

# FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies  
Affecting FDA-Regulated Products*

## **The Food and Drug Administration's Import Alerts *Appear to Be "Misbranded"***

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VOLUME 58 NUMBER 4 2003

# The Food and Drug Administration's Import Alerts Appear to Be "Misbranded"

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## I. INTRODUCTION

Misbranding is, among other things, the act of labeling something in a misleading way.<sup>1</sup> The Food and Drug Administration (FDA) prohibits misbranding through its enforcement of the Federal Food, Drug, and Cosmetic Act<sup>2</sup> (FDCA). Under the FDCA, FDA has the authority to issue regulations affecting foods, drugs, cosmetics, biologics, medical devices, and other products.<sup>3</sup> The purpose of this congressional grant of authority is to ensure that consumers in the United States receive FDA-regulated products that are both safe and effective.<sup>4</sup> This protection extends to products that are imported as well as to products that are manufactured domestically and introduced into interstate commerce.<sup>5</sup>

Compared to domestic manufactured products, imported products are held to stricter standards under the FDCA. Both domestic and imported products are prohibited from being adulterated or misbranded, but imported products also are in violation of the FDCA if they merely "appear" to be adulterated or misbranded.<sup>6</sup> FDA's regulations, however, do not define "appearance."<sup>7</sup> It seems plausible, however, that Congress intended to afford FDA greater latitude to regulate imports. Unlike foreign manufactur-

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<sup>1</sup> 21 U.S.C. § 381 (FDCA § 801) (2002); *see also* BLACK'S LAW DICTIONARY 418 (17th ed. 1999).

<sup>2</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301-397 (2000)).

<sup>3</sup> *See* Center for Drug Evaluation and Research, Food and Drug Admin., FDA Related Laws, Regulations, and Guidances, *available at* <http://www.fda.gov/cder/about/smallbiz/Laws.htm> (last visited Oct. 20, 2003):

The mission of the FDA is to enforce laws enacted by the U.S. Congress and regulations established by the FDA to protect the consumer's health, safety, and pocketbook. The Federal Food Drug and Cosmetic Act is the basic food and drug law of the U.S. With numerous amendments it is the most extensive law of its kind in the world. The law is intended to assure the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

*Id.* *See also* 21 U.S.C. § 371 (FDCA § 701).

<sup>4</sup> Food and Drug Admin., About the U.S. Food and Drug Administration, *at* <http://www.fda.gov/opacom/hpview.html> (last visited Oct. 20, 2003).

<sup>5</sup> *See* 21 U.S.C. § 381 (FDCA § 801).

<sup>6</sup> *Id.* § 381(a) (FDCA § 801(a)).

<sup>7</sup> Under section 801(a), FDA must refuse all food, drugs, devices, and cosmetics that "appear" to be violative (e.g., adulterated or misbranded), however, there is no specific statutory language in the FDCA, nor are there any regulations or interpretive rules, that defines what appearance means under section 801.

ers, domestic manufacturers and distributors are inspected routinely to ensure compliance with the FDCA and related regulations. Because FDA has no cooperate authority to mandate inspections of foreign manufacturers, the agency must determine, on a case-by-case basis, whether an FDA-regulated product that reaches the U.S. border complies with the FDCA. FDA accomplishes these determinations of admissibility through informal adjudications.<sup>8</sup>

FDA's control over imports in the twenty-first century faces growing challenges due to globalization of the marketplace. For example, more than twenty-five cents of every U.S. consumer dollar is spent on FDA-regulated products but over 80% of all seafood and 20% of all fresh produce consumed in the United States originates abroad.<sup>9</sup> In Fiscal Year 2002, FDA estimated that 5.2 million entry lines of food products alone were imported into the United States.<sup>10</sup> The overwhelming increase in the amount of FDA-regulated imported products is buttressed by the fact that in 2001, imports of every type of FDA-regulated product reached only over seven million shipments.<sup>11</sup> These imports enter the United States through more than 150 U.S. ports of entry. Because FDA cannot enforce its rules and regulations through inspections of foreign firms, the agency assesses compliance at the border. Part of this assessment may involve the collection of physical samples of the product; verification that certain products, like low-acid canned foods, originate from registered facilities; verification of FDA approval of various drugs and devices; or label examinations of products.

