

# What Every Foreign OEM, Importer Should Know

*A review of medical device warning letters issued to foreign manufacturers by the FDA, 1997-2007.*

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The manufacturing of medical devices has become increasingly global as U.S. medical device companies contract with non-U.S. companies for their manufacturing operations, and foreign device companies seek to penetrate the U.S. market. The foreign manufacturing of medical devices for import into the United States presents regulatory challenges that are different than those confronted by U.S. device manufacturers. Notably, Section 810(a) of the U.S. Food, Drug and Cosmetic Act (FDCA) authorizes the U.S. Food and Drug Administration (FDA) to refuse to permit the importation of medical devices from foreign countries if they “appear” to be adulterated.

Devices in U.S. commerce are actionable only if the FDA determines they are adulterated. In addition, due to logistical and budgetary constraints, the FDA inspects only about 5 percent of all foreign Class II or III medical device establishments each year, compared to 27 percent of all U.S. Class II or III medical device establishments. However, approximately 6.5 percent of foreign inspections result in warning letters, as compared to 4.4 percent of domestic inspections. Furthermore, of the warning letters issued to foreign manufacturers, approximately 40 percent restrict the import of devices into the United States.

This article examines warning letters issued to medical device companies between 1997 and 2007 to explore the qualitative and quantitative differences between warning letters issued to U.S. and foreign device companies. This review provides insights into the challenges faced by foreign medical device manufacturers and their effect on FDA enforcement. These insights may assist foreign manufacturers, auditors and U.S. companies that contract with foreign manufacturers to prepare for and respond to FDA inspections. In particular, the review of warning letters issued to medical device companies between 1997 and 2007 reveals the following:

- More than 40 percent of warning letters issued to foreign medical device manufacturers include notice of detention without physical examination, otherwise known as automatic detention.
- A slightly greater percentage of inspections of foreign device manufacturers result in warning letters, compared to inspections of

U.S. medical device manufacturers.

- The rate of warning letters per inspection varies by country, with higher than-average rates found in two English-speaking countries (Canada and the United Kingdom).

- The types of Quality System Regulation [21 C.F.R. Part 820] (QSR) citations identified in warning letters issued to foreign manufacturers differ in significant respects from those cited in warning letters issued to U.S. manufacturers.

- The QSR citations in warning letters issued to manufacturers in English-speaking countries differ from those cited against manufacturers located in non-English-speaking countries, suggesting differences in the way that FDA conducts foreign medical device inspections between English and non-English speaking countries.

- The Corrective and Preventive Action [21 C.F.R. 820.100] and Design Control [21 C.F.R. 820.30] citations in warning letters issued to foreign countries suggest a focus on specific corrective and preventive actions and design changes, instead of a top-down review of each system.

- It takes significantly longer for the FDA to issue warning letters to foreign manufacturers than to U.S. manufacturers.

This series examines these differences and their implications for foreign device manufacturers.<sup>1</sup> This information highlights the significant consequences of a warning letter for foreign device manufacturers. A warning letter, particularly one combined with notice of automatic detention, can effectively shut a foreign manufacturer out of the U.S. market until the issues identified in the warning letter are resolved, which, if the FDA requires a follow-up inspection, can keep the manufacturer out of the U.S. market for years. This series concludes by suggesting ways to prepare for an FDA inspection and provides guidance on responding to inspectional observations in order to minimize these risks.

## Methodology

This series examines information from publicly available warning letters posted on “FDA’s Electronic Freedom of Information Reading Room—Warning Letters and Responses.”<sup>2</sup> Particular focus is given to FDA warning letters involving foreign medical device manufacturers over a 10-year period (1997 to 2007). These warning letters were or-

ganized by the country in which the inspection took place, as well as by the FDA fiscal year<sup>3</sup> of the last day of the inspection.<sup>4</sup> A report issued by the U.S. Government Accountability Office (GAO) provides detailed information on medical device inspections that the FDA conducted between 2002 and 2007, which helps to put the warning letters issued to U.S. and foreign firms in context.<sup>5</sup>

