



# The FDA's Authority to Recall Products

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August 4, 2010

**Congressional Research Service**

7-5700

[www.crs.gov](http://www.crs.gov)

RL34167

## Summary

The Food and Drug Administration (FDA) has fielded increasing numbers of questions regarding recalls of unsafe imports, including jalapeño peppers, pet food, the blood thinner heparin, and toothpaste. Additionally, several domestic drug and food products—such as over-the-counter children's medications, adult pain relief and allergy drugs, spinach, chili, and peanut products—have been voluntarily recalled by businesses in the last few years. Recalls may decrease consumer confidence in the recalling company, food imports, or product safety agencies such as the FDA. The products later subject to a recall may have sickened or killed people or pets. The FDA has the authority to order recalls of four types of products: infant formula, medical devices, human tissue products, and tobacco products. The agency may request that a company voluntarily recall other FDA-regulated products, such as food, drugs, and cosmetics.

Congress has demonstrated a significant interest in the issue of food safety and recalls, holding several hearings and introducing many pieces of legislation. The 110<sup>th</sup> Congress passed P.L. 110-85, the FDA Amendments Act of 2007 (FDAAA), which contained provisions addressing communications and information postings during a food recall. The 111<sup>th</sup> Congress passed the Family Smoking Prevention and Tobacco Control Act, P.L. 111-31, which provided authority for the Secretary of the Department of Health and Human Services, acting through the FDA, to order a recall of tobacco products if there is a reasonable probability that the tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death.

Additionally, the 111<sup>th</sup> Congress has introduced several bills that would grant the FDA the ability to order recalls of food and other products, including H.R. 841, the Protect Consumers Act of 2009; H.R. 875, the Food Safety Modernization Act of 2009; H.R. 999, the Keeping America's Food Safe Act of 2009; H.R. 2726, the Counterfeit Drug Enforcement Act of 2009; H.R. 2749, the Food Safety Enhancement Act of 2009; S. 510, the FDA Food Safety Modernization Act; and S. 3690, the Drug Safety and Accountability Act of 2010. H.R. 2749 is a revised version of H.R. 759, the Food and Drug Administration Globalization Act of 2009.

In July 2009, the House passed H.R. 2749, a comprehensive food safety measure that would provide the FDA with authority to require recalls of food products after issuing an order to immediately cease distribution of a food (either after an opportunity for an informal hearing or on an emergency basis if there is credible evidence that a food presents an imminent threat of serious adverse health consequences or death), require facility food safety plans to describe their procedures for recalling articles of food, and enable the FDA to assess and collect fees from entities for the fiscal year in which the entity is subject to a food recall. S. 510 would similarly enable the FDA to order a recall of a food product and would require the FDA to assess and collect fees to cover food recall activities associated with a recall order. It has been reported by the Senate Committee on Health, Education, Labor, and Pensions and is expected to see floor action this year.

This report provides an overview of the FDA's statutory authority with regard to the products that the agency can recall, as well as FDA regulations for designating the particular class of recall, publicizing and monitoring the effectiveness of recalls, and carrying out recalls.

## Contents

Background .....	1
Views on FDA Recall Authority .....	3
Current Statutory Authority for Mandatory Recalls.....	6
Infant Formula .....	6
Medical Devices .....	7
Biological Products .....	8
Tobacco Products .....	8
Current FDA Regulations Regarding Voluntary Recalls .....	9
Industry-Initiated Recalls .....	9
FDA-Requested Recalls .....	10
Classification of Recalls .....	11
Communication Regarding a Recall .....	12
Monitoring and Termination of a Recall .....	12
Food and Drug Administration Amendments Act of 2007 (FDAAA) .....	13
Bills in the 111 <sup>th</sup> Congress .....	15

## Contacts

Author Contact Information .....	15
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## Background

The Food and Drug Administration (FDA) has fielded increasing numbers of questions regarding recalls of unsafe imports, including jalapeño peppers, pet food, the blood thinner heparin, and toothpaste. Additionally, several domestic drug and food products have been recalled in the past few years: infants' and children's Tylenol, Motrin, Zyrtec, and Benadryl because some products "may not meet required quality standards";<sup>1</sup> peanut butter and peanut products contaminated with *Salmonella*; spinach linked to *E. coli* 0157:H7; and canned meat products such as chili sauce spoiled by *Clostridium botulinum* (botulism). A recall is "a firm's removal or correction of a marketed product that the [FDA] considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure."<sup>2</sup>

Recalls may decrease consumer confidence in the recalling company, food imports, or product safety agencies such as the FDA; products later subject to a recall may have sickened or killed people or pets.<sup>3</sup> Recalls of one type of product may impact that product's industry generally, as well as the local economy where the product is grown, if it is a crop.<sup>4</sup> Recalls of tainted or defective products can be costly to the recalling company in terms of the costs of the recall, injury to reputation, and exposure to liability via class actions and other lawsuits, which may lead to economic, noneconomic, and punitive damages.<sup>5</sup> For example, pet owners whose pets had eaten

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<sup>1</sup> Press Release, McNeil Consumer Healthcare, McNeil Consumer Healthcare Announces a Voluntary Recall of Certain OTC Infants' and Children's Products (Apr. 30, 2010), [http://www.mcneilproductrecall.com/page.jhtml?id=/include/new\\_recall.inc](http://www.mcneilproductrecall.com/page.jhtml?id=/include/new_recall.inc). Earlier in 2010, a moldy odor linked to the breakdown of a chemical used on wooden shipping pallets for product packaging materials led to a recall of products such as Tylenol, Benadryl, Motrin, and Roloids. Press Release, McNeil Consumer Healthcare, Product Recall Information (Jan. 15, 2010), <http://www.mcneilproductrecall.com/page.jhtml?id=/include/press.inc>.

<sup>2</sup> 21 C.F.R. § 7.3(g). The definition of a recall "does not include a market withdrawal or a stock recovery." *Id.* A market withdrawal is "a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the [FDA] or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs." 21 C.F.R. § 7.3(j). A stock recovery is "a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use." 21 C.F.R. § 7.3(k).