According to a 1998 General Accounting Office report, FDA physically inspects less than two percent of all FDA-regulated products coming across the U.S. borders.<sup>12</sup> The increasing numbers of FDA-regulated imports and the continual decline in agency resources has made it even more difficult for FDA to adequately regulate imports at the border on a case-by-case basis.<sup>13</sup> Congress is aware of this problem, especially in the context of regulating imported foods. Congressional responses have included proposals ranging from the creation of a single independent food agency<sup>14</sup> to broadening existing FDA authority to include foreign inspection authority,<sup>15</sup>—similar to the authority given to the U.S. Department of Agriculture.<sup>16</sup> Meanwhile, FDA has taken its own action.

FDA currently places the burden on the importers<sup>17</sup> to demonstrate that the products they want to bring into the United States comply with FDA rules and regulations.<sup>18</sup> The

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<sup>8</sup> See 21 U.S.C. § 381(a) (FDCA § 801(a)). Under the FDCA, a hearing may be held at the request of an owner or consignee (importer) of imports subject to refusal. Importers have the opportunity to submit evidence and offer testimony. The FDCA, however, does not require a formal hearing. The formal hearing requirements of the Administrative Procedure Act (APA) apply "in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing ... ." (5 U.S.C. § 554(a); see also *Wong Yang Sung v. McGrath*, 339 U.S. 33, 48 (1950)), but only if a statute other than the APA requires a determination on the record.

<sup>9</sup> See Fact Sheet, Food and Drug Admin., FDA's Global Shield for American Consumer; The Agency Acts World-Wide to Ensure High Quality Imports, Pub. No. FS 01-12 (Feb. 2002), at <http://www.fda.gov/opacom/factsheets/justthefacts/12inter.html> (last visited Oct. 31, 2003).

<sup>10</sup> See, e.g., Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974 (Oct. 10, 2003).

<sup>11</sup> FDA Fact Sheet, *supra* note 9.

<sup>12</sup> U.S. GENERAL ACCOUNTING OFF., FOOD SAFETY: FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE, ch. 0:3 (GAO/RCED-98-103) (Apr. 1998) [hereinafter GAO REPORT, FOOD SAFETY: FEDERAL EFFORTS], available at <http://www.gao.gov> (last visited Oct. 20, 2003).

<sup>13</sup> *Id.* ch. 2:1.

<sup>14</sup> U.S. GENERAL ACCOUNTING OFF., FOOD SAFETY: U.S. NEEDS A SINGLE AGENCY TO ADMINISTER A UNIFIED, RISK-BASED INSPECTION SYSTEM (GAO/T-RCED-99-256) (Apr. 1999), available at <http://www.gao.gov> (last visited Nov. 4, 2003).

<sup>15</sup> GAO REPORT FOOD SAFETY: FEDERAL EFFORTS, *supra* note 12, ch. 2:1.

<sup>16</sup> *Id.* See also 9 C.F.R. § 327.2

<sup>17</sup> See Treas. Reg. § 48.0-2(a)(4)(i) (1988) (defining importer as any person bringing an article into the United States from outside the United States ...).

<sup>18</sup> See *supra* note 3.

agency accomplishes this through Import Alerts (Alerts).<sup>19</sup> For example, if FDA becomes aware that a product appears to violate the agency's rules and regulations, the product may be put on an Alert. This means that future shipments of that product will not be allowed entry into the United States unless the importer demonstrates that the product is in compliance with the FDCA.<sup>20</sup> Through Alerts, FDA shifts the burden of determining compliance onto the importer. Given the limits on FDA resources, placing the burden on U.S. importers appears, at first glance, to be a good thing. This article suggests, however, that Alerts—labeled as “guidance”—do not provide fair notice. The aggregate effect is an administrative scheme that undermines principles of uniform enforcement, and moreover, fundamental fairness and procedural due process, which are the hallmarks of the Administrative Procedure Act's (APA's) notice-and-comment procedures.

## II. OVERVIEW OF IMPORTS AND ALERTS

### A. Importation Process

Imported products can enter the United States at seaports, airports, courier hubs, and border crossings after clearing U.S. Customs and Border Protection (CBP).<sup>21</sup> The CBP clearance process begins once an importer submits all of the information required by CBP to bring a product into the United States. Most importers use brokers as agents for the purpose of filing the information with CBP. The brokers electronically transmit the data through CBP's Automated Commercial System. If the CBP determines that the product is an FDA-regulated product, the broker will forward the entry information to FDA for review.<sup>22</sup> FDA field staff at the port of entry then decide whether to 1) release the shipment for entry, 2) examine the shipment for possible refusal due to violations of FDA laws and regulations, or 3) detain it until the broker furnishes additional information.<sup>23</sup>

