics; 3) economic and political pressures in the US and exporting countries; and 4) spillover effects among exporting countries.

FDA plays a critical role in ensuring the safety and efficiency of imported food, medical, and cosmetic products. Therefore, FDA staff numbers and their experience play an important role in operating the system and implementing inspections; and consequently, affect the number of refusals. It is assumed that the higher the working staff numbers are for the FDA, the greater the number of inspections performed and the larger the number of violations identified. As a result, staff numbers or number of inspections can contribute to the number of refusals. On the other hand, FDA’ s annual budget will impact whether it can sustain and expand its mission of protecting and promoting the health and well-being of the American people (DHHS, 2014). With limited funding or budget cuts, FDA could reduce imported inspections and affect its staff presence overseas. Because the appearance of a violation may be based on the testing of foreign samples, fewer inspections may imply that the number of refusals may also be reduced. Overall, number of employees, inspections, and the budget scenario of FDA can all cause collinearity in the model. Test results and chosen variables will be presented in the results and discussion.

Moreover, FDA regulations, programs, and innovations would have a strong effect on its operational system efficiency, specifically on import refusals. Up to now, hundreds of rules and regulations have been issued to upgrade FDA's authority to deal with not only fast-growth globalization and imports, but also with rapid development of many domestic products. This research focuses on only two recent laws that improve FDA's position in dealing with these issues. The first law is The FDA Food Safety Modernization Act (FSMA), established in early 2011, considered as the first overhaul of food safety laws in more than 70 years. Although this Act strengthens FDA's powers to prevent, detect, and respond to food safety issues, it nevertheless affects the budget and inspectors for drugs and cosmetics. The relationship between the FSMA and refusals is expected to be positive once the scan system is improved and more inspections are conducted. However, if the inspectors and the funds are controlled, there could be more concentration on food safety, with less FDA resources allocated to drug and cosmetics. Consequently, fewer inspections for drugs and cosmetics could decrease the total number of refusals. Overall, the total refusals may increase or decrease or remain stable, depending on FDA resource allocation. In order to eliminate inaccurate influence of this program on drug and cosmetic refusals, the dummy variable for before and after this program will be used to interact with whether refusals are related to food, drug or cosmetics. Another significant change for FDA came in late 2008 or early 2009, when the agency established representive offices in particular countries or regions beside its main office in the homeland country. One of the major activities of FDA's foreign offices is to ensure product quality and safety and conduct foreign inspections in order to prevent problems before they occur, thereby preventing products that do not meet FDA requirements from reaching any of the US ports of entry (FDA, 2012). FDA's overseas staff can often obtain information that is more complete, accurate, timely, and robust than information obtained from US locations and sources. The presence of these foreign offices obviously reduces the violations from exporting countries in those cases where FDA inspectors work efficiently in these countries to improve the safety of imported food and medical products. Countries and regions where FDA has established oversea offices include Mexico, China, India, the Middle East, Europe, and Latin America. This variable is dummied as one if the FDA opens an office in a specific country and zero otherwise. This variable indicates not only the relationship between import refusals and whether an FDA foreign office exists or not but also the

efficiency of these offices in providing information to support FDA's strategy.

Although there is no available variable representing the quality of imported products, the proxy indicators nevertheless can determine whether FDA rejects merchandise due to its quality violations. The FDA data from 1998 to 2004 show that the top imported food categories refused due to food safety and other violations were vegetable and vegetable products, fishery and seafood products, and fruits and fruit products. These products were refused due to such risks of perishable, contaminated, and mainly imported from developing countries. This paper does not go into detail of these products, instead it classifies the imported merchandise into three major categories of food, drugs, and cosmetics. Although drugs and cosmetic products have some similar features in terms of transportation risks and potential contamination, food, medical, and cosmetic products, obviously, have different features in terms of quality measurement and storage conditions. Hence, a dummy variable for the three cases of food, drug, and cosmetics is applied to identify whether the refusals or ratio of refusal is different among these types of products. Food, for example, is expected to have a higher number refusals or ratio of refusals compared to medical and cosmetic products, because not only is food the higher imported proportion but also the most perishable and most likely to be contaminated. Another proxy indicator for product quality is past import refusals from a specific country. Because of limited resources, FDA now detains or refuses to import certain products based on past history (Becker, 2008). Therefore, the correlation between past and present import refusals named as owner reputation (Jouanjean, Maur, and Shepherd, 2012) is expected to be positive. In other words, any country with history of compliance will have fewer refusals and vice verse.

This research also intends to quantify the economic and political pressures applied in the US and exporting countries, and how these impact number of refusals and ratio of refusals. In particular, Gross Domestic Production (GDP) per capita and total import value are representive of the domestic economic status of a country. Although GDP per capita is not an accurate indicator for economic growth, it is assumed to have a positive correlation with import refusals. GDP growth leads to an increase in imports because of higher domestic demand and the higher import causes higher refusals. Even though GDP per capita and import value would be collinear, the import value is still measured in this model to identify the hidden pressure of domestic economic policy on FDA inspections. If FDA is influenced to protect the domestic economy or

domestic manufactures, then a specific country's imports into the US could be restricted by increasing refusal to protect domestic production. The sign of refusal-ratio and import-value coefficient is expected to be positive. On the other hand, the correlation between domestic politics and import demand or trade policy have been mentioned by Helpman (1995), Goldberg and Maggi (1999), and Lopez and Matschke (2005), and impact of political pressure and import refusals have been investigated. A positive correlation between political pressure and number of refusals has been tested in the food industry by Baylis, Martens and Nogueira (2009) and Nakuja (2012). This study is extended to examine the effect of domestic politics on ratio of refusals, with unemployment rate, the US-antidumping user, and lobbying expenditure used as proxy variables for political pressure. Unemployment rate is one of the major indicators that reflects the economic and political policies in every country. Wherever a country experiences growth in unemployment rate, the government will change trade policy to protect its domestic industry. Its hypothesized that such a rise in unemployment rate will be associated with an increase in import refusals. Antidumping cases are usually initiated by producers of products in the US that are experiencing a loss of market share or profits due to lower priced imports of foreign like products. Such cases are usually initiated by domestic groups pressuring politicians to impose import restrictions, hence it gives the effect on industry-specific international trade. The dummy variable used to estimate the effect of antidumping on import refusals is equal to one if an antidumping case was filed against a country in the previous year. This coefficient is expected to be negative within antidumping cases. Finally, the rent-seeking interested group may lobby the US government to minimize the amount of imports into the US, which would cause rising import refusals. We would expect greater lobby expenditure by a specific industry to result in higher import refusals. The lobby expenditure is measured as the amount of money spent on the food and medical and cosmetic industries. In order to figure out the influence of lobby expenditure in each industry, this variable is interacted with a dummy variable representing type of products. The coefficients will explain whether lobby spending on food and medical and cosmetic industries affect the food-imported refusals or medical and cosmetics-imported refusals, respectively.