<sup>3</sup> Peanut butter and peanut products have been linked to 9 deaths and more than 690 people sickened in 46 states in a *Salmonella* poisoning outbreak dating from September 2008. Lyndsey Layton, *Ripples From Peanut Scandal Affect Companies Big and Small*, WASH. POST, Mar. 1, 2009, at A05; Centers for Disease Control, Investigation Update: Outbreak of *Salmonella* Typhimurium Infections, 2008-2009, <http://www.cdc.gov/salmonella/typhimurium/update.html> (final Web update: Mar. 17, 2009). More than 1,250 people were sickened in an outbreak linked to jalapeño peppers; 246 deaths of patients receiving heparin were reported to the FDA (though "[i]n the majority of reports with a death outcome, there was not enough clinical information to assess the relationship between death and use of heparin"); and reportedly about "1,950 cats and 2,200 dogs died from kidney failure from eating melamine-contaminated pet food." Annys Shin, *Salmonella-Tainted Jalapeño Found in Texas*, WASH. POST, July 22, 2008, at A1; FDA, Information on Adverse Event Reports and Heparin, [http://www.fda.gov/cder/drug/infopage/heparin/adverse\\_events.htm](http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm); John Pacenti, *Animal Owners Seek Class Action Status in Suit Over Pet Food Additives*, Law.com, June 10, 2008.

<sup>4</sup> See GAO, Federal Oversight of Food Safety: High-Risk Designation Can Bring Attention to Limitations in the Government's Food Recall Programs, at 3 (Apr. 24, 2007) (Statement of Lisa Shames, Acting Director, Natural Resources and Environment) (reporting industry estimates of losses from a spinach *E. coli* outbreak at \$37 million to \$74 million).

<sup>5</sup> Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59:4 FOOD & DRUG L. J. 563, 568 (2004). Economic damages are out-of-pocket expenses incurred by the plaintiff, such as medical bills or loss of income. Noneconomic damages are damages payable for items other than out-of-pocket expenses, such as pain and suffering or punitive damages. Punitive damages (also called "exemplary damages") are (continued...)

food contaminated with melamine filed a suit against Menu Foods that settled for \$24 million.<sup>6</sup> Eligible pet owners may receive economic damages for the purchased pet food products, veterinary bills, “expenses related to [the] pet’s illness and/or death, and other expenses such as lost wages and property damage.”<sup>7</sup>

Additionally, Federal Food, Drug, and Cosmetic Act (FFDCA) penalties and other enforcement provisions may apply when food or other agency-regulated products are recalled.<sup>8</sup> The agency has discretion to pursue penalties or other enforcement actions.<sup>9</sup> In the pet food case, a federal grand jury returned an indictment against two foreign nationals and their businesses, as well as an American company, its president, and chief executive officer.<sup>10</sup>

While the FDA only has the authority to order recalls of infant formula, medical devices, human tissue products, and tobacco products, the agency may request that a company voluntarily recall other products, such as food, animal feed, human and animal drugs, radiation-emitting products, and cosmetics. Companies typically recall tainted products voluntarily, but this may not always be the case.<sup>11</sup> In 2008, one company reportedly initially refused to recall cookies contaminated with melamine, but began silently withdrawing the cookies from the market instead, without publicizing information regarding the contaminated products until weeks later.<sup>12</sup> For this reason and others discussed below, supporters of stronger food safety laws have argued that the FDA should be given statutory authority to mandate recalls of food and other products.

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(...continued)

damages awarded, in addition to economic damages and other noneconomic damages, to punish a defendant for willful or wanton conduct. Depending on the jurisdiction, some damages may be barred or restricted by statute. Also, some damages may be hard to prove and thus be considered too speculative by the court. As a result, they may be struck or restricted. Punitive damages may require a higher level of proof.

<sup>6</sup> Pet Food Products Liability Settlement, <http://www.petfoodsettlement.com>. The company began testing its pet food on animals at the end of February 2007, “one week after it began hearing from owners who said the food had made their pets ill.” Katie Zezima, *Tests by Pet Food Maker Killed 7 Animals Before Recall*, N.Y. TIMES, Mar. 20, 2007, at A12. However, the company did not contact the FDA or begin a recall of more than 60 million containers of pet food until March 2007. Chuck Neubauer, *FDA Officials Will Face Senate Inquiry on Pet Food*, L.A. TIMES, Apr. 8, 2007, at A18; *Hearing on Pet Food Safety Before the Senate Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies*, 110<sup>th</sup> Cong. 6 (Apr. 12, 2007) (statement of Duane Ekedahl, President, Pet Food Institute), <http://appropriations.senate.gov/hearings.cfm>.

<sup>7</sup> Pet Food Products Liability Settlement, <http://www.petfoodsettlement.com>.

<sup>8</sup> For more information, see CRS Report R40450, *Penalties Under the Federal Food, Drug, and Cosmetic Act (FFDCA) That May Pertain to Adulterated Peanut Products*, by Vanessa K. Burrows and Brian T. Yeh.

<sup>9</sup> See *Heckler v. Chaney*, 470 U.S. 821 (1985) (holding that “[t]he FDA’s decision not to take the enforcement actions requested by respondents is therefore not subject to judicial review under the [Administrative Procedure Act]” and that the FFDCA enforcement provisions do not overcome the agency’s “decisions not to institute proceedings”).

<sup>10</sup> FDA, Charges Filed in Contaminated Pet Food Scheme, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048139.htm>.

<sup>11</sup> Center for Science in the Public Interest, Support H.R. 1612 and S. 908—The Consumer Food Safety Act of 1999, <http://www.cspinet.org/foodsafety/hr1612.html>. According to this advocacy organization, “[i]n August 1997, FDA tried to recall Royal Line smoked salmon contaminated with *Listeria*, a bacteria that causes serious illnesses and deaths. The salmon, sold in plastic packages, was imported from Denmark. However, the salmon’s U.S. distributor refused to cooperate in the recall, leaving American consumers at risk of food poisoning from the product.” *Id.*

<sup>12</sup> *Company Resisted FDA’s Recall Requests, But FDA Kept Quiet*, Inside Health Policy, Nov. 14, 2008, [http://www.insidehealthpolicy.com/secure/health\\_docnum.asp?f=health\\_2001.ask&docnum=11142008\\_quiet&DOCID=11142008\\_quiet](http://www.insidehealthpolicy.com/secure/health_docnum.asp?f=health_2001.ask&docnum=11142008_quiet&DOCID=11142008_quiet).