The methodology used to generate data presented in this series is only intended to identify general trends and is not capable of measuring the regulatory compliance of any country or of identifying any nonpublic FDA inspectional guidance. As noted throughout this series, there are significant gaps in the data used to compile the tables provided herein. For example, there is disagreement in the press as to the total number of medical device warning letters issued by the FDA.<sup>6</sup> Also, the rate of warning letters per inspection for certain countries<sup>7</sup> is extrapolated from the number of FDA inspections conducted in Italy, the foreign country with the fewest inspections identified in the GAO report.<sup>8</sup>

This series reviews these warning letters on two levels. The first part examines the rates at which warning letters were issued in particular foreign countries as compared to the rate at which warning letters were issued to manufacturers in the United States. The second part will examine (in the next issue of *MPO*) the most frequent citations in warning letters issued to domestic and foreign manufacturers, the average time between the close of an inspection, and the issuance of a warning letter and some common problems encountered by foreign manufacturers when responding to inspectional observations.

Particular focus is given to the years 2002 through 2007. This reflects the period during which FDA’s Office of Chief Counsel began a program to review all warning letters and untitled letters for legal sufficiency and consistency with FDA policy in March 2002.<sup>9</sup> Furthermore, this data begins about three years after implementation of FDA’s Quality System Inspection Technique and five years after implementation of the FDA’s QSR [21 C.F.R. Part 820], which represented a paradigm shift in the way that FDA conducted inspections of medical device manufacturers.

## Warning Letter Frequency

Although the FDA inspects foreign medical device facilities at a lower rate than domestic

**Table 1: Number of FDA Inspections of Medical Device Establishments, Fiscal Year 2002-2007<sup>11</sup>**

Country	Number of Inspections						Total	Number of Registered Class II or III Manufacturers as of Sept. 2007
	2002	2003	2004	2005	2006	2007		
Germany	39	30	34	51	25	52	231	581
United Kingdom	25	31	28	14	25	43	166	351
Canada	17	17	24	11	13	26	108	340
Japan	7	8	20	21	16	25	97	264
Ireland	15	22	13	13	16	11	90	67
France	16	14	17	14	12	10	83	190
Switzerland	6	12	19	9	7	18	71	134
China	0	0	21	19	11	13	64	675
Mexico	10	7	12	8	12	11	60	143
Italy	8	7	10	6	13	11	55	202
All other countries	66	83	102	67	69	69	456	2,036
Total Foreign	209	231	300	233	219	289	1,481	4,983
United States	1,261	1,736	1,631	1,471	1,501	1,362	8,962	5,616

facilities, the chances that a foreign inspection will result in a warning letter are higher than that for a U.S. manufacturer. Furthermore, a significant percentage of warning letters issued to foreign manufacturers include notice of conditions that support detention without physical examination. These factors highlight the importance of adequately preparing for an FDA foreign inspection.

According to testimony before the U.S. House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, the FDA inspects about 5 percent of all foreign Class II or III medical device establishments each year, compared to 27 percent of all U.S. Class II or III establishments. This inspection rate suggests that approximately 70 percent of registered foreign device firms have never been inspected.<sup>10</sup> In contrast, the number of FDA inspections in the United States suggests that most, if not all, of the U.S. facilities have been inspected at least once since 2002. Table 1 reports the numbers of inspections per country per year and the number of registered facilities in each country as of September 2007.

FDA is required by statute<sup>12</sup> to inspect U.S. Class II or III medical device establishments once every two years; however, there is no comparable requirement for foreign manufacturers. This statutory requirement appears to affect the rate of inspections conducted by the FDA (despite the fact that FDA has found it difficult to meet its domestic statutory inspection requirement). The GAO reports that U.S. Class II manufacturers are inspected once every five years, and U.S. Class III manufacturers are inspected once every three years.<sup>13</sup> By contrast, foreign Class II manufacturers are inspected once every 27 years, and foreign Class III manufacturers are inspected once every six years.<sup>14</sup>

In addition to conducting far fewer inspections of foreign device manufacturers as compared to U.S. manufacturers, the FDA faces a number of budgetary and logistical constraints

when conducting a foreign inspection. The FDA is responsible for funding travel expenses for foreign inspections<sup>15</sup>, and the FDA will typically contact foreign manufacturers in advance for assistance in arranging local travel and lodging and to ensure that the manufacturer will be producing medical devices for the U.S. market during the inspection.<sup>16</sup>