Some studies have found that an exporting country's economic growth can influence import refusals (Baylis, Martens, and Nogueira, 2009; Grant and Anders, 2010; Jouanjean, Maur, and Shepherd, 2012). This study measures this effect via proxy variables, including country-

income classification (high, low, or middle), exporting value, and corruption perceptions index. Theoretically, an exporting with lower income should have more import refusals. Such a trend in reflected in developing countries since many of them have no extensive food safety systems, and do not have the appropriate infrastructure in place to develop such a system so they can comply with export acquirements. On the other hand, safety regulations could in fact benefit producers in developing countries by forcing technological progress and learning through the implementation of stricter standards, thereby, creating a competitive advantage that could lead to gains in international trade. Hence, the correlation between import refusals and a country's income is expected to be negative. The richer countries will get fewer rejections. Export value for a country also has potential to affect the number of import refusals, because it can be assumed that the higher the value of a country's exports to the US, the greater the number of refusals that would be issued. Hence, the expected sign of this factor is positive. In order to eliminate the multicolinearity issue in the model, the ratio of exporting value to GDP is used for a consistent comparison among countries. Getting a high ratio implies that a country has more experience in exporting into the US market, and that it could identify a strategy to reduce import refusals. This coefficient is assumed to be negative. Another indicator for the exporting country's economic development is corruption perception index. This index scores countries based on how corrupt a country's public sector is perceived to be. The rank is scaled from 0 to 100, where 0 means that a country is perceived to be highly corrupt and 100 means that a country is perceived as being very clean. The cleaner country would be expected to have less import refusals.

There is little information in the literature about spillover effects of import refusals. Baylis, Martens, and Nogueira (2009) are the first researchers to analyze this effect. The authors presumed that if EU countries find a product-country pair violation, the FDA would see this as cause for increased vigilance in their inspections. The latest research on a sector-spillover effect and a neighbor-spillover effect was conducted by Jouanjean, Maur, and Shepherd (2012). The probability of refusals and number of refusals for a particular product or a given product from a particular country might be more likely if their closely related products or neighboring exporters of the same product has a history of non-compliance. In this study I use two proxy variables of spillover effects. The first one is the China imported food scandal in 2008, and the second is past refusals of the most influential countries in the world free zone convention to include India,

China and South East Asia, Middle East, North and South America, Russia and Central Asia, Europe, and Africa. One of the top food scandals that shocked the world occurred in 2008 when high levels of the industrial chemical melamine was found in powdered and ordinary milk from leading companies across China. The scandal sparked worldwide food safety concerns. As a result, FDA issued an alert which called for "detention without physical examination of all milk products, milk derived ingredients and finished food products containing milk from China due to the presence of melamine and/or melamine analogs. Therefore, a test of the effects of this scandal on import refusals since FDA would be expected to take a more serious look at these imported products is implemented. The dummy variable equals to one for every country after 2008, is used to to test whether the scandal about unsafe food from China impacted import refusals from other countries. This variable may not only present the spillover effect from China into other countries but also show whether a food scandal can cause changes in refusals of drugs and cosmetics. On the other hand, the lag refusal of the most effective-neighbor country is assumed to have a positive relationship with country-specific refusals. In this case, the most effective-neighbor country is a country that got the highest number of refusals in the same free zone convention. We assume that imports from a country are less likely to be rejected if its neighbor has a history of compliance.

We also control other factors that have potential influence on the number of import refusals or ratio of import refusals. One possible factor that can change the number of refusals is experience of the exporting country. It is assumed that new exporters may have more difficulty meeting US import standards than traditional more experienced exporters. This variable is represented by the number of years that a country has been a member of the World Trade Organization (WTO), and it is expected to have a positive effect sign. Inaccurate labeling and a manufacture's lack of proper registration are common violations diagnosed by the FDA. Labeling mistakes usually show a lack of clear English labeling to identify the ingredients, nutritional information, weight, etc. Such mistakes accounted for 22% of 2007-08 violations from China. Whereas, lack of proper registration generally occurs when a manufacture fails to file information on its scheduled process, or fails to register its plant with FDA if they produce low-acid canned food. Hence, exports from English-speaking countries might be less likely to be rejected because the exporters can more easily interpret and meet US English requirements. A dummy variable equals one if the exporter is an English-speaking country, and it is expected to

be a negative effect. Lastly, imports from countries that have a free trade or bilateral trade agreement with the US are less likely to have their products rejected because the exporters have more experience in exporting into the US. They have also investigated the processes and information they need to know to meet the US import requirements.

Since all above explanatory variables are inserted into a model the multicolinearity may be an issue. The model is tested to determine a set of significant variables in terms of both statistics and reality.

In the first model, number of refusals is the dependent variable. We apply the regression approach for the quantitative outcome measured with discrete variable and standard Poisson probability distribution for count data. The Poisson parameter λ is presented as specific form $\log \lambda_{nt} = X_{nt}\beta$, where X is a vector of regressors, the basic Poisson probability specification is

$$Prob[Y_n = J/X_n] = \frac{\exp(-\lambda_n)\lambda_n^j}{j!} \quad (2)$$

$$\lambda_n = \exp(\beta' X_n) = E[Y_n/X_n] \quad (3)$$

The log likelihood of a sample of 20 countries over a 12-year period for this Poisson specification is

$$L(\beta) = \sum_{n=1}^{N} \sum_{t=1}^{T} [n_{nt}! - e^{X_{nt}\beta} + n_{nt} X_{nt}\beta] \quad (4)$$

The general form of the model is:

$$\text{Refusal}_i = \beta_0 + \text{Staff}_i.\beta_1 + \text{Inspt}_i.\beta_2 + \text{FSMA}.\beta_3 + \text{FSMAType}.\beta_4 + \text{FDAFPO}.\beta_5 + \text{Dtype}.\beta_6 + \text{GDP}_t.\beta_7 + \text{ltttrade}_t.\beta_8 + \text{Unemp}_t.\beta_9 + \text{AD}_{it}.\beta_{10} + \text{llobby}_t.\beta_{11} + \text{Country}_i.\beta_{12} + \text{lExport}_{it}.\beta_{13} + \text{Corrupt}_{it}.\beta_{14} + \text{Country}_i.\beta_{15} + \text{Scandal}.\beta_{16} + \text{Spillover}_i.\beta_{17} + \text{WTO}_i.\beta_{18} + \text{English}_i.\beta_{19} + \text{Fretrade}_i.\beta_{20} + \text{Bitrade}_i.\beta_{21} + \mu_{it} \quad (5)$$

The simplest model to deal with this panel data is the within-group estimator characterized by the coefficient of the lagged dependent variable and it is downward biased. This bias only disappears after increasing the time series dimension (Santos and Barrios, 2011). In order to deal with inconsistency of the within group estimator, the instrumental variable (IV) of either the dependent variable is lagged two periods or its first differences are recommended. In addition, the generalized method of moments (GMM) is also an alternative.