This report provides an overview of the FDA's statutory authority with regard to the four types of products for which the agency can require recalls, as well as FDA regulations for designating the particular class of recall, publicizing and monitoring the effectiveness of recalls, and carrying out recalls.

## Views on FDA Recall Authority

This section highlights different views on the FDA's uses of its current voluntary recall authority, as well as support and opposition to granting the FDA mandatory recall authority. Some lawmakers have reportedly asserted that the current food safety system, which "relies on voluntary recalls[,] implicitly protects industry before it protects public health."<sup>13</sup> According to the Government Accountability Office (GAO), the FDA may not be using the regulations on voluntary recalls that the agency currently has in place to their maximum effectiveness.<sup>14</sup> A 2004 GAO report found that

FDA do[es] not know how promptly and completely the recalling companies and their distributors and other customers are carrying out recalls, and neither [the FDA nor the U.S. Department of Agriculture (USDA)] is using its data systems to effectively track and manage its recall programs. For these and other reasons, most recalled food is not recovered and therefore may be consumed.<sup>15</sup>

A 2009 GAO report highlighted issues with cooperation between the FDA and states during a recall and cited the agency's unwillingness to share product distribution lists and other information during a recall as an action that "impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses."<sup>16</sup> The same report also indicated that certain states may have the authority to issue recalls and could do so faster than the FDA could seek a voluntary recall.<sup>17</sup>

The FDA also has been accused of failing to aggressively pursue investigations of products that were later recalled.<sup>18</sup> For example, lawsuits have been brought against ConAgra Foods, Inc., by individuals who allegedly became sick, sometimes more than once, because they ate peanut butter tainted with *Salmonella*. According to the plaintiffs, ConAgra did not recall contaminated peanut butter from one plant until February 2007, though the FDA "suspected that peanut butter

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<sup>13</sup> *Veggie Booty Recall Grows, Prompting Criticism of Weak FDA*, Inside Health Policy, July 6, 2007, [http://www.insidehealthpolicy.com/secure/health\\_docnum.asp?f=health\\_2001.ask&docnum=FDA-13-27-15&DOCID=FDA-13-27-15](http://www.insidehealthpolicy.com/secure/health_docnum.asp?f=health_2001.ask&docnum=FDA-13-27-15&DOCID=FDA-13-27-15).

<sup>14</sup> See GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, at 13-16, 21-22 (Oct. 2004), <http://www.gao.gov/new.items/d0551.pdf>.

<sup>15</sup> *Id.* at initial summary page.

<sup>16</sup> GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (Sept. 2009), at 7, 30.

<sup>17</sup> *Id.* at 29-30.

<sup>18</sup> "A similar lack of aggressiveness on the part of FDA may have contributed to the peanut butter contamination deaths and illnesses." *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply—Part 2: Hearing Before the H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations*, 110<sup>th</sup> Cong. (July 17, 2007) (Staff Statement at 16), [http://energycommerce.house.gov/cmte\\_mtg/110-oi-hrg.071707.Staff-testimony.pdf](http://energycommerce.house.gov/cmte_mtg/110-oi-hrg.071707.Staff-testimony.pdf) (hereinafter "Subcommittee Staff Statement").

manufactured by ConAgra Foods under different brand names might have been contaminated with salmonella” as early as 2005.<sup>19</sup>

Consumer rights groups seek new statutory authority that would allow the FDA to mandate recalls of food and other products.<sup>20</sup> In 2008, the FDA’s Associate Commissioner for Foods stated that “[w]e encourage Congress to provide these authorities, which would ... empower FDA to issue a mandatory recall of food products if voluntary recalls are not effective.”<sup>21</sup> In 2009, the FDA’s Assistant Commissioner for Compliance Policy testified that mandatory recall authority “would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.”<sup>22</sup> GAO has designated general food safety oversight as a high-risk area and has “proposed that Congress consider legislation” giving the FDA and USDA the authority to order recalls.<sup>23</sup>

Some have argued that in situations where the manufacturer of a product cannot be determined—such as the case of tainted toothpaste found in discount stores, prisons, hospitals, and luxury hotels—granting the FDA the ability to order a recall of such products would expedite the process of removing adulterated articles from store shelves.<sup>24</sup> Such authority also would enable the agency to take actions beyond issuing a warning about a particular product.<sup>25</sup> Additionally, the authority to order a recall may be useful in cases in which the discovery of the source of contaminated products may not immediately be identified.<sup>26</sup> However, in difficult foodborne illness outbreak investigations, initial data may result in the wrong food product being identified as the source of the outbreak and potentially recalled.<sup>27</sup>

According to the FDA, both the agency and industry share an interest in removing unsafe and/or defective products from the marketplace.<sup>28</sup> In the past, the agency had asserted that “cooperation between FDA and its regulated industries has proven over the years to be the quickest and most

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<sup>19</sup> Marian Burros, *Who’s Watching What We Eat?*, N.Y. TIMES, May 16, 2007, at D1; R. Robin McDonald, *ConAgra Faces 39 Suits Over Bad Peanut Butter*, Fulton County Daily Report, Aug. 13, 2007. A Centers for Disease Control and Prevention network that monitors food-borne diseases observed a “slowly rising increase” in cases of a certain type of *Salmonella* that were connected to one peanut butter plant. *Id.*

<sup>20</sup> See Caroline Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest, Statement at the National Food Policy Conference (May 9, 2003), [http://www.cspinet.org/foodsafety/new\\_bioact.html](http://www.cspinet.org/foodsafety/new_bioact.html).

<sup>21</sup> *Before the Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the S. Comm. on Appropriations*, 110<sup>th</sup> Cong. (Sept. 17, 2008) (statement of David Acheson), <http://www.fda.gov/ola/2008/fpp091708.html>.

<sup>22</sup> *Before the Subcomm. on Regulations and Healthcare of the H. Comm. On Small Business*, 111<sup>th</sup> Cong. (Mar. 11, 2009) (statement of Steven M. Solomon), <http://www.fda.gov/NewsEvents/Testimony/ucm152511.htm>.

<sup>23</sup> GAO, *supra* note 4, at 8.