These budgetary and logistical constraints provide two key advantages for foreign device manufacturers. First, foreign manufacturers typically receive a longer pre-announcement period than U.S. manufacturers, allowing foreign manufacturers more time to identify and correct any outstanding regulatory issues. The FDA typically notifies foreign device manufacturers nearly a month before the inspection occurs.<sup>17</sup>

This compares to only a week for those U.S. manufacturers that are eligible to receive notice of an inspection.<sup>18</sup> Second, foreign device inspections have an artificially compressed inspection schedule, with the majority of foreign FDA device inspections limited to one investigator and four days on site. This may limit the number of observations identified by the investigator during the inspection, as well as the inspector's understanding of the extent of the problems posed by those observations. The FDA generally has fewer logistical restrictions when conducting U.S. device inspections, and FDA investigators are permitted to extend domestic inspections and request the assistance of additional FDA investigators as needed.

Despite the budgetary and logistical constraints confronting the FDA, a significant number of foreign inspections result in serious enforcement actions. The FDA issued warning letters in approximately 6.5 percent of the foreign inspections conducted between 2002 and 2007. This compares to 4.4 percent of U.S. manufacturers inspected by the FDA over the same period.

In addition, more than 40 percent of the

warning letters issued to foreign device manufacturers included observations significant enough to support a detention without physical examination (or automatic detention) action by the FDA. A foreign manufacturer whose products are subject to automatic detention must prove that the product meets FDA's requirements before they can be released by U.S. Customs.<sup>19</sup> This can significantly delay or limit imports into the United States.

The higher rate and severity of warning letters issued to foreign manufacturers by the FDCA sets a higher standard for devices that are imported into the United States than for those manufactured domestically. Section 801(a)<sup>20</sup> of the FDCA requires the FDA to refuse admission of a device into the United States if it "appears" that the device is adulterated or misbranded. By comparison, the FDCA prohibits the introduction or delivery in interstate commerce of a domestically manufactured device that is actually adulterated or misbranded.<sup>21</sup> As a result of this difference in the statutory standard, the FDA requires investigators to provide less documentary evidence to establish violations by foreign device manufacturers.<sup>22</sup>

Another factor that may contribute to the increased rate of warning letters issued to foreign manufacturers may be the difference between the regulatory approaches taken by the FDA and regulatory authorities in other countries. Foreign regulatory authorities rely on certification to International Organization for Standardization (ISO) medical device quality system standard 13485 ("Medical devices—Quality Management Systems—Requirements for Regulatory Purposes") as the basis for manufacturing compliance. This ISO standard has not, however, been adopted by the FDA. While the FDA has sought to harmonize its regulations with those of foreign countries, particularly through the Global Harmonization Task Force,<sup>23</sup> the FDA inspection approach continues to differ from that used in foreign countries.

The FDA's approach to conducting medical device inspections has historically differed from that used by regulatory authorities of other countries. FDA has conducted its medical device inspections following a bottom-up approach, while ISO auditing follows a top-down approach.<sup>24</sup> A top-down approach begins with an evaluation of whether the firm has addressed the basic regulatory requirements, followed by an analysis of whether the firm has adequately implemented those requirements by defining, documenting and implementing appropriate procedures.<sup>25</sup> Applying a top-down approach is intended to provide a systematic and transparent process for conducting an inspection.<sup>26</sup> By contrast, a bottom-up approach starts by examining a particular quality problem, then

working up through a manufacturer's QMS to manage responsibility.<sup>27</sup> While lacking a degree of transparency, a bottom-up approach facilitates the assessment of a specific product or problem by examining how the quality system created or caused the specific product issue or problem under examination.<sup>28</sup>

Although the FDA's quality system inspection technique instructs investigators to follow a top-down approach,<sup>29</sup> changing the approach employed by FDA investigators in the field has been difficult due to the long-standing practice of bottom-up inspections by senior investigators. Moreover, the FDA's risk-based enforcement strategy reinforces a bottom-up approach, as most enforcement actions focus on specific problems that may be carried through to the quality of the final product, as opposed to procedural or systems problems that are more commonly observed from a top-down perspective.