Overall, for the time small and individual large data, GMM performs better than LSDV (Bun and Carree, 2005). With the large time dimension, except OLS, the efficiency and bias of all

other estimators is not significantly different. However, the AH (Anderson-Hsiao) estimator is preferred to other methods because it generates the lowest average bias. The refusal dataset of 12 years and 20 countries (T:12; N:20) is considered as a short time dimension and larger country dimension. Therefore, the Arellano‐Bond Dynamic Panel GMM Estimator is used to identify the triggering factors for the US import refusals.

Equation (1) is a panel regression with a lag dependent variable on the right-hand side. To deal with the potential issues of the lagged dependent variable and random/fixed effect, the different GMM uses first-differences (DIF) to transform equation (1) into:

$$\Delta R_{nt} = \mathcal{E} + \alpha \Delta R_{n,t-1} + \Delta X'_{nt}\beta + \mu_{nt} - \mu_{nt-1} \quad (6)$$

where Δ is the first difference of each variable.

The country-specific effects η_n (unobserved heterogeneity) are wiped out and the moment conditions are utilized where endogenous differences of the variables are instrumented by their lagged levels for the DIF. However, with a finite-time dimension, this estimation gives bias and less precise estimation (Alonso-Borrego and Arellano, 1996). In addition, the lagged levels in the series provide weak instruments for DIF. Therefore, the system GMM estimator is proposed for use with the lagged differences of Y_{nt} as instruments in the levels equations in addition to lagged levels of Y_{nt} as instruments for equations in DIF.

The assumption that error term λ_t is not serially correlated would imply that

$$E[R_{n,t-s}(\mu_{n,t} - \mu_{n,t-1})] = 0 \text{ for } s \geq 2;\ t = 3, \ldots, T \quad (7)$$

The moment condition for strictly exogenous variables must be

$$E[(\Delta X_{n,t-s}\ R_{n,t-s-1})(\mu_{n,t} - \mu_{n,t-1})] = 0 \text{ for } s=1;\ t = 3, \ldots, T \quad (8)$$

The additional moment condition follows condition (7) and (8) by the level moment conditions

$$E[\mu_{n,t}\Delta R_{n,t-s}] = 0 \text{ for } t = 3, \ldots, T \quad (9)$$

In addition, for weakly exogenous explanatory variables, the level moment conditions are

$$E[\mu_{n,t}\Delta X_{n,t-s}] = 0 \text{ for } s \geq 1;\ t=3,\ldots,T \quad (10)$$

And for strictly exogenous explanatory variables, the appropriate level moment conditions would be as follows:

$E[\mu_{n,t}\Delta X_{n,t-s}] = 0$ for all s; t=3,...,T (11)

We use the moment conditions from equation (7) to (11) to calculate the GMM estimators based on the stacked system comprising all (T-2) equations in the first differences and the (T-2) equations in the level corresponding to period 3,....,T, for which instruments are observed. The instrument matrix for this system is:

$$Z_n^+ = \begin{bmatrix} Z_n & 0 & 0 & \dots & 0 \\ 0 & \Delta Y_{n2} & 0 & \dots & 0 \\ 0 & 0 & \Delta Y_{n3} & \dots & 0 \\ . & . & . & \dots & . \\ 0 & 0 & 0 & \dots & \Delta Y_{n,T-2} \end{bmatrix}$$

where Z_n is the (T-2) x m matrix given by

$$\begin{bmatrix} Y_1 & 0 & 0 & \dots & 0 & \dots & 0 \\ 0 & Y_1 & Y_2 & \dots & 0 & \dots & 0 \\ . & . & . & \dots & . & \dots & . \\ 0 & 0 & 0 & \dots & Y_1 & \dots & Y_{T-2} \end{bmatrix}$$

This model not only greatly improves the precision but also greatly reduces the finite sample bias (Blundell and Bond, 1998).

Data

Monthly data are more appropriate to reflect changes in FDA policies related to quality or safety scandals. However, some macro indicators are not available for monthly (GDP, CPI, lobby expenditure, antidumping, and FDA budget), so the SPLINE method for transferring annual data into monthly data was applied. Consequently, a multicolinearity error exists in the model. Therefore, I used the annual data instead of monthly data for the analyses and results presented in this paper.

Data from the FDA website listed total refusals of 290, 200 for a period from Jan. 2002 to Dec. 2013, in which, the number of refusals by the top-20 countries was 228,968. In particular, the drug refusals accounted for 55.36%, food refusals accounted for 39.59%, and the last 5.05% was cosmetics refusals. Number of FDA employees was collected from FedScope, US Office of Personnel Management from 2002 to 2013 annually. The inspection observations were also collected from this website, where FDA's Office of Regulatory Affairs was the lead office for all field activities including inspections. Observations for annual inspection observations were

available only for a period from 2006 to 2013. The former years, from 2002 to 2005 were traced based on refusals because both refusals and inspections reflect the producers' compliance values for FDA's annual budget allocation. Outlays of the US Department of Health and Human Services (HHS), were collected from the HHS annual budget reports from 2002 to 2013. In addition, information on the Food Safety Modernization Act and FDA's foreign offices were also obtained from FDA's website.

The GDP per capital of the US and exporting countries and exporting-country classification based on country income of high, middle, or low were obtained from the World Bank's World Development Indicators and United Nation Accounts (2014). Annual US total imports in millions of dollars, with seasonal adjustment, were taken from US foreign trade census data on the historical series of international trade in goods and services. I used a US Bureau of Labor Statistics database to obtain annual unemployment rates. Antidumping data are presented as annual-accumulated-antidumping cases given by the Global Antidumping Database, World Bank (2014). Lobby data were sourced from the Center for Responsive Politics. I classified annual lobby expenditure for the food industry and drug and cosmetic industries by filtering the expenditure by industry. The food lobby cost includes expenditures for agricultural service/products, food processing and sales, crop production and basic processing, dairy, livestock, poultry and eggs, and miscellaneous agriculture. The lobby expenditure for health includes pharmaceuticals/heath products, health professionals, hospitals/nursing homes, health services, and other miscellaneous health costs of the drug and cosmetic industry. Spillover effects by region were sourced from the world free zone convention. I obtained information on English-official-language countries from The Nation's Leading English Advocates. Years that exporters have been a member of WTO are obtained from the WTO website, and information on bilateral trade and free trade with the US was collected from the US International Trade Commission and the US International Trade Administration.