<sup>24</sup> Press Release, Senator Charles Schumer, Schumer Reveals: Chinese Product Dangers Go Far Beyond Tires, Seafood and Toothpaste (July 1, 2007), <http://schumer.senate.gov/SchumerWebsite/pressroom/record.cfm?id=278328>; *see also* FDA, Imported Toothpaste, <http://www.fda.gov/oc/opacom/hottopics/toothpaste.html>.

<sup>25</sup> *See Veggie Booty*, *supra* note 13.

<sup>26</sup> *See id.*

<sup>27</sup> *See Hearing to Review the Legal and Technological Capacity for Full Traceability in Fresh Produce: Hearing Before the Subcomm. on Horticulture and Organic Agriculture of the House Comm. on Agriculture*, 110<sup>th</sup> Cong. (July 30, 2008) (statement of David Acheson), <http://www.fda.gov/NewsEvents/Testimony/ucm096397.htm> (discussing the initial focus on raw tomatoes in a foodborne illness outbreak ultimately linked to Serrano and jalapeño peppers).

<sup>28</sup> FDA, Center for Food Safety and Applied Nutrition, Industry Affairs Staff Brochure, *FDA Recall Policies* (June 2002), <http://vm.cfsan.fda.gov/~lrd/recall2.html>. The FDA’s recall policies are described in detail in this document.

reliable method to remove potentially dangerous products from the market.”<sup>29</sup> An industry representative involved in the pet food recall has argued against additional regulation, saying that industry “could have been a more valuable partner” in the recall process if it received access to the same information as the FDA.<sup>30</sup> According to the head of the Pet Food Institute, which represents U.S. pet food manufacturers, the communication of such information would have allowed the organization to “cross-reference ... lot numbers, shipping information, and other data.”<sup>31</sup>

In addition, advocates for a single food safety agency argue that a single contact point could save time and lives in the event of a food recall.<sup>32</sup> As demonstrated by the chili products recall due to the potential for botulism, more than one agency may have jurisdiction over adulterated or contaminated food.<sup>33</sup> In that situation, the FDA website listed all the recalled product numbers but only included photos of the labels for chili products that did not contain meat and pet food products involved in the same recall. Consumers were directed to the USDA Meat and Poultry Hotline website for products containing meat, over which the USDA has jurisdiction.<sup>34</sup> The linked USDA Web page provided general information, but did not provide information about the meat products recalled due to being potentially contaminated with botulism.<sup>35</sup> Some have argued that the lack of complete information regarding the recall, as well as links to Web pages not specifically associated with the chili product recall, could result in consumers overlooking relevant information and potentially consuming tainted products. The Food Marketing Institute—a nonprofit association of retailers and wholesalers that account for the majority of U.S. grocery store sales—and others have contended that the creation of a single food safety agency would help in a food crisis, because the “public is faced with a lengthy delay while overlapping bureaucracies creak into some attempt at a coordinated response. While the search for who knew what and when goes on, the crisis worsens and public confidence erodes.”<sup>36</sup>

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<sup>29</sup> *Id.*

<sup>30</sup> Ekedahl, *supra* note 6, at 8-9.

<sup>31</sup> *Id.* at 9.

<sup>32</sup> The U.S. government does have a single website dedicated to product recalls, <http://www.recalls.gov>. However, this website apparently does not address the concerns of supporters of a single food safety agency, such as two agencies—the FDA and USDA—maintaining jurisdiction over eggs in shell, processed, and liquid forms.

<sup>33</sup> In 2004, the FDA found contaminated animal feed but did not report the contamination to the USDA, which inspects livestock that consume such feed, or the state involved, which has authority to prevent such meat from entering the market. The state seized and destroyed the animals before the FDA even sent a warning letter to the feed mill. GAO, *Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness*, 24 (Feb. 2005), <http://www.gao.gov/new.items/d05101.pdf>.

<sup>34</sup> FDA, *Chili Products (Botulism) Recall (Includes Canned Chili, Stew, Hash, BBQ, Gravy, and Pet Food Products)*, <http://www.fda.gov/oc/opacom/hottopics/castleberry.html#meat>.

<sup>35</sup> USDA, *Food Safety Education, USDA Meat & Poultry Hotline*, [http://www.fsis.usda.gov/Food\\_Safety\\_Education/USDA\\_Meat\\_&\\_Poultry\\_Hotline/index.asp](http://www.fsis.usda.gov/Food_Safety_Education/USDA_Meat_&_Poultry_Hotline/index.asp). A press release found after clicking on several links in the USDA website details the chili products with meat that were recalled. Press Release, USDA, *Georgia Firm Expands Recall of Canned Meat Products that may Contain *Clostridium botulinum**, [http://www.fsis.usda.gov/News\\_&\\_Events/Recall\\_033\\_2007\\_expanded/index.asp](http://www.fsis.usda.gov/News_&_Events/Recall_033_2007_expanded/index.asp).

<sup>36</sup> Timothy M. Hammonds, *It is Time to Designate a Single Food Safety Agency*, 59:3 *FOOD & DRUG L. J.* 427, 428 (2004); see also Richard J. Durbin, *Food Safety Oversight for the 21<sup>st</sup> Century: The Creation of a Single, Independent Federal Food Safety Agency*, 59:3 *FOOD & DRUG L. J.* 383 (2004); Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59:3 *FOOD & DRUG L. J.* 441 (2004).



Those opposed to the idea of combining the FDA and USDA into a single food safety agency assert that such a measure would distract the agencies involved from their mission while the reorganization process occurs.<sup>37</sup> They argue that “food security would be compromised” and that overlap between agencies “is not as significant [an issue] as many assume.”<sup>38</sup> Furthermore, critics of a single food safety agency point out that coordination between federal, state, and local government agencies would still be required to address threats to the food supply.<sup>39</sup>

## Current Statutory Authority for Mandatory Recalls

The FDA possesses mandatory recall authority only with regard to four products: infant formula,<sup>40</sup> medical devices,<sup>41</sup> biologic products,<sup>42</sup> and tobacco products.<sup>43</sup> This section provides an overview of the statutory authorities that exist for recalling these four products. The FDA is one of several agencies that comprise the Department of Health and Human Services (HHS). Therefore, FFDCA provisions refer to the Secretary of HHS, who, in turn, delegates authority to the FDA.