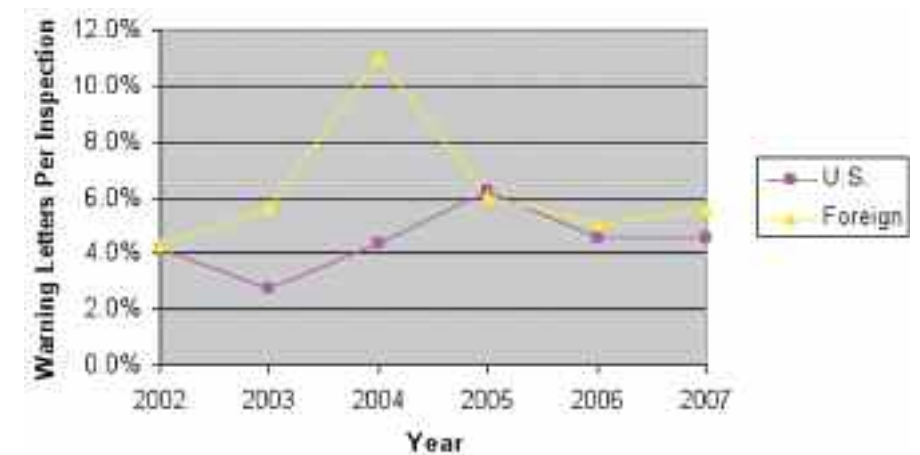
### Frequency by Country

Although the overall numbers of inspections in each country are relatively small and somewhat variable, an examination of the number and rates of foreign warning letters by country since 2002 reveals some interesting information that challenges some common perceptions.

All of the foreign countries surveyed except Japan (3.1 percent) and Ireland (3.3 percent) had higher rates of warning letters than U.S. manufacturers (4.4 percent). German manufacturers had the highest absolute number (16) of warning letters issued since 2002. However, the rate of warning letters per German inspection (6.9 percent) is the seventh highest among the countries inspected, although still greater than the average rate (6.5 percent). Canadian companies had the highest overall rate of warning letters at 12 percent.

The higher-than-average rates estimated for South Korea and Taiwan might suggest a compliance problem among Asian countries. However, manufacturers in China<sup>31</sup> received only three device warning letters between 2002 and 2007, for a rate of only 4.7 percent. This is particularly interesting given recently reported safety concerns with exported drugs and foods from China, and recent warning letter data suggests this trend may be changing.<sup>32</sup> Furthermore, it is not currently known what impact the opening of the FDA office in China will have on the number of inspections conducted in China and the number of warning letters issued.<sup>33</sup>

Companies in the two major English-speaking countries, Canada (12 percent) and the United Kingdom (7.2 percent), had higher rates of warning letters than the average foreign firm, suggesting that the higher rate of warning letters issued to foreign manufactur-

**Chart 1: Rate of Warning Letters Per Inspection, Foreign and U.S.****Table 2: Warning Letters Issued to Foreign Medical Device Manufacturers<sup>30</sup>**

Fiscal Year of Inspection	Number of Warning Letters	Conditions Supporting Detention Without Physical Examination	Percentage
1997	37	21	56.8%
1998	21	9	42.9%
1999	18	15	83.3%
2000	33	19	57.6%
2001	18	6	33.3%
2002	9	7	77.8%
2003	13	6	46.2%
2004	33	12	36.4%
2005	14	5	35.7%
2006	11	4	36.4%
2007	16	5	31.3%

ers may not be a result of a language barrier. Further, companies in Canada (12 percent), Switzerland (8.5 percent), Italy (9.1 percent) and certain other western European countries had among the highest rates of warning letters issued. This suggests that the higher overall rate for foreign manufacturers might not be attributed to deficiencies in the foreign regulatory systems, as Canada, the United Kingdom and the European Union all have fairly robust domestic regulatory systems. In particular, Health Canada shares a number of similarities with the FDA, including an inspectorate that conducts its own inspections.<sup>34</sup>

### Foreign vs. Domestic Inspections

The data provided in this series demonstrate real differences between foreign inspections and domestic inspections, as revealed through the warning letters issued to U.S. and foreign manufacturers. These differences include the rate at which the FDA issues warning letters following an inspection, the number of days between the close of the inspection and the issuance of the warning letter, and the citations noted in the warning letters. Companies should consider these differences in their pre-inspection preparations and in their responses to Form FDA-483s and warning letters.