Results and discussion

Model tests and bootstrap

Distribution of residuals and plot of residuals for number of refusals and refusal ratio show some distortions and non-white-noise. In addition, the Hausman test shows that data issues related to

both fixed effects and random effects exist in both models. The Wooldridge test shows autocorrelation for both number of refusals and refusal ratio models (in the context of panel data), with the null hypothesis (H_0) indicating that there is no serial correlation in this specification, and the alternative hypothesis indicating a serial correlation with idiosyncratic errors. The Fisher statistic in the model of refusals (model 1) is equal to 43.374 (p=0.000), which implies that the hypothesis of no serial correlation is strongly rejected. Whereas, this parameter in the model of refusal ratio (model 2) is equal to 0.081 (p= 0.7771) showing that no autocorrelation exists in this model. Moreover, the test for heteroskedasticity is determined by the Breusch-Pagan test with the null hypothesis indicating homoskedasticity. With model 2, the chi square distribution is equal to 2775.60 (p=0.000), and with model 1 the chi square distribution is equal to 5163.76 (p=0.000). Hence, the null hypothesis of non-heteroskedasticity is strongly rejected. In other words, heteroskedasticity exists in both models. In order to manage these issues and bootstrap for model 1, the GMM estimator, developed by Arellano and Bond (1991) and named the two-step GMM estimator, is used to deal efficiently with autoregressive and heteroskedasticity data. This choice also follows recommendations from the literature review which indicates that the GMM estimator performs well for panels with wider cross-sectional dimensions. Conversely, there is no evidence of autocorrelation for the refusal ratio model. Therefore, the count data model is a more accurate GMM estimator, and the model form test shows that a negative binominal estimation is more preferable to Poisson estimation since the data had variance greater than the mean. On the other hand, the Hausman test identifies endogeneity with the US total import values, total value of country-specific exports, and the FDA budget allocation. The variables of exchange rate and the budget outlays of the US Department of Health and Human Services (HHS) serve as instrumental variables. The tests show that US total imports and HHS expenditures are two valid endogenous variables. Therefore, implementing the two-stage instrumental variables approach for a negative binomial with endogenous predictor solves this issue. Finally, we use the robust option to obtain robust standard errors for the parameter estimates as recommended by Cameron and Trivedi (2009) to control for mild violation of underlying assumptions.

Factors Affecting of number of refusals

The output presented in table 1 in the appendix result from using the estimator Stata. The two-step Sargan test rejects the validity of the null hypothesis of overidentifying restrictions.

Whereas, the two-step Hansen test indicates that the overidentification restrictions are valid. The paper uses the Hansen test instead of the Sargan test to accept the instruments as valid. The Hansen test is used because it is more robust than the Sargan test which is not distributed as chi-square under heteroskedasticity, and because the number of instruments is greater than the number of groups. In other words, the heteroskedasticity and many instruments could cause the Sargan test to incorrectly reject the null hypothesis. On the other hand, the Arellano-Bond test for the first-order serial correlation rejects the null hypothesis of no first-order serial correlation, but it does not reject the null hypothesis of there being no second-order serial correlation. These are what we expected from overidentification and autocorrelation diagnostics in the two-step GMM estimation. Moreover, the result of this model is also robust to have consistent standard errors with panel-specific autocorrelation and heteroskedasticity.

Overall, most of the coefficients in the two-step GMM model have the expected signs and are statistically significant. In particular, the first group of variables that represents FDA human and financial resources, number of employees, establishment of an FDA office in a particular country, and implementation of the Food Safety Modernization Act, all present positive impacts on number of annual refusals, and are statistical significant from the 1% to 10% level. Therefore, FDA would be expected to implement more inspections as more employees are hired. More inspections would be expected to lead to more rejections. The elasticity indicates that if FDA's staff increases by 1%, the number of refusals would grow by 1.77%. With more technicians for each inspection site, FDA could be more efficient and generate a larger archive due to shorter-time investigations. They could also inspect a larger proportion of imported goods and diagnose more violations. The statistical data show that the number of FDA employees rose 2.78% annually for a period from 2002 to 2013, whereas the number of inspections grew by 2.25% each year on average from 2008 to 2013. The analysis presented in this paper does not cover the influence of inspections on refusals, because the statistical data for inspections before 2008 is not available. The FDA could use more inspectors because of the increased volume of FDA-regulated products in both domestic and foreign markets during recent years. However, information presented in this paper is limited to the effect of FDA staff numbers on refusal quantity efficiency, without any detailed analysis of product variety or expert demand of specific industry inspections. Recently, the US significantly expanded imports of goods and services from around the globe, and FDA set up inspection offices in the top exporting countries. This is

viewed as an essential manner to better collaborate with foreign government counterparts to prevent unsafe problems before actual goods reach the US market. A dummy variable is used for two cases where FDA post is established in a specific export country, and for the main office in the US. The number of import refusals decreases when FDA establishes a representative office, regardless of whether it is in the US or in the export country. However, only the coefficient for a foreign inspection office is statistically significant at the 1% level. This occurred because the presence of FDA representatives in a foreign country contribute to diminished violations from that country by 46% per year. This result proves the efficiency and necessity for having an FDA office located in an export country.

On the other hand, the FSMA that was recently signed into law resulted in significant effects on import refusals, but only for food products and not for drugs and cosmetics. This program proves to have significant impacts once it was applied in a broader scope in 2011. Specifically, the program causes the number of violation diagnoses from foods, cosmetics, and drugs to increase by 21%, 47%, and 53%, respectively. Although this Act may provide lagged effects, this program generated significant effects right after it is implemented. In addition, up to the latest data available in 2013, this program has been implementing for only two years. Hence, this paper does not mention any lagged effects from this program. The effects of this program on refusals of drugs and cosmetics, however, imply that although FDA establishes a special Act that targets a particular product, the program also influences other products and causes changes in the overall operation of the FDA system. Moreover, FDA apparently does not allocate more resources just for the imported food program, but simultaneously concentrates more on cosmetics and drugs as well. As a result, when this program is implemented, more violations are diagnosed and more products are rejected. As unexpected, FDA funding provides a negative effect on the number of refusals. Eventhough the FDA budget increased gradually from 2002 to 2013, at an average of 8% per year, this growth does not show a statistically significant influence on the number of import rejections. This funding growth may have been offset by inflation or increased wages that did not allow FDA to hire more employees, or encourage current employees to work more efficiently.