### Infant Formula

Congress required the HHS Secretary to prescribe regulations for manufacturer-initiated recalls of infant formula.<sup>44</sup> The regulations address the scope and extent of infant formula recalls as “necessary and appropriate for the degree of risks” that the affected formula presents to human health.<sup>45</sup> The regulations for infant formula recalls are available at 21 C.F.R. Part 107, Subpart E, Infant Formula Recalls. Upon a determination by the FDA that the adulterated or misbranded formula presents a human health risk, the manufacturer is required to “immediately take all actions necessary to recall that formula, extending to and including the retail level,” that are consistent with the regulations.<sup>46</sup>

Infant formula manufacturers who initiate a recall because of a human health risk must “request each retail establishment at which such formula is sold or available for sale to post at the point of purchase ... a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall.”<sup>47</sup> Manufacturers of infant formula are also required to create and keep “records respecting the distribution of infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor

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<sup>37</sup> Stuart M. Pape et al., *Food Security Would be Compromised by Combining the Food and Drug Administration and the U.S. Department of Agriculture Into a Single Food Agency*, 59:3 FOOD & DRUG L. J. 405, 406 (2004).

<sup>38</sup> *Id.* at 405-06.

<sup>39</sup> *Id.* at 406.

<sup>40</sup> Federal Food, Drug, and Cosmetic Act (FFDCA) § 412(f).

<sup>41</sup> FFDCA § 518(e).

<sup>42</sup> Public Health Service Act § 351; 42 U.S.C. § 262.

<sup>43</sup> FFDCA § 908(c).

<sup>44</sup> FFDCA § 412(f)(1).

<sup>45</sup> FFDCA § 412(f)(2).

<sup>46</sup> 21 C.F.R. § 107.200.

<sup>47</sup> FFDCA § 412(f)(3); *see* 21 C.F.R. § 107.230(d); *see also* 21 C.F.R. § 107.250.

recalls.”<sup>48</sup> The manufacturer must retain such records for “at least one year after the expiration of the shelf life of the infant formula,”<sup>49</sup> and the Secretary may promulgate regulations regarding recordkeeping if the Secretary determines that the required records “are not being made or maintained.”<sup>50</sup>

## Medical Devices

The FFDCA’s medical device recall authority provisions place requirements on device manufacturers, importers, distributors, retailers, and other “appropriate persons.” If the HHS Secretary “finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death,” then the Secretary must issue an order requiring “the appropriate person” to (1) immediately stop distributing the device, (2) immediately notify health professionals and device user facilities of the Secretary’s order, and (3) instruct health professionals and device user facilities to stop use of the device.<sup>51</sup> Thus, the first step of the statute does not require a mandatory recall of a device for which the Secretary makes the above determination.

However, the order may be amended to mandate a recall of such device. The Secretary’s order must “provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall.”<sup>52</sup> If the Secretary determines, after the informal hearing, that the order should be amended as such, the Secretary must amend the order to require the recall, set a timetable for the recall, and require periodic reports describing the recall’s progress.<sup>53</sup> The Secretary’s amended order must not include a recall of the device from individuals and must not include a recall from device user facilities “if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use.”<sup>54</sup>

Additionally, the Secretary’s amended order must provide “notice to individuals subject to the risks associated with the use of such device.”<sup>55</sup> To notify individuals regarding the device, the statute provides that “the Secretary may use the assistance of health professionals who prescribed or used such a device.”<sup>56</sup> However, if “a significant number” of individuals cannot be identified, the Secretary must notify them via FFDCA § 705(b). That provision gives the Secretary the broad authority to “cause to be disseminated information ... in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer.”<sup>57</sup> Recalling a device is only one of the methods that the Secretary may use to address the risk it presents to the public health. The Secretary may also notify health professionals who prescribe or use the device; order

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<sup>48</sup> FFDCA § 412(g)(1).

<sup>49</sup> *Id.*

<sup>50</sup> FFDCA § 412(g)(2).

<sup>51</sup> FFDCA § 518(e)(1); *see also* 21 C.F.R. §§ 810.1-810.18.

<sup>52</sup> FFDCA § 518(e)(1).

<sup>53</sup> FFDCA § 518(e)(2)(A).

<sup>54</sup> FFDCA § 518(e)(2)(B)(i).

<sup>55</sup> FFDCA § 518(e)(2)(B)(ii).

<sup>56</sup> FFDCA § 518(e)(2)(B).

<sup>57</sup> FFDCA § 705(b).

the manufacturer, importer, or any distributor to submit a plan for repairing or replacing the device, or refunding all or part of the purchase cost of the device; and may require the manufacturer, importer, distributor, or retailer to reimburse, for expenses incurred in carrying out the Secretary's order, "any other person who is a manufacturer, importer, distributor, or retailer."<sup>58</sup>

## Biological Products

For biological products such as blood, blood components, and human tissue, the Secretary must issue an order immediately requiring a recall of "a batch, lot, or other quantity of a product licensed under [42 U.S.C. § 262, Regulation of Biological Products]" once a determination is made that that quantity "presents an imminent or substantial hazard to the public health."<sup>59</sup> The Secretary's order must be issued in accordance with 5 U.S.C. § 554, which addresses formal adjudications after an opportunity for an agency hearing. Violators of these provisions may face inflation-adjustable civil penalties of up to \$100,000 per day of violation.<sup>60</sup>

## Tobacco Products

The 111<sup>th</sup> Congress passed the Family Smoking Prevention and Tobacco Control Act, P.L. 111-31, which amended the FFDCA and provided the HHS Secretary, acting through the FDA, with regulatory authority over tobacco products, including the authority to issue orders for recalls.<sup>61</sup> If the Secretary finds there is a reasonable probability that the tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary must order the appropriate persons to immediately cease distribution. As with medical devices, the Secretary's order must provide an opportunity for an informal hearing, within 10 days of the order's issuance.<sup>62</sup> The Secretary may then amend the order to require a recall of the tobacco product. The Secretary must also set a timetable for the recall and require periodic reports describing the recall's progress.<sup>63</sup> The amended order must not include a recall of the tobacco products from individuals, but must provide notice to persons of the risks associated with the use of the recalled tobacco product.<sup>64</sup> To provide such notice, the Secretary may use retailers and distributors of the tobacco product, or, if a significant number of persons cannot be identified, the Secretary may disseminate information under the FFDCA's statutory provision on publicity.<sup>65</sup>

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<sup>58</sup> FFDCA § 518(a), (b), (c), (e)(3).