The next part of this series, which will appear in the September issue of *Medical Product Outsourcing*, will examine the most

frequent citations in warning letters issued to domestic and foreign manufacturers, the average time between the close of an inspection and the issuance of a warning letter, as well as some common problems encountered by foreign manufacturers when responding to inspectional observations. It concludes with recommendations for foreign device manufacturers facing an FDA inspection. ♦

### References:

1. *Carolynne Hathaway, John Manthei and Seth Mailhot, "What You Don't Know Can Hurt You: Understanding the FDA's Foreign Inspection Program," Medical Devices Litigation Reporter, Feb. 4, 2008.*
2. Available at [www.fda.gov/foi/warning.htm](http://www.fda.gov/foi/warning.htm). As of the date of this series, 2008 figures could not be compiled.
3. FDA fiscal years run from Oct. 11 of the previous year through Sept. 30 of the given year.
4. In the few situations where the inspection date was not given in the text of the warning letter, the fiscal year of the inspection was estimated based on the average time it took the FDA to issue a warning letter following an inspection.
5. GAO, *Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, Medical Devices: "Challenges for FDA in Conducting Manufacturer Inspections, Statement of Marcia Crosse, Director Health Care, GAO-08-428T, Jan. 29, 2008."*

6. Compare Sven Pommeranz, "Medical Devices Warning Letters Report 2008—CAPA 1st," *European Compliance Academy* (Feb. 25), available at [www.gmp-compliance.org/eca\\_news\\_01363.html](http://www.gmp-compliance.org/eca_news_01363.html) with F-D-C Reports Inc., "Changes May Be In Store For FDA's Quality System Inspection Technique," *The Silver Sheet* 8 (March 2008) (reporting different totals for the number of medical device warning letters issued per year). For the purposes of this series, calculations were based on the total number of medical device warning letters reported by the European Compliance Academy. The numbers reported by the European Compliance Academy generally were greater than those reported in The Silver Sheet.

7. Specifically, South Korea, Taiwan and Denmark.

8. GAO, *Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, "Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, Statement of Marcia Crosse, Director Health Care, GAO-08-428T, Jan. 29, 2008." These rates are represented in this paper as greater than the stated percentage (">").

9. FDA, *Regulatory Procedures Manual, Exhibit 4-1, "Procedures for Clearing FDA Warning Letters and Untitled Letters"*, July 2008 (available at [www.fda.gov/ora/compliance\\_ref/rpm/exhibits/Exhibit\\_4-1.pdf](http://www.fda.gov/ora/compliance_ref/rpm/exhibits/Exhibit_4-1.pdf)).

10. This rough approximation is based on the number of registered facilities as of September 2007 and does not account for the unknown percentage of foreign firms inspected since 2002 that have commenced or ceased business operations or the number of facilities that experienced multiple inspections.

11. Source: United States Government Accountability Office, *Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, "Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, Statement of Marcia Crosse, Director Health Care, GAO-08-428T, Jan. 29, 2008."

12. U.S.C. § 360(h).

13. GAO Study, page 5.

14. GAO Study, pages 5-6.

15. See FDA, *Division of Field Investigations, "Guide to International Inspections and Travel"*, § 406 (November 2002), available at [www.fda.gov/ora/inspect\\_ref/igii/default.htm](http://www.fda.gov/ora/inspect_ref/igii/default.htm).

16. See *Id.* at § 302.1.

17. Carolyne Hathaway, John Manthei and Seth Mailhot, "What You Don't Know Can Hurt You: Understanding the FDA's Foreign Inspection Program," *Medical Devices Litigation Reporter*, Feb. 4, 2008.

18. *Inspections of U.S. firms with a history of violations and domestic inspections triggered by an immediate and urgent response to complaints, informant information or recall due to a health hazard are generally not preannounced.* FDA, "Guide