A group of proxy variables used to represent product quality, overall, has expected effects in terms of size and significance. The number of violations is different among food, drug, and cosmetic imports, with food rejections higher than drug rejections by 30.43%, and cosmetic

imports violated less than drug imports by 93%. Obviously, these results support the assumptions that higher-risk food products have more violations because they are more perishable and more easily contaminated once in transport in comparison to cosmetics and drugs. Cosmetics being rejected less than drugs could imply that cosmetics are not as likely to cause serious injury or death as drugs or food. Thus, the requirements and inspection levels for these products are not as tight as for drugs. For instance, FDA does not require the cosmetic firms to register their establishments, file cosmetic product ingredients, or have a registration number for cosmetics imported into the United States. On the other hand, at the 1% level of significance, a 10% growth in past import refusals has a 1% positive effect on current refusals for cosmetics. This result indicates that FDA may rely somewhat on a product's compliance history profile to refuse a particular product. Under this hypothesis, if a product in a specific country had a good compliance last year, it would be at less risk for rejection in the current year. This output agrees with the literature review that rejections can be path dependent because FDA has limited resources.

The next factor group studies are the effects of exporter's and importer's economic development on the number of import violations. A variable used to represent importer economic growth is the US GDP per capita. For this variable, the higher the economic development, the less the number of refusals diagnosed. Although the import proportion increases gradually in comparison to annual American consumption, domestic economic development has a negative effect on refusals. This implies that increased US economic growth does not put more pressure on FDA to better inspect imports or the American importers in order to improve their classification or choose better importers who have less violation. However, this variable is not statistically significant. As expected, the GDP per capita of an exporter has a negative influence on import violations. In particular, the number of refusals is reduced by 0.12% when the GDP per capita of these countries increase by 1%. This makes sense since the standard system of management and more technologically advanced applications in richer countries are better than those in the less developed countries. In other words, those countries with a higher GDP can invest more on exporting in terms of technological improvements, updated legislation, and more financial support to help their exporters do a better job of complying with FDA regulations and requirements. This result is consistent with the conclusions of Baylis et al. (2009) and Buzby and Regmi (2009), and indicates that lower-income countries do not have as extensive or effective

food safety standards, practices, and regulations in place as the US or other more-developed countries. Another statistically significant factor that supports this result is country-income classification. This coefficient shows that high-income countries got 1.46% less rejections than the low-income countries. However, the difference in violations between low-income countries and the upper-average-income countries is not statistically significant. The estimation output also shows that the index of corruption perceptions of export countries generates a positive effect on violations, although it is not significant in statistical terms. Another variable that effected import refusals, as we expected in terms of magnitude and sign, is export value for exporters. The coefficient indicates that a 1% increase in export values causes the rejection numbers to decrease by 0.26%. This implies that when the export proportion of a country grows, that country puts more emphasis on understanding US import requirements in order to reduce the risk of rejections. This also implies that countries with more export have a competitive advantage in exports in comparison to countries with less export.

The group of factors representative of US political pressures on FDA's import rejections, provides expected signs and statistical significance. The first variable, that shows a positive effect and is statistical significant at the 1% level, is annual US unemployment rate. A 1% growth in unemployment rate causes the refusal numbers to increase by 0.15%. Obviously, the significance of this factor proves that domestic economic and political circumstances can influence FDA actions. According to our analysis, when unemployment rate is higher, the government would encourage domestic enterprises to employ more US workers. In order to create more US jobs, these enterprises would need to be protected via reduction in competition from export products. As a result, import restrictions would be applied to reduce foreign exports and this would simultaneously increase the possibility of import rejections. Another political factor that influences import violations is US annual lobby expenditures from different industries. This variable is interactive with the type of industry, so we examine whether lobby from the food industry impacts food rejections or whether lobby from the drug and cosmetic industry causes changes in refusal numbers for these products. The analysis indicates that lobby in the food industry and in the drug and cosmetic industry cause positive effects on import refusals for both industries. This can be explained by the fact that domestic industries lobby government to seek more protectionism and this happens via minimizing the mount of imports accepted into the country. The greater the lobby expenditure, the more congress reacts to protect

domestic producers, sometimes via imposing illegitimate, overly strict, or excessively costly standards to eliminate foreign competition. As a result, the model used indicates that import refusals would rise by 1.17% and 1.43% for food products, and for drug and cosmetic products, respectively, when lobby expenditure increases by 1%. The last political factor that shows a statistically significant affect on import refusals is US implementing antidumping with their trade partners. The principle of how antidumping protects domestic producers is not much different from industry lobby payments. Countries with more antidumping implemented by the US Department of Commerce, the International Trade Commission (ITC), and US Customs and Border Protection, leads FDA to inspect more of their imports or spend more time on the inspections of their products. This results in a greater portion of a country's product being refused for import.

Turning to the group of factors representative for spillover effects, this research finds that all signs and magnitudes are statistically significant from the1% to 10% level. Particularly, the dummy variable for the China food scandal in 2008 causes a positive effect on import rejections. By comparison with refusals before and after, the violation number in this year was higher than other years by 78%. Although this scandal mainly occurred in the food industry, all product refusals were affected. Surprisingly, two other dummy variables representative for refusals in 2009 and years after 2009 show that import rejections are reduced by 27% and 155%, respectively. This implies that after a year of scandal, refusal numbers are decreased gradually. Because of the fast response of food, drug and cosmetic industries to scandal and the high flexibility of FDA to unsafe events, the food scandal is most pronounced the same year because FDA immediately decides to reject every import product related to melamine-contaminated milk. However, just one year after the scandal, the refusals are reduced substantially. This occurs because import countries concentrate more on either following US import standards or because they are so alarmed by the high possibility of rejections they improve their own production technology. However, since 2008 is also a year of global economic crisis, imports and exports from many countries also changed. This could have effects on import refusals. Another statistically significant variable is neighbor refusal effects. This effect is examined by using the correlation of refusals between a country and refusals of their highest-rejected neighbor country in the same global economic region. This variable, however, is not statistical significant. But the violations from China caused effects on most of the top-twenty rejected countries regardless of

their economic region/location. The refusals from China cause to increase refusals from all countries, with Columbia and Philippine imports effected the most and the least affected country is India. The various magnitudes of effects are related to distance from an importer to the US market, or correlated to the kinds of products rejected from China and export products from a specific country.