<sup>59</sup> 42 U.S.C. § 262(d)(1); FDA, FDA 101: Biological Products, <http://www.fda.gov/consumer/updates/biologics062608.html>.

<sup>60</sup> 42 U.S.C. § 262(d)(2). The statute provides a formula for adjusting the maximum amount of the civil penalty for violations of the recall statute. *Id.*

<sup>61</sup> In the event that the Secretary determines that a tobacco product presents an unreasonable risk of substantial harm to the public health and that notification is necessary to eliminate such risk, the Secretary is authorized to issue an order to ensure adequate notification of all appropriate persons. However, compliance with such an order does not relieve persons from liability under other federal or state law. FFDCA § 908(a), (b).

<sup>62</sup> FFDCA § 908(c).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

## Current FDA Regulations Regarding Voluntary Recalls

Part 7, Subpart C, of Title 21, Code of Federal Regulations gives “guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction” of an FDA-regulated product on the market that violates the FFDCA or other laws that the FDA administers.<sup>66</sup> Chapter Seven of the FDA’s Regulatory Procedures Manual also serves as a reference for FDA employees and industry as to recall procedures; the manual is not law and does not bind the FDA or industry.<sup>67</sup> As a result, only FDA regulatory authorities and not the manual are discussed in this report.

The FDA views voluntary, industry-initiated recalls as an alternative to FDA legal actions to remove or correct products that violate laws.<sup>68</sup> For example, the FDA has the power to seize adulterated and misbranded products under the FFDCA.<sup>69</sup> However, the agency states that a company recall “is generally more appropriate and affords better protection for consumers than seizure, when many lots of the product have been widely distributed.”<sup>70</sup> The FDA may turn to seizure as a remedy if “the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.”<sup>71</sup>

### Industry-Initiated Recalls

The FDA recommends that companies undertake certain practices that may prepare them for a recall or assist them during a recall. These include (1) creating a contingency plan, (2) using codes on FDA-regulated products that will make it possible to identify and recall the defective products, and (3) keeping records—even beyond the shelf or expected use life of a product—that can be used to find the tainted products.<sup>72</sup> If a company initiates a recall, the FDA regulations suggest that the firm immediately notify the closest FDA district office. If the product being recalled would be subject to a court action, such as seizure for being misbranded or adulterated, then the FDA deems the company’s action to be a recall and will ask the business to provide the agency with information on the amount and identity of the product, as well as communications about the recall and other data.<sup>73</sup>

FDA regulations also provide for instances in which a company decides to recall a product after being informed by the agency that “the product in question violates the law, but the agency has not specifically requested a recall.”<sup>74</sup> In this case, the company’s decision to recall the product is

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<sup>66</sup> 21 C.F.R. §§ 7.1, 7.40.

<sup>67</sup> FDA, FDA REGULATORY PROCEDURES MANUAL, [http://www.fda.gov/ora/compliance\\_ref/rpm](http://www.fda.gov/ora/compliance_ref/rpm).

<sup>68</sup> See 21 C.F.R. § 7.40(a).

<sup>69</sup> 21 U.S.C. § 334; FFDCA § 304.

<sup>70</sup> 21 C.F.R. § 7.40(c).

<sup>71</sup> *Id.*

<sup>72</sup> 21 C.F.R. § 7.59.

<sup>73</sup> 21 C.F.R. § 7.46.

<sup>74</sup> *Id.* One example of this may be Menu Foods’ expansion of its pet food recall to include cat food varieties. The FDA “had confirmed test results it received from a laboratory ... [that] found that canned cat food which had not been included in Menu Foods’ earlier recalls tested positive for melamine, a chemical used as a fertilizer and in the (continued...)”

treated as an industry-initiated recall. Furthermore, agency regulations provide procedures if a company begins to remove or correct a product in a way that the company believes would constitute a market withdrawal. A market withdrawal is “a firm’s removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the [FDA] or which involves no violation, e.g., normal stock rotation practices.”<sup>75</sup> If the business is conducting a market withdrawal, but the reason for the need to remove the product is not clear, the FDA is willing to help the company ascertain the cause of the problem. For example, consumers may have experienced adverse reactions to the product, but the source of the problem may not be “obvious or clearly understood.”<sup>76</sup>

## FDA-Requested Recalls

The FDA can request a business to voluntarily recall an FDA-regulated product; however, such requests are “reserved for urgent situations.”<sup>77</sup> The FDA would make such a request to the company with “primary responsibility for the manufacture and marketing” of the defective product.<sup>78</sup> The FDA Commissioner can request a company to conduct a recall after these three determinations have been made:

- (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
- (2) That the firm has not initiated a recall of the product.
- (3) That an agency action is necessary to protect public health and welfare.<sup>79</sup>

If the company refuses to recall its products after the FDA makes its request, the agency may then turn to seizures or other court actions to protect the public health.<sup>80</sup> According to its regulations, if the FDA requests a recall, the agency should take into account the factors listed in its recall strategy, such as “the degree to which the product remains unused in the marketplace” and the “ease in identifying the product.”<sup>81</sup>

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(...continued)

manufacture of cutlery and kitchenware.” The FDA informed Menu Foods, Inc., and the company acted to expand the recall. It is unclear whether the FDA requested the expanded recall or simply informed Menu Foods that the cat food varieties violated the FFDCA. Press Release, FDA, FDA Warns Consumers that Retailers May Still Have Recalled Pet Food on Shelves (Apr. 12, 2007), <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01605.html>.

<sup>75</sup> 21 C.F.R. § 7.3(j); *see supra* note 2.

<sup>76</sup> 21 C.F.R. § 7.46(d).

<sup>77</sup> 21 C.F.R. § 7.40(b).

<sup>78</sup> *Id.* The FDA’s Associate Commissioner for Regulatory Affairs, who leads the FDA’s Office of Regulatory Affairs, “has direct responsibility for approval of all recalls requested by FDA and Class I recalls.” Sandra Nowlin Whetstone, *ORA’s Role at FDA Headquarters and in the Field for Product Recalls*, 53:3 FOOD & DRUG L. J. 513, 513 (1998).