**Table 3: Number of FDA Warning Letters Issued to Medical Device Establishments, FY 2002-2007**

Country	Number of Warning Letters Fiscal Year						Total	Rate of Warning Letters Inspection
	2002	2003	2004	2005	2006	2007		
Per								
Germany	1	3	3	5	4	0	16	6.9%
Canada	3	2	5	0	0	3	13	12.0%
United Kingdom	3	1	4	0	1	3	12	7.2%
Switzerland	0	1	1	1	1	2	6	8.5%
Italy	0	0	3	1	1	0	5	9.1%
South Korea	0	0	3	0	0	1	4	> 7.3%
Taiwan	1	0	1	1	1	0	4	> 7.3%
France	1	1	1	1	0	0	4	4.8%
Denmark	0	1	1	0	1	0	3	> 5.5%
Mexico	0	0	1	2	0	0	3	5.0%
China	0	0	1	0	0	2	3	4.7%
Ireland	0	0	0	1	0	2	3	3.3%
Japan	0	0	2	0	0	1	3	3.1%
All other countries	0	4	8	2	2	4	20	Unknown
<b>Total Foreign</b>	<b>9</b>	<b>13</b>	<b>33</b>	<b>14</b>	<b>11</b>	<b>16</b>	<b>96</b>	<b>6.5%</b>

to *Inspections of Medical Device Manufacturers*, Attachment A, § I. B. (December 1997).

19. FDA, *Regulatory Procedures Manual: "Chapter 9 Import Operations/Actions, Automatic Detention"* (September 2002), available at [www.fda.gov/ora/compliance\\_ref/rpm/chapter9/ch9-6.html](http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-6.html).

20. 21 U.S.C. 381(a).

21. See 21 U.S.C. 331.

22. Carolyne Hathaway, John Manthei and Seth Mailhot, "What You Don't Know Can Hurt You: Understanding the FDA's Foreign Inspection Program," *Medical Devices Litigation Reporter*, Feb. 4, 2008.

23. FDA, "Regulation of Medical Devices: Background Information for International Officials," 19 (Apr. 14, 1999), available at [www.fda.gov/cdrh/manual/ireas.pdf](http://www.fda.gov/cdrh/manual/ireas.pdf).

24. See FDA, "Guide to Inspections of Quality Systems," 7 (August 1999), available at [www.fda.gov/ora/inspect\\_ref/igs/qsit/QSITGUIDE.PDF](http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF).

25. FDA, "Guide to Inspections of Quality Systems," 8 (Aug. 1999), available at [www.fda.gov/ora/inspect\\_ref/igs/qsit/QSITGUIDE.PDF](http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF).

26. *Id.*

27. *Id.*

28. See FDA, "Guide to Inspections of Quality Systems," 7-8 (Aug. 1999), available at [www.fda.gov/ora/inspect\\_ref/igs/qsit/QSITGUIDE.PDF](http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF).

29. FDA, "Guide to Inspections of Quality Systems," 7 (Aug. 1999), available at [www.fda.gov/ora/inspect\\_ref/igs/qsit/QSITGUIDE.PDF](http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF).

30. Rates represented as greater than (">") the stated percentage were calculated based on the number of inspections conducted in Italy from 2002 to 2007 (55). The 55 inspections conducted in Italy are the lowest number of FDA inspections conducted for a foreign country identified in the GAO report. Therefore, any country not specifically identified in the GAO Report (including South Korea, Taiwan and Denmark) is assumed to have, at most, 55 inspections from 2002 to 2007. See United States Government Accountability Office, *Testimony Before the Subcommittee on Oversight and Investigations, Committee on*

*Energy and Commerce, House of Representatives, "Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, Statement of Marcia Crosse, Director Health Care, GAO-08-428T, Jan. 29, 2008."

31. *Attorneyatlaw.com, "Food from China Poses 'Serious Issues,' U.S. Lawmaker Says"* (March 18, 2009), at [www.attorneyatlaw.com/2009/03/food-from-china-poses-serious-issues-us-lawmaker-says/](http://www.attorneyatlaw.com/2009/03/food-from-china-poses-serious-issues-us-lawmaker-says/).

32. Two of the three warning letters issued to China between 2002 and 2007 included notice of automatic detention. Furthermore, incomplete information on warning letters issued to foreign device manufacturers inspected in FY 2008 suggests China's rate may be increasing. Through March 14, China has received two warning letters for inspections conducted in fiscal year 2008, one of which included notice of automatic detention.

33. FDA, "FDA Beyond Our Borders" (Dec. 9, 2008), at [www.fda.gov/consumer/updates/beyondborders120908.html](http://www.fda.gov/consumer/updates/beyondborders120908.html).

34. In some instances, these inspections are unannounced. Health Canada, Health Products and Food Branch Inspectorate, "Guidance on the Medical Device Inspection Programme," 4, Feb. 6, 2004.

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