The other explanatory variables related to US import refusals, that resulted in significant effects on import violations, are years a country has been a WTO member, whether a country has signed a free trade agreement with the US, and whether a country uses English as an official language or not. The effect of the WTO member variable is negative, as expected, and statistically significant at the 5% level. The longer a country has membership in WTO, the fewer the number of import refusals. This indicator reveals that the more experience a country has in international trade deals, the less likely the risk of their imports being rejected. On the other hand, any country with English as its official language does not necessarily receive lower rejection numbers. Conversely, this country appears to have a high number of refusals in comparison to a country that does not use English as an official language. A reasonable explanation for this pattern could be because a country uses English does not mean it necessarily follows the US requirements for labeling or product information, and these failures do not account for high in the total refusals either. Country classification by economic regions also has a statistically significant effect on import refusals. The results show that export countries from both the Americas and Caribbean, as well as from the European Union, have more violations in comparison to countries from Asia. However, only difference from American and Caribbean shows statistically significant influence by 9.5% in comparison to refusals from the Asian region. Finally, countries that have signed a free trade agreement with the US receive more import rejections. Evidently, having a signed trade agreement with the US does not mean a country can export their products into the US market any easier. However, the positive effect of increased refusals with these free trade countries could be related to the fact that they export more products into the US market. As a result, the more they export, the greater the number of inspections, which could cause more refusals while the overall percentage of refusals is still very low.

Triggering factors of refusal ratio

In this part, we use the negative binomial regression (NBR) model with endogenous regressors via a two-stage instrumental variable approach applied with the dependent variable being ratio of refusal number to total export values. This ratio is used in order to eliminate the biases caused by the endogenous variable of export values. It is expected, that with use of the ratio of refusals instead of refusal numbers, various factors can be more appropriately assessed for their triggering effects. The coefficient in the NBR model is the difference in the log of the expected count to a unit of change in the independent variable. The coefficients in the model are converted into marginal effects and the dependent variables are logged, hence, the coefficient interprets how refusal number per million of US dollars in export responds to a 1% change in the explanatory variable and it is consistent.

Overall, the NBR model provides effect signs that are consistent with those of the first model, but the number of statistically significant variables drops some. Specifically, within the group of factors representing FDA human and financial resources, the FDA annual fund allocation, and number of FDA staff personnel, there is no statistically significant effect on the refusal ratio. However, the factor representative of FDA office location, whether in the US or in a specific country, contributes to a decrease in import violations. In addition, implementation of the FSMA causes the number of refusals per million of US dollars in export value to increase. These results further support the theory that efficiency of FDA is enhanced by establishment of additional offices to achieve the goal of diminishing violations before products reach the US market. Conversely, FDA's current violation ratio does not relate to its history of compliance and there is no difference of refusal ratio among food, cosmetics, and drugs.

For factors representative of economic and political conditions in the domestic and exporter markets, most variables are consistent with those of the first model in terms of sign effect and statistical significance. Exceptions are the number for antidumping, which does not show a statistically significant impact on ratio of refusal, and the CPI index, which does not adjust the violation per export value. The negative marginal effect of the antidumping variable implies that a country with higher antidumping into the US would have less violation per export value. This means that countries with more antidumping must either lessen their exports into the US market or improve their quality to better follow FDA requirements to avoid risk of rejection.

On the other hand, the variables of spillover effect related to the China food scandal in 2008 do not show any effect on the refusal ratio in 2008. However, the ratio of violation is lessened in 2009, just one year after the scandal occurred, and the other years after 2009 have no significant effects on the ratio. This response is understandable, because right after the food safety scandal, FDA take action to prevent several types of food products from being imported into the US market without a thorough field inspection. Moreover, the spillover effect of refusal ratio from China on refusal ratio from other countries is different from that of the first model. In particular, the China refusal ratio causes an increase in the rejection per export value from Columbia, Indonesia, India, Thailand, Taiwan, and Vietnam. China refusals, however, cause the refusal ratio from Canada, France, England, Hong Kong, Italia, and Korea to decrease. It is obvious that the China refusal ratio causes rejections from its neighbors and less-developed countries to be higher, and lowers the probability of exports being rejected from developed and EU countries. This result is more apparent in comparison to results form the first model, because a refusal from one country may affect other countries in different ways instead of causing refusals from every country to increase. Whenever the imports from one country are reduced, this will cause increased substitute imports from other countries in order to maintain stability in US imports. As a result, in order to protect domestic consumers, the FDA may give priority to import more products from a country that has high quality standards and restrict imports from less developed countries. Other control variables present effect signs and statistically significant levels that are similar to those of the first model. However, the NBR model shows that there are differences in refusal probability for countries in different economic regions. The EU countries, for example, have the lowest import rejections, whereas Asian countries have the highest violations. This implies that a rich country with more advanced technological applications would better follow FDA requirements and regulations. Therefore, refusal per export value from a rich country would be less than that from developing countries, where production efficiency, standards of management, and technological applications would all be lower.

Conclusions

The FDA plays an important role in ensuring that imported products are safe and wholesome for American citizens. US imports have increased gradually during recent years and now account for a significant portion of domestically consumped products, especially food products. Therefore, FDA inspection and approval procedures for import entrance into the US market, is interest not

only to domestic consumers but also to US trade partners. This study has investigated factors that influence FDA's decision to reject or approve a product. The hypothesis is proposed that other than product quality and safety indicators, FDA's decisions may also be influenced by their financial and human resource capacity, by economic and political pressures in the US as well as in the export countries, by compliance history of the product and export country, and by the neighbor country's reputation. The analyses are based on the annual panel data collected from 2002 to 2013 for the top twenty countries with the highest number of rejections by FDA during this period. The number of annual refusals from each country for food, drug, and cosmetics served as the dependent variable in the basic model. In addition, the model is adjusted to use the dependent variable ratio of refusals to million dollars of export value to solve the issues related to endogeneity and make the model more robust. Because autocorrelation occurs in the model using number of refusals but not the ratio of refusals model, the two-step GMM estimation and two-stage negative binomial estimation are more appropriate for the number of refusals estimator and ratio of refusals, respectively. Robust techniques are applied for both these models to improve the standard deviation and generate more accurately estimated coefficients. Although there is no indicator to conclude which is the better model, the refusal ratio model reduces the endogenous issues of export values, and this model is more robust once export values do not have a big significant explanatory variable to cause bias of other factors.

Overall, both models provide similar effect signs and statistical significance. The models give proof that FDA's decisions to reject or accept imports depends on four groups of factors. These factors include FDA's human resource and financial capacity, product-specific characteristics, economic and political pressures in the US and exporting countries, and spillover effects among exporting countries. As expected, a greater number of FDA employees and the FSMA program provide a positive influence on violation diagnoses and, thus, more refusals. In addition, whether FDA has other representative offices located in a specific exporting country or in the US itself result in a reduction in violations. Even though, increased FDA annual fund has a negative effect on rejections, this variable is not statistically significant. The only variable representative of product quality shows that total annual refusals are different among food, drug, and cosmetic products, with rejections for food being the highest. This result is not consistent with that of the refusal ratio model. Although US GDP per capita does not impact either refusal number or refusal ratio, the exporter's GDP per capita has a negative effect on import rejection.