<sup>79</sup> 21 C.F.R. § 7.45. When making its request, the FDA notice of the above determinations will state the violation of the FDA-administered laws, the classification of the recall, the recall strategy, and any agency instructions on carrying out the recall. *Id.*

<sup>80</sup> 21 C.F.R. § 7.40(c).

<sup>81</sup> 21 C.F.R. § 7.42(a).

## Classification of Recalls

The FDA categorizes recalls in three classes. Class I recalls are the most serious and involve “situation[s] in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.”<sup>82</sup> Class II recalls involve “situation[s] in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote,” while Class III recalls involve “situation[s] in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.”<sup>83</sup> The FDA posts information regarding all three classes of recalls on its website in the agency’s weekly FDA Enforcement Report.<sup>84</sup> Additionally, the FDA’s Web page devoted to “Recalls, Market Withdrawals, and Safety Alerts” contains press releases and information for mostly Class I recalls.<sup>85</sup>

In order to determine what classification to assign a recall, an ad hoc committee of FDA scientists, perhaps at the closest FDA district office, will first examine the factors below.

- (1) Whether any disease or injuries have already occurred from the use of the product.
- (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
- (3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- (4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- (5) Assessment of the likelihood of occurrence of the hazard.
- (6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.<sup>86</sup>

However, the committee is not limited to evaluating the health hazard posed by a product based on these factors alone.<sup>87</sup> The FDA is to then use the committee’s health hazard evaluation as the basis for assigning a classification.<sup>88</sup>

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<sup>82</sup> 21 C.F.R. § 7.3(m)(1).

<sup>83</sup> 21 C.F.R. § 7.3(m)(2) and (3).

<sup>84</sup> FDA, FDA Enforcement Report Index, <http://www.fda.gov/opacom/Enforce.html>.

<sup>85</sup> FDA, Recalls, Market Withdrawals and Safety Alerts, <http://www.fda.gov/opacom/7alerts.html>. Table 1 of CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*, by Sarah A. Lister and Geoffrey S. Becker, details Class I and Class II recalls of FDA-regulated foods by product type for FY2005-2009.

<sup>86</sup> 21 C.F.R. § 7.41(a).

<sup>87</sup> 21 C.F.R. § 7.41.

<sup>88</sup> *Id.* The FDA’s Office of Regulatory Affairs’ Associate Commissioner “may, and has, delegated designation of certain Class I recalls to the agency’s Center directors,” such as the Center for Food Safety and Applied Nutrition (continued...)

## Communication Regarding a Recall

The company that recalls a product “is responsible for promptly notifying each of its affected direct accounts about the recall.”<sup>89</sup> The FDA regulations set out what information should be specified in the notification, such as the identity of the product, the need to stop distributing the product, that the notified person should in turn notify its customers, and what other steps to take with the recalled product. The agency also provides instructions about the contents—or lack thereof, in the case of including promotional materials that could distract from the recall information—and appearance of the communication that will inform a customer of the recall. Those who purchased, received, or used the product being recalled who are notified via a recall communication should also promptly notify their customers or the individuals who may have received or used the product.<sup>90</sup> As mentioned above, the FDA will place information regarding recalls in its weekly FDA Enforcement Report, with two exceptions: (1) product removals or corrections that the FDA finds are market withdrawals or stock recoveries<sup>91</sup> and (2) “intentionally delay[ed] public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential.”<sup>92</sup>

## Monitoring and Termination of a Recall

The FDA regulations request that companies recalling products send progress reports on the recall to the appropriate FDA district or field office. The FDA is to inform the firm, based on the urgency of the recall, how often it should submit recall status reports.<sup>93</sup> The recalling company should continue to send recall progress reports until the FDA terminates the recall, and such reports should include information on the numbers of individuals who were notified, who responded, or who failed to respond to the company’s recall communication. The reports should also state the number of products returned and accounted for, how many verification checks were conducted to determine if the recall was effective and the results of such checks, and the firm’s estimate of the time until the recall is completed.<sup>94</sup> The FDA field office “is responsible for determining whether the recall was effective and that disposition of the product was completed properly.”<sup>95</sup>

Once the FDA “determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed” and either disposed of or corrected, the agency is

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(CFSAN). Whetstone, *supra* note 78, at 513. “CFSAN’s director has been delegated authority for certain routine Class I food recalls, e.g., listeria and undeclared allergen Class I recalls.” *Id.*

<sup>89</sup> 21 C.F.R. § 7.49.

<sup>90</sup> 21 C.F.R. § 7.49.

<sup>91</sup> *See supra* note 2.

<sup>92</sup> 21 C.F.R. § 7.50.

<sup>93</sup> 21 C.F.R. § 7.53. The regulations state that “generally the reporting interval will be between 2 and 4 weeks.” *Id.*

<sup>94</sup> 21 C.F.R. § 7.53. For example, in the Menu Foods pet food recall, the FDA conducted approximately 400 effectiveness checks in retail stores. *See* Press Release, *supra* note 74.

<sup>95</sup> Whetstone, *supra* note 78, at 514.

to issue a written notice that the recall is terminated.<sup>96</sup> The FDA's determination may depend on the degree of public health hazard associated with the product being recalled.<sup>97</sup> For Class I recalls, the FDA district office is to prepare a recommendation for the appropriate FDA center, such as the Center for Food Safety and Applied Nutrition, that the Class I recall be terminated. However, Class II and III recalls do not need approval from an FDA center.<sup>98</sup> Alternately, the recalling company can request, in writing, that the FDA terminate the recall. This request should include a statement in writing that the recall is effective, in line with the type of determination that the FDA would make when terminating a recall.<sup>99</sup> The FDA's Regulatory Procedures Manual states that the time from when a company considers its recall complete to the time when the agency terminates the recall should generally not exceed three months.<sup>100</sup>

## Food and Drug Administration Amendments Act of 2007 (FDAAA)

The 110<sup>th</sup> Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), P.L. 110-85, which contains provisions addressing communications and information postings during a food recall.<sup>101</sup> To enhance communication during a recall, the law requires the Secretary to post information regarding recalled human or pet food products on the FDA website; work with industry, professional organizations, and others to gather information relevant to the recall; and communicate with the public.<sup>102</sup> The law mandates that the HHS Secretary “establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food.”<sup>103</sup> FDAAA also requires the Secretary to work with notification networks during a pet food recall “to inform veterinarians and relevant stakeholders.”<sup>104</sup>

FDAAA also created § 417(d) of the FFDCFA, which requires persons who register a food facility with the FDA (registration is required of facilities that manufacture, process, pack, or hold food for consumption in the United States) to report to the FDA within 24 hours after they have determined that an article of food is a “reportable food.” A “reportable food” is defined as a food “for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.”<sup>105</sup> There is an

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<sup>96</sup> 21 C.F.R. § 7.55(a).