If FDA decides to detain the product, the agency will provide notice to the importer or consignee that the product appears to be subject to refusal of admission under section 801.<sup>24</sup> The shipment will remain under detention and, ultimately, will be refused entry unless the importer of record overcomes the appearance of a violation.<sup>25</sup> A product refused under section 801 may be destroyed or exported.<sup>26</sup>

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<sup>19</sup> See FOOD AND DRUG ADMIN., REGULATORY PROCEDURES MANUAL, ch. 9, subch. *Automatic Detentions* (Aug. 1997, last updated Jan. 2003), available at [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9auto.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html) (last visited Oct. 20, 2003).

<sup>20</sup> FDA has argued that Import Alerts are guidance documents that instruct FDA field staff to exercise discretion when determining whether to detain a shipment. See *infra* note 57. Whenever FDA issues an Alert, however, it is likely that the product subject to the Alert will be detained because FDA's field staff is required to follow guidance documents. See 21 U.S.C. § 371(h) (FDCA § 701(h)).

<sup>21</sup> For more detailed information about the CBP, see the CBP website at <http://www.cbp.gov/> (last visited Oct. 20, 2003). On March 1, 2003, the border inspection functions of the U.S. Customs Service, the Immigration and Naturalization Service, and the Animal and Plant Health Inspection Service, along with the U.S. Border Patrol, were transferred to CBP. The CBP's responsibilities include assessing and collecting revenues from imports, enforcing customs and related laws, and assisting in the administration and enforcement of other provisions of laws and regulations on behalf of 60 federal agencies.

<sup>22</sup> U.S. GENERAL ACCOUNTING OFF., FDA IMPORT AUTOMATION: SERIOUS MANAGEMENT AND SYSTEMS DEVELOPMENT PROBLEMS PERSIST (GAO/AIMD-95-188) (Sept. 28, 1995), available at <http://www.gao.gov> (last visited Oct. 20, 2003).

<sup>23</sup> See FOOD AND DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL, ch. 6, *Imports* (2003), available at [http://www.fda.gov/ora/inspect\\_ref/iom/contents/ch6\\_toc.html](http://www.fda.gov/ora/inspect_ref/iom/contents/ch6_toc.html) (last visited Oct. 20, 2003).

<sup>24</sup> 21 U.S.C. § 381 (FDCA § 801). Section 801 gives an importer the right to “introduce testimony bearing on the admissibility of the products.” As a result, FDA detains (without physical examination) the product that “appears violative” and then provides notice to the importer of the nature of the violation and the right to present testimony regarding the admissibility of the article. The established time period for presenting testimony is within ten working days of the detention. See 21 C.F.R. § 1.94.

<sup>25</sup> See 21 U.S.C. § 381 (FDCA § 801); 21 C.F.R. § 1.94.

<sup>26</sup> 21 U.S.C. § 381 (FDCA § 801).

### B. *Function of Import Alerts*

FDA's Import Alerts identify products that may be Detained Without Physical Examination (DWPE). FDA claims its authority to DWPE, and thus issue Alerts, on the basis of section 801(a), which states, "If it appears from the examination of such samples *or otherwise* that (1) such article has been manufactured, processed, or packed under insanitary conditions . . . then such article shall be refused admission. . . ."<sup>27</sup> According to FDA, Congress authorized the agency to refuse admission of regulated articles based on information, *other than the results of examination of sample*.<sup>28</sup> Information that identifies that past entries, of similarly manufactured and/or processed product from a foreign source, offered for import have been in violation of the FDCA, among other things, may cause an article to "appear" adulterated, misbranded, or otherwise in violation of the FDCA, as described in section 801(a).