Contrary to expectations, the indicator of corruption perception index does not have a significant influence on refusal number, but it does affect the ratio of refusal. Two factors representative for pressures from US politics on FDA decisions prove to be statistically significant, with positive signs for unemployment rate and domestic lobby expenditures. There are significant spillover effects from China's refusals due to the China food scandal in 2008 and annual refusal number/ratio from China. Although all countries have to deal with a higher number of refusals when more violations are diagnosed from China exports, the refusal per export value from China causes the ratio of refusals to increase from their neighbor's and less developed countries and decrease from more developed countries in EU. Other factors, which show a significant impact on FDA's rejections are, trade agreement with the US, English as official language, number of years a country has been a WTO member, and number of antidumping the US had assigned to the exporter. Results also showed that violations are significantly different among economic regions, with EU countries dealing with the lowest rejections and Asian countries the highest. Finally, the number of refusals is path dependent, but the ratio of refusals is not.

In this study, as many factors as possible are combined to explain FDA's import rejections. The hypothesis that the factors besides product quality and safety impact FDA's decision to approve or reject imports has been substantiated. In fact, this work shows that, economic and political pressures, and FDA self-capacity all contribute significantly to FDA decisions. The models, both present nearly consistent results. However, the annual data in these models may not accurately reflect past responses of FDA to changes of explanatory factors, especially in reference to food scandals and standards. In addition, food, cosmetic, and drug products all covered in the models may not accurately reflect the difference in import quality because there are other individual features of each type of products contributing to affect FDA inspection procedures. For example, a drug is more likely to deal with patent infringement than food and cosmetics. Therefore, further researches to classify products with similar evaluations for quality are needed.

References

Allen, A. J., A. E. Myles, S. Shaik, and O. Yeboah. 2008. An Analysis of Trends in Food Import Refusals in the United States. *Journal of Food Distribution Research* 39(1): 1–10

Alonso-Borrego, C. and M. Arellano. 1996. Symmetrically Normalised Instrumental Variable Estimation Using Panel Data. *CEMFI Working Paper* No. 9612

Anderson, T. and C. Hsiao. 1981.Estimation of Dynamic Models with Error Components. *Journal of the American Statistical Association*, 76, 598-606

Anders, M.S., S. Westra. 2011. A Review of FDA Imports Refusals – US Seafood Trade 2000 – 2010. *AAEA and NAREA Joint annual meeting*, Pennsylvania

Arellano, M. and S. Bond. 1991. Some Tests of Specification for Panel Data: Monte Carlo Evidence and an Application to Employment Equations. *The Review of Economic Studies*. 58(2), 277-297

Baylis, K., A. Martens and L. Nogueira. 2009. What Drives Food Import Refusals?. *AAEA annual meeting*, Milwaukee.

Becker, G. S. 2008. Food and Agricultural Imports from China, Congressional Research Service *Report for Congress*. Accessed at

Behr, A. 2003. A Comparison of Dynamic Panel Data Estimators: Monte Carlo Evidence and An Application to the Investment Function. *Discussion Paper 05/03. Economic Research Centre of the Deutsche Bundesbank*

Blundell, R. and S. Bond. 2000. GMM Estimation with Persistent Panel Data: An Application to Production Functions. *The Institute for Fiscal Studies*. Working Paper Series No. W99/4

Bun, M. and J. Kiviet. 2003. On the Diminishing Return of Higher Order Terms in Asymptotic Expansion of Bias. Economics Letters. 79. 145-152

Bun, M., and M. Carree. 2005. Bias-Corrected Estimation in Dynamic Panel Data Models. *Journal of Business & Economic Statistics*. 23.200-210

Buzby, C.J. and A. Regmi. 2009. FDA Refusals of Food Imports by Exporting Country Group. *The Magazine of Food, Farm, and Resource Issues CHOICE*. 2nd Quarter 2009 24(2)

Buzby, J.C., L.J. Unnevehr, and D. Roberts. 2008. Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports. *Washington DC: US Department of Agriculture, ERS Economic Information Bulletin* 39

Cameron A. C. and P. K. Trivedi. 2009. Microeconometrics: Methods and Applications. Cambridge University Press. Text Book.

DeWaal, C.S. and D. V. Plunkett. 2009. Building a Modern Food Safety System for FDA Regulated Foods. *Center for Science in the Public Interest*

Elder, D. 2013. Ensuring the Safety of Imported Products: Q&A with David Elder. *FDA Consumer Updates*

Everaert, G. and L. Pozzi. 2007. Bootstrap-Based Bias Correction for Dynamic Panels. *Journal of Economic Dynamics and Control*. 31(4). 1160-1184

Gale, F. and J. C. Buzby. 2009. Imports from China and Food Safety Issues. *Economic Research Service, USDA*

Goldberg, K.B. and G. Maggi. 1999. Protection for Sale: An Empirical Investigation. *The American Economic Review*, 89(5). 1135-1155

Grant, J. and S. Anders. 2010. Trade Deflection Arising from US Import Refusals and Detention in Fishery and Seafood Trade. *Amer. J. Agr. Econ*. 93(2): 573-580

Hansen, G. 2001. A Bias-Corrected Least Square Estimator of Dynamic Panel Models. *Allgemeines Statistisches Archiv*. 85. 127-140

Hahn, J., G. Kuersteiner, and M. Hyeon. 2004. Asymptotic Distribution of Misspecified Random Effects Estimator for a Dynamic Panel Model with Fixed Effects when both n and T are Large," *Working Paper*, Boston University

Helpman, E. 1995. Politics and Trade Policy. *Tel Aviv Sackler Institute of Economic Studies Working Paper.* No. 30/95

Jouanjean, A.M., J.C. Maur, and B. Shepherd. 2012. Reputation Matter Spillover Effects in the Enforcement of US SPS Measures. *Policy Research Working Paper. The World Bank. WPS5935*

Lopez, R.A. and X. Matschke. 2005. Food Protection for Sale. *Food Marketing Policy Center Research Report* No. 85

Nakuja, T. 2012. Political Influence and the Implications of the US Food Safety Modernization Act for Fruit and Vegetable Trade. *Master Graduation Thesis. University of Saskatchewan, Saskatoon*

Nickell, S. 1981. Biases in Dynamic Models with Fixed Effects. *Econometrica*. 49(6). 1417-1426

Kiviet, J. 1995. On Bias, Inconsistency, and Efficiency of Various Estimators in Dynamic Panel Models. *Journal of Econometrics*. 68. 53-78

Knox, R. 2007. Why China Tops the FDA Import Refusal List. The FDA Q&A

Santos, L. and E. Barrios. 2011. Small Sample Estimation in Dynamic Panel Data Models: A Simulation Study. *Open Journal of Statistics*. 1(2) 58-73 doi: 10.4236/ojs.2011.12007