<sup>97</sup> *Id.*

<sup>98</sup> Whetstone, *supra* note 78, at 514.

<sup>99</sup> 21 C.F.R. § 7.55(b).

<sup>100</sup> FDA, REGULATORY PROCEDURES MANUAL ch. 7, at 7-49, [http://www.fda.gov/ora/compliance\\_ref/rpm/pdf/ch7.pdf](http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch7.pdf).

<sup>101</sup> These provisions were similar to those the Senate approved, by a vote of 94-0, in Senator Durbin's amendment to the FDA Revitalization Act (S. 1082).

<sup>102</sup> P.L. 110-85, § 1003.

<sup>103</sup> P.L. 110-85, § 1002. The FDA's “Consumer Complaint Reporting System (CCRS) is the Agency's present effective Early Warning System for pet food; FDA is actively promoting the CCRS to the veterinary profession through American Veterinary Medical Association and Veterinary Information Network (VIN).” FDA, FDAAA Implementation—Highlights One Year After Enactment, <http://www.fda.gov/oc/initiatives/advance/fdaaa/accomplishments.html>.

<sup>104</sup> P.L. 110-85, § 1002.

<sup>105</sup> 21 U.S.C. § 350f(a).



exception to the reporting requirement if the responsible party destroys the reportable food or corrects the adulteration, as well as takes other actions with regard to the reportable food. The reports to the FDA regarding reportable food were required through an electronic portal to be established by the agency one year from the date of the enactment of FFDCCA § 417, and, although the initial implementation of the Reportable Food Registry took longer than the one-year time period allotted in FDAAA, the registry has been available since September 2009.<sup>106</sup>

FDAAA also added two prohibited acts sections based on the mandatory reporting requirements: FFDCCA § 301(mm) prohibits the failure to submit a report or provide the notification required by FFDCCA § 417(d),<sup>107</sup> and FFDCCA § 301(nn) prohibits the falsification of such report or notification.<sup>108</sup> Violators of these provisions would be subject to the penalties provisions of the FFDCCA.

FFDCCA § 417 is presently worded in a manner that allows the “responsible party,” such as a manufacturer, to make the determination that a food is a “reportable food.”<sup>109</sup> A test that showed a product was not definitively contaminated may not rise to the level of a requirement to report because a manufacturer may not determine that there is a “reasonable probability” that a food will cause serious adverse health consequences or death, and therefore, that such food is reportable under § 417.<sup>110</sup> Additionally, the FFDCCA does not define what “correct[ing] such adulteration” means, but if the adulteration is corrected, no report is required.<sup>111</sup> However, FDA guidance on the Reportable Food Registry, which is not legally binding, suggests that if a food receives one positive microbiological test, and a second test result does not show the pathogen, the food would still be reportable.<sup>112</sup>

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<sup>106</sup> FDA, Reportable Food Registry for Industry, <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>. The FDA announced a “delay in the implementation of the Reportable Food Registry” and stated that it expects the system to “be operational in the spring 2009.” FDA, Reportable Food Registry as Required by the Food and Drug Administration Amendments Act of 2007; Announcement of Delay in Implementation and Request for Comments, 73 Fed. Reg. 30405 (May 27, 2008).

<sup>107</sup> 21 U.S.C. § 350f(d); FDA, Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Sept. 2009), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm180761.htm> [hereinafter FDA Guidance].

<sup>108</sup> 21 U.S.C. §§ 331(mm), (nn).

<sup>109</sup> 21 U.S.C. § 350f(d)(1).

<sup>110</sup> FDA Guidance, *supra* note 108, at Question 29 (“Some test methods do not yield presumptive positive results with sufficient reliability to create a reasonable probability that the use of, or exposure to, the related article of food will cause serious adverse health consequences or death to humans or animals; however, in some cases a *presumptive* positive result could indicate such a reasonable probability. In contrast, for a *confirmed* positive, a test method would be expected to be sufficiently reliable to trigger the reporting requirement.”) (emphasis added).

<sup>111</sup> 21 U.S.C. § 350f(d)(2)(C).

<sup>112</sup> FDA Guidance, *supra* note 108, at Question 23.

## **Bills in the 111<sup>th</sup> Congress**

The 111<sup>th</sup> Congress has introduced several bills that would grant the FDA the ability to order recalls of food and other products, including H.R. 841, the Protect Consumers Act of 2009; H.R. 875, the Food Safety Modernization Act of 2009; H.R. 999, the Keeping America's Food Safe Act of 2009; H.R. 2726, the Counterfeit Drug Enforcement Act of 2009; H.R. 2749, the Food Safety Enhancement Act of 2009; S. 510, the FDA Food Safety Modernization Act; and S. 3690, the Drug Safety and Accountability Act of 2010. H.R. 2749 is a revised version of H.R. 759, the Food and Drug Administration Globalization Act of 2009.

In July 2009, the House passed H.R. 2749, a comprehensive food safety measure that would provide the FDA with authority to require recalls of food products after issuing an order to immediately cease distribution of a food (either after an opportunity for an informal hearing or on an emergency basis if there is credible evidence that a food presents an imminent threat of serious adverse health consequences or death); require facility food safety plans to describe their procedures for recalling articles of food; and enable the FDA to assess and collect fees from entities for the fiscal year in which the entity is subject to a food recall. S. 510 would similarly enable the FDA to order a recall of a food product and would require the FDA to assess and collect fees to cover food recall activities associated with a recall order. It has been reported by the Senate Committee on Health, Education, Labor, and Pensions and is expected to see floor action in 2010.<sup>113</sup>

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<sup>113</sup> For a comparison of the recall and other provisions in these House and Senate bills, see CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*, by Renée Johnson.