Alerts identify a manufacturer, shipper, grower, importer, or a geographic area—which may be a specific country—as being the source of a product that appears to be violative and instruct FDA field personnel to DWPE all imports that meet the criteria set forth in the Alert.<sup>29</sup> Products will continue to "appear" to be in violation of the FDCA until the violation is corrected.<sup>30</sup>

Alerts significantly reduce the number of imports requiring physical FDA inspection to determine admissibility, thus making them, in light of FDA's lack of resources, an important enforcement tool in FDA's arsenal. DWPE has the effect of reminding the importing community that FDA is a regulatory agency, rather than a quality control laboratory.<sup>31</sup> Prior to the use of Alerts, importers continually would offer the same types of imports for entry that FDA previously had identified as adulterated or misbranded. Knowing that FDA had limited resources, importers would wait and see whether their product would be chosen for sampling or get a "may proceed."<sup>32</sup> FDA asserts that automatic detention (i.e., DWPE) properly places the responsibility for ensuring compliance with the law on the importer, rather than on FDA.<sup>33</sup>

### C. *Issuance of Alerts*

The *Regulatory Procedures Manual* offers some examples of what may warrant recommendation of an Alert, but overall, FDA's field staff exercises extremely broad discretion.<sup>34</sup> Any of FDA's twenty district field offices or five Centers<sup>35</sup> has the power

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<sup>27</sup> See *id.* (emphasis added).

<sup>28</sup> See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions*.

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

<sup>30</sup> *Id.*

<sup>31</sup> See *id.*

<sup>32</sup> *Id.*

<sup>33</sup> See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions*. There is no statute or regulation that speaks directly to FDA's authority to DWPE products. In fact, the words "detention" and "detain," in the context of imports, are not found in either FDA's regulations or the FDCA. FDA's *Regulatory Procedures Manual* is the only place where the concept of a "detention" is found—much less that of the agency's "automatic detention."

<sup>34</sup> See *id.* A recent Alert, #16-125, demonstrates FDA's broad interpretation of appearance under section 801. FDA's Center for Food Safety and Nutrition (CFSAN) issued an Alert that *all* vacuum packaged fresh seafood "appears" to be in violation of the FDCA. The Alert provided that districts could DWPE all vacuum packaged refrigerated raw fish and fishery products because there was a danger of *Clostridium botulinum* contamination. Most, if not all, of the products FDA regulates have inherent dangers. Alert #16-125 makes it clear that an Alert may issue simply on the basis of an inherent hazard associated with a particular product. Under this reasoning, all products could be subject to an Alert because all products—foods, drugs, devices and cosmetics—are prone to various hazards.

<sup>35</sup> See FDA INVESTIGATIONS OPERATIONS MANUAL, *supra* note 23, ch. 2, *Organization*.

to recommend an Alert "when it believes that such action is warranted."<sup>36</sup> An Alert must be adequately supported, however, by information that indicates that future shipments "may be violative."<sup>37</sup>

FDA issues Alerts for a variety of reasons.<sup>38</sup> For example, prior shipments of products from a specific importer, shipper, or foreign manufacturer may have been refused entry based on analytical results, taken from physical samples, which identify an FDA violation. There does not have to be scientific analytical evidence, however, to prompt an Alert. FDA's *Regulatory Procedures Manual* states that agency personnel may recommend an Alert "whenever there is information that would cause future shipments of FDA regulated products offered for entry to 'appear' to be in violation of the FDCA within the meaning of section 801(a)."<sup>39</sup>

#### D. Notice

FDA does not have a formal procedure for notifying parties potentially affected by the issuance of an Alert. The *Regulatory Procedures Manual* states that "[i]n most instances, a copy of the Import Alert will suffice for notification,"<sup>40</sup> however, there are no procedures specifically requiring or even stating that an importer or foreign manufacturer will be sent a copy of the Alert. In contrast, when an importer offers a product identified in an Alert for entry into the United States, the importer will receive a notice from FDA, titled "Notice of FDA Action,"<sup>41</sup> stating that the product is subject to refusal.<sup>42</sup> The notice does not, however, state that the product is subject to refusal *because* of the specific information that initiated the Alert.

Although Alerts are not sent to "affected parties," they are available on FDA's website.<sup>43</sup> Practically speaking, most brokers who have experience with the importation of FDA-regulated products are aware that if a product is on Alert, the Alert will initiate a notice that the product is subject to refusal. And, similarly, an importer probably is aware of an Alert if the products the importer routinely imports have been subject to an Alert. New importers entering the marketplace or dealing with a foreign supplier for the first time, however, will not have notice. Only the importer whose product "appears" to be in violation of the FDCA importer will receive *actual* notice.

#### E. Removal of Alerts

FDA will cancel an Alert only after receipt of evidence establishing that future entries will be in compliance and that the conditions that gave rise to the appearance of a

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<sup>36</sup> FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions*. FDA may issue an Alert as a result of a single violative sample or after multiple violative samples. In addition, analyses performed by state or local agencies can serve as the basis for an Alert if FDA determines that the sampling and testing is accurate, acceptable, and representative of the product on which the recommendation is based. Any other credible information that imported products are noncompliant with good manufacturing practices (GMPs) also may result in an Alert being issued.