FDA. 2014. Global Engagement U.S. Food and Drug Administration http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM298578.pdf

FDA. 2012. Annual Report http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/ResearchAccomplishmentsPlans/

The US Food and Drug Administration (FDA). Import Refusal Report. http://www.accessdata.fda.gov/scripts/importrefusals/ (accessed Mar.-Jun. 2014)

FDA Economic Impact Analyses of FDA Regulations. http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm (accessed Mar. 20-27, 2014)

U.S. Department of Health and Human Service (DHHS). 2014. http://www.hhs.gov/strategic-plan/goal3.html

Appendix

Table 1. Two-step GMM estimation (all variables in first differences)

Variables	Coefficients	Standard error
Lag of logged number of refusals	0.0001*	0.0000
Log of FDA annual budget	-.1993	0.4112
Log of the US total imports	-0.1474***	0.0497
Log of FDA number of annual staffs	1.7737**	0.8902
Log US GDP per capita	-0.2090	0.5330
Log of exporter GDP per capita	-0.1190**	0.0600
Log of annual lobby for food industry	1.1726**	0.6651
Log of annual lobby for pharmacist and cosmetics	1.4292***	0.4887
Food	0.3043*	0.1310
Cosmetics	-0.9310***	0.0366
Free trade agreement with the US	0.6039*	0.3200
High-income countries	-1.4629**	-0.2210
Upper-average-income countries	-0.0264	0.6573
English as official language	0.5868***	0.2152
Food scandal 2009	-0.2747***	0.1064
Food scandal 2008	0.7885***	0.1521
Food scandal after 2009	-1.5540***	0.5130
Countries in America + Caribbean	0.0956*	0.0567
Countries in EU	0.0318	0.0953
Number of anti dumping	.01434 ***	0.0055
Corruption perceptions index of exporters	0.5648*	0.3039
Years have being with WTO	-2.6437 **	1.2383
Bilateral trade agreement with the US	0.0010	0.0010
The US annual unemployment rate	0.1567*	0.0977
Spillover effect of refusals	0.0011***	0.0000
FDA Foreign Post Office in a particular country	-0.4656***	0.1777
FDA Foreign Post Office in the US main office	-0.0838	0.1609
Log of export value	0.2590***	0.0200
Food Safety Modernization Act for food	0.2137**	0.0702
Food Safety Modernization Act for cosmetics	0.4724***	0.1758
Food Safety Modernization Act for drugs	0.5267*	0.2323
_cons	-23.2110 *	14.0788
Canada	2.9631***	0.2685
Columbia	3.2495***	0.2685
Germany	0.7156**	0.2704

Domenica	1.7277***	0.2685
Spain	1.3474***	0.2685
France	1.1616***	0.2685
England	2.0947***	0.2685
Hong Kong	2.4212***	0.2685
Indonesia	1.3593***	0.2685
India	0.5697*	0.2685
Italia	3.1044***	0.2685
Japan	1.8290***	0.2685
Korean	1.8392***	0.2685
Mexico	2.0692***	0.2685
Philippines	3.2104***	0.2685
Pakistan	1.5007**	0.2685
Thailand	0.7720***	0.2685
Taiwan	1.2832***	0.2685
Vietnam	1.8586***	0.2376
Arellano-Bond test for AR(1) in first differences	z = -3.29	Pr > z = 0.001
Arellano-Bond test for AR(2) in first differences	z = -1.31	Pr > z = 0.189
Sargan test of overid. restrictions	chi2(55) = 161.54	Prob >chi2=0.000
Hansen test of overid. restrictions	chi2(55) = 33.11	Prob>chi2= 0.992

Table 2. Triggering Factors of Refusal Ratio from Negative Binomial Model with Endogenous Predictors

Variable	Coefficients	ME	Standard error
Log of FDA annual budget	-0.8900	-0.6464	1.5790
Log of the US total imports	-0.5261	-0.5255***	0.0954
Log of FDA number of annual staffs	1.0556	0.7667	2.885
Log US GDP per capita	1.3326	0.9679	5.542
Log of exporter GDP per capita	-0.8309	-0.6034***	0.109
Log of annual lobby for food industry	2.9100	2.1135*	1.139
Log of annual lobby for pharmacist and cosmetics	2.0689	1.5027**	0.7212
Food	-0.9330	-0.7395	0.5831
Cosmetics	0.7262	0.6084	0.6020
Free trade agreement with the US	0.5994	0.5221*	0.2502
English as official language	0.7501	0.6241***	0.1030
Food scandal 2008	0.1860	0.1252	0.5220
Food scandal 2009	-1.0498	-0.5152***	0.1382
Food scandal after 2009	-1.9504	-1.4042	1.883
Countries in America + Caribbean	-0.1511	-0.0894	0.1568
Countries in EU	-2.7960	-1.3844***	0.2180
Number of anti dumping	-0.0202	-0.0141***	0.0021
Corruption perceptions index of exporters	0.1320	0.1061	0.0951
Years have being with WTO	0.0615	0.0451*	0.0273
Bilateral trade agreement with the US	0.0204	0.0148***	0.0021
The US annual unemployment rate	0.3747	0.2941**	0.1380
FDA Foreign Post Office in a particular country	-0.6858	-0.4030***	0.1519
FDA Foreign Post Office in the US	-0.8046	-0.4414***	0.1625
Food Safety Modernization Act for food	1.1650	1.4459***	0.4844
Food Safety Modernization Act for cosmetics	1.4435	2.0719***	0.4963
Food Safety Modernization Act for drugs	1.8085	3.1688***	0.5832
_cons	-219.248	-36.3072	30.4216
Canada	-1.0912	-1.1202***	0.4108
Columbia	0.4027	0.3803*	0.2232
Germany	0.3834	0.3577	0.2596
Domenica	-0.1745	-0.1868	0.2600
Spain	0.0945	0.0830	0.2150
France	-0.5300	-0.5365*	0.2920
England	-2.3478	-2.3325***	0.5422
Hong Kong	-2.7857	-2.7816***	0.5931
Indonesia	0.3862	0.3751*	0.2246
India	1.3264	1.3071***	0.2319
Italia	-0.8069	-0.8309**	0.3497
Japan	-0.4376	-0.4341	0.3142

Korean	-2.5582	-2.5770***	0.4247
Mexico	0.0316	0.0322	0.2231
Philippines	0.1245	0.0747	0.3884
Pakistan	-0.0861	-0.0913	0.2179
Thailand	0.4376	0.5166*	0.2316
Taiwan	-0.2483	0.2618***	0.0239
Vietnam	0.5256	0.5152**	0.2333