<sup>37</sup> *Id.*

<sup>38</sup> *See id.*

<sup>39</sup> *See id.*, ch. 9, subch. *Import Information Directives*. This section identifies specific information that can support a finding that a product "appears" to violate the FDCA.

<sup>40</sup> *Id.* Firms or products placed under an Alert because of a violative establishment inspection, or GMP violation, generally may be removed from the alert following a re-inspection. The re-inspection, which, in some instances, may be performed by a reliable entity other than that which performed the initial violative inspection, must confirm that after concurrence by the appropriate Center, corrective actions have been instituted. In some instances, the firm itself presents information or documentation sufficient to be removed from the Alert.

<sup>41</sup> *See id.*, ch. 9, subch. *Notice of Sampling*.

<sup>42</sup> *See id.*, ch. 9, subch. *Notice of Refusal*.

<sup>43</sup> *See* [http://www.fda.gov/ora/fiars/ora\\_import\\_alerts.html](http://www.fda.gov/ora/fiars/ora_import_alerts.html) (last visited Oct. 20, 2003).

violation no longer exist.<sup>44</sup> The *Regulatory Procedures Manual* does not address specifically *how* an importer or other interested party can remove the “appearance” of a violation.<sup>45</sup> In contrast, at least one Alert does provide specific criteria to be met in order to overcome the appearance of a violation.<sup>46</sup>

### III. THE APA: AGENCY ACCOUNTABILITY AND CHOICE

#### A. Accountability

Agency accountability is one of the fundamental goals of the notice-and-comment procedure of section 553 of the APA.<sup>47</sup> Public participation discourages arbitrary agency actions and assures that when an agency creates a legislative rule, it will have before it the facts and information relevant to a particular problem.<sup>48</sup> Because FDA exercises broad powers to create regulations, the APA requires that FDA-made rules undergo both notice and comment and the opportunity for judicial review.

The APA is grounded in the belief that fair processes result in better regulations, and that participatory processes result in regulations that people can accept. More importantly, fair processes allow people to better understand the ground rules, which increase compliance even if there is disagreement with the rules. Indeed, procedural fairness is so fundamental a principle in that the Framers expressly guaranteed it in the Constitution.<sup>49</sup>

#### B. Exceptions

There are, of course, exceptions under section 553(b)(3)(A) that allow agencies to promulgate certain rules without following notice-and-comment procedures.<sup>50</sup> The exceptions include general statements of policy, interpretive rules, and rules of agency organization, procedure, or practice. Additionally, case-by-case adjudications<sup>51</sup> do not require adherence to notice-and-comment procedures presumably because the agency will have before it the facts and information relevant to a particular problem. These exceptions encompass “nonlegislative” documents,<sup>52</sup>—documents do not require publication in the *Federal Register* for purposes of notice and comment.

<sup>44</sup> *Id.*

<sup>45</sup> See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions*. It does provide that a minimum number of consecutive nonviolative commercial shipments may demonstrate that an appearance of the violation has been overcome and, thus, that it may be appropriate to cancel the Alert.

<sup>46</sup> See Food and Drug Admin., Import Alert #16-125, Detention Without Physical Examination of Refrigerated (Not Frozen) Vacuum Packaged or Modified Atmosphere Packaged Raw Fish and Fishery Products Due to the Potential for Clostridium Botulinum Toxin Production (Sept. 25, 2002), available at [http://www.fda.gov/ora/afiars/ora\\_import\\_ia16125.html](http://www.fda.gov/ora/afiars/ora_import_ia16125.html) (last visited Oct. 20, 2003).

<sup>47</sup> SENATE COMM. ON THE JUDICIARY, 79TH CONG., 2D SESS., S. DOC. NO. 248 (Comm. Print 1945), reprinted in LEGISLATIVE HISTORY OF THE ADMINISTRATIVE PROCEDURE ACT 18-20 (1946).

<sup>48</sup> See *Guardian Fed. Sav. & Loan v. Fed. Sav. and Loan Ins. Corp.*, 191 U.S. App. D.C. 135, 589 F.2d 658, 662 (D.C. Cir. 1978).

<sup>49</sup> See U.S. CONST. amend. V (“No person shall ... be deprived of life, liberty, or property, without due process of law . . .”).

<sup>50</sup> See 5 U.S.C. § 553(b)(3)(A).

<sup>51</sup> 5 U.S.C. § 551(7): “[A]djudication” means agency process for the formulation of an order.” An order is “the whole or a part of a final disposition. A final disposition is one that has “some determinate consequences” for the parties. See *id.* § 551(6). “Informal adjudication” refers to adjudication that is not conducted in a trial-type, on-the-record proceeding governed by the APA, *id.* § 554, or a substantially equivalent trial-type hearing. See generally PETER L. STRAUSS, AN INTRODUCTION TO ADMINISTRATIVE JUSTICE IN THE UNITED STATES 255 (1989).

<sup>52</sup> Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1322-23 (1992).

According to FDA, Alerts are documents that provide "guidance" to the field offices. By labeling the Alerts as guidance documents, FDA claims a section 553 exception to the notice-and-comment procedures.

### C. Agency Choice and Consequence

Many administrative agencies choose to regulate using the section 553 exceptions because they can interpret their statutes without undergoing time-consuming adjudication on a case-by-case basis, and avoid the costs of time-consuming notice-and-comment procedures.<sup>53</sup> Although choosing to legislate through "guidance"—also labeled as "policy statements" and "interpretative rules"—seems to provide many benefits to an agency, "Congress intended the exceptions to section 553's notice and comment requirements to be narrow ones."<sup>54</sup>

Most of the time, agencies are conscientious about issuing their documents in the way Congress has authorized.<sup>55</sup> Some agencies, however, including FDA, issue practically binding new requirements, like Alerts, in low-profile documents labeled as "guidance."<sup>56</sup>

## IV. FDA CASE LAW: USE OF SECTION 553 EXCEPTIONS

There have been only three cases involving APA challenges against FDA's use of a *specific* Alert.<sup>57</sup> Other cases, alleging FDA's failure to follow APA notice provisions, demonstrate that the APA's notice provisions *do apply* to rules that FDA chooses to label as guidance, policy statements, or interpretative rules.<sup>58</sup>

In 1985, a district court ordered the re-exportation, in lieu of destruction, of unapproved animal drugs offered for import.<sup>59</sup> The court analyzed FDA's failure to adopt Alerts as published regulations. The Alerts—dated March 26, 1982, and November 4, 1983—stated that most of the new animal drugs listed in the Alerts "are subject to approved NADAs for specified sponsors and bulk drug sources," and provided that "it is the responsibility of the distributor, whether the import broker or some other firm, to assure that these drugs are only shipped to processors legally entitled to receive them."<sup>60</sup> The court found that the Alerts were not exempt from the notice-and-comment requirements of section 553 because the Alerts were "substantive rules of general applicability."<sup>61</sup>

The next APA challenge specifically addressing an Alert came in 1988.<sup>62</sup> In *Bellarno*, the result of the challenge rested, in part, upon the words "automatic detention" con-

<sup>53</sup> See 57 Fed. Reg. 47,314, 47,316 (1992); 65 Fed. Reg. 56,468 (2000).

<sup>54</sup> See *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987); *Alcaraz v. Block*, 746 F.2d 593, 612 (D.C. Cir. 1984) (ruling that Congress intended exceptions to section 553 to be construed narrowly).

<sup>55</sup> See *Non-Codified Documents: Hearings Before the House Comm. on Government Reform*, 105th Cong. (2000) (statement of Robert A. Anthony, George Mason Univ. Foundation Professor of Law).

<sup>56</sup> *Id.*

<sup>57</sup> See *Bellarno Int'l, Ltd. v. Food & Drug Admin.*, 678 F. Supp. 410 (E.D.N.Y. 1988); see also, e.g., *Community Nutrition Inst. v. Young*, 818 F.2d 943, 947-48 (D.C. Cir. 1987); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 93-94 (D.C. Cir. 1997).

<sup>58</sup> *Id.* Courts characterizing them as rules that violate the notice-and-comment provision have struck down FDA Alerts and other "guidance" documents. Notwithstanding, FDA seems to have a preference for labeling rules as "guidance."

<sup>59</sup> See *United States v. Articles of Drug*, 634 F. Supp. 435 (N.D. Ill. 1985).

<sup>60</sup> *Id.* at 455.

<sup>61</sup> *Id.*

<sup>62</sup> *Bellarno Int'l, Ltd. v. Food and Drug Admin.*, 678 F. Supp. 410 (E.D.N.Y. 1988).

tained within Alert #66-14. The Alert "dictated" that agency personnel should automatically detain and refuse all U.S. Goods Returned drug products<sup>63</sup> when the importer could not supply a complete chain of custody.<sup>64</sup> The court disagreed with FDA's contention that FDA enjoys "plenary authority"<sup>65</sup> to automatically detain a product.<sup>66</sup> The court held that Alert was a "substantive rule of general applicability, to which no exceptions would apply, rather than a discretionary general statement of policy."<sup>67</sup>

To arrive at the conclusion that the Alert was a substantive rule, the court first analyzed the present binding effect of the Alert. FDA refused admission of the products because the importer failed to provide the information required by the Alert.<sup>68</sup> As a result, the products appeared to violate the FDCA and FDA detained the products. The automatic detention (which now would currently be labeled as DWPE) had a present binding effect.<sup>69</sup>

The court then looked at the degree of discretion left to FDA once the Alert was issued. A memorandum that stated, "The subject Import Alert which follows is to be enforced *effective Monday, September 9, 1985. There should be no exceptions to strict enforcement*" accompanied the Alert. According to the court, the statements in the memorandum limited any discretion accorded to agency personnel.<sup>70</sup>

The actual language used in the Alert was the court's next consideration. The court found that FDA's use of the term "automatic detention" was illustrative of the Alert's binding effect. Despite this decision, substantial numbers of Alerts continue to use language such as "automatically detain" and provide "instructions" for agency personnel to follow.<sup>71</sup>

Finally, the court recognized that deference was to be given to FDA's own characterization of the Alert, but in this case, according to the court, any deference owed to FDA's characterization was outweighed by the present binding effect, degree of discretion, and the language of the Alert.<sup>72</sup>

Some recent FDA Alerts have been identical to the Alert struck down in *Bellarno*.<sup>73</sup> For example, Alert #16-125 establishes criteria that importers must meet in order to overcome the "appearance" of a violation. Alert #16-125 requires importers to establish

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<sup>63</sup> *Id.* at 415.

<sup>64</sup> See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Import Information Directives*. Like current Alerts, #66-14 was labeled as "guidance."

<sup>65</sup> See 21 U.S.C. § 381 (FDCA § 801); see also FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions* (Using the "otherwise" language in section 801, FDA states that there are no limitations on its authority to initially detain an article offered for import, pending a determination of its admissibility.).

<sup>66</sup> See *Bellarno*, 678 F. Supp. at 411-13.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 413.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 414. ("Even were this Court to find that a modicum of discretion exists, that finding alone is insufficient to classify the pronouncement as a general statement of policy.") See also *Guardian Fed. Sav. & Loan v. Fed. Sav. and Loan Ins. Corp.*, 191 U.S. App. D.C. 135, 589 F.2d 658, 677 (D.C. Cir. 1978).

<sup>71</sup> Even after *Bellarno*, at least 24 new and revised Alerts remain titled "automatic detention" and provide "instructions" for agency personnel to detain specific products.

<sup>72</sup> *Bellarno*, 678 F. Supp. at 414-16.

<sup>73</sup> See Food and Drug Admin., Import Alert #16-125, Detention Without Physical Examination of Refrigerated (Not Frozen) Vacuum Packaged or Modified Atmosphere Packaged Raw Fish and Fishery Products Due to the Potential for Clostridium Botulinum Toxin Production (Sept. 25, 2002), available at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia16125.html](http://www.fda.gov/ora/fiars/ora_import_ia16125.html) (last visited Oct. 20, 2003). The Alert states, in part, "... FDA considers refrigerated fresh fish products in vacuum packaging or modified atmosphere packaging to be adulterated under section 402(a)(4) of the Food, Drug and Cosmetic Act when the C. botulinum toxin hazard is not controlled ...".

that their fresh vacuum packaged seafood products have been held under continuous temperature controls to prevent *clostridium botulinum* formation. Importers must provide FDA with "proof" that their product has been maintained at or below 38°F (3.3°C) from the time of packaging through the time of importation in order for a product covered under this Alert to "overcome" the "appearance" of adulteration.<sup>74</sup>

In *Syncor International Corporation v. Shalala*, the D.C. Circuit ruled that an FDA rule was not within the exceptions to the APA's notice-and-comment procedures.<sup>75</sup> Rather, the "interpretative rule," as FDA had characterized it, was in reality a substantive rule. The case involved a manufacturer's challenge to FDA's decision that radiopharmaceutical drugs should be regulated under the FDCA. The manufacturer argued that FDA had violated the APA's requirement of public notice prior to rulemaking.<sup>76</sup> The court primarily focused on whether, in the absence of the rule, there would be an adequate legislative basis for enforcement action. Because the rule did not interpret any language in a statute or regulation, the rule was not interpretative. The court thus vacated the rule as not in accordance with the APA.

Current Alerts mirror the lack of interpretation addressed in the *Syncor* case—they do not purport to interpret any language in a statute or regulation. For example, Alert #99-14 instructs field personnel to "Automatically detain without analysis any ... products where countrywide detention has been initiated ... if the shipper or grower fails to provide a valid certificate of analysis showing the product does not contain illegal residues ... of pesticide(s)."<sup>77</sup> There is no statutory requirement for an importer to provide a certificate of analysis at the time of importation. The only reference to an *actual* statutory requirement is the statement that "The article is subject to refusal of admission pursuant to Section 381(a)(3) in that it appears to contain a pesticide chemical ... in violation of section 402(a)(2)(B)." While the Alert references an *actual* statutory violation, it fails to interpret the language of "appearance," which is the exact language that FDA must "interpret" to find the authority to DWPE.

Only by interpreting "appearance" in the Alert ("guidance") itself, could FDA extend its regulatory authority to DWPE. The reason for this is simple. A product not accompanied by a certificate of analysis, as in this example, cannot "appear" to contain a pesticide because there is no such requirement in a statute or regulation. The *only* actual statutory requirement is that product, if it "appears" to be in violation of the FDCA, shall be refused. Until FDA "interprets" "appearance" under section 801, an Alert cannot be an interpretative document excepted from notice and comment. In the absence of the Alert, there would be no adequate legislative basis for refusing the product, unless FDA Alerts interpret "appearance." Even if Alerts did interpret "appearance," the Alerts would be binding. As the next case demonstrates, binding rules are not exempt from the APA's notice provisions.

In *Community Nutrition Institute v. Young*, a public interest group sued FDA for issuing "action levels" without conducting informal rulemaking under the APA.<sup>78</sup> CNI challenged FDA's action level for aflatoxins in corn because the agency did not follow the APA's notice-and-comment provisions prior to enforcement of the action level. FDA argued that the action level was an interpretative rule, or in the alternative, a general

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<sup>74</sup> *Id.*

<sup>75</sup> 127 F.3d 90, 93-94 (D.C. Cir. 1997).

<sup>76</sup> *See id.* at 5-6; 5 U.S.C. § 553(b).

<sup>77</sup> *See* Food and Drug Admin., Import Alert #99-14, Countrywide Automatic Detention of Raw Agricultural Products for Pesticides (July 11, 1994, last updated Oct. 16, 2003), available at [http://www.fda.gov/ora/riars/ora\\_import\\_ia9914.html](http://www.fda.gov/ora/riars/ora_import_ia9914.html) (last visited Oct. 20, 2003).

<sup>78</sup> *Community Nutrition Inst. v. Young*, 818 F.2d 943, 947-48 (D.C. Cir. 1987).

statement of policy. The court considered three criteria in order to determine whether the action level was an interpretative rule, a general statement of policy, or a substantive rule.

First, the court looked at the language used by FDA to describe action levels. FDA's regulation, 21 C.F.R. § 109.4, states that an action level may *prohibit any detectable amount of substance in food and as such, the food will be deemed to be adulterated*. The court found that the language reflected an interpretation of action levels as presently binding norms.<sup>79</sup>

Second, the court considered FDA's requirement for food manufacturers to secure *exceptions* to the action levels. According to the court, the need to secure an "exception" implies that in the absence of an exemption, all food containing aflatoxin over the action level would be considered adulterated.<sup>80</sup> The court found that the action level was a binding norm because the adulteration determination was derived from the action limit itself. If action levels did not bind FDA or the manufacturers, it was not necessary to require "exceptions."

Third, the court looked at FDA's previous characterizations of its aflatoxin action level. In a formal notice published in the *Federal Register*, FDA wrote that "Any food that contains aflatoxin in excess of 20 ppb ... is considered by FDA to be adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 342(a)(1)), and therefore may not be shipped in interstate commerce."<sup>81</sup> FDA's own language suggested the action levels that the agency deemed permissible. Therefore, the court held that the action levels were substantive rules and, therefore, invalid because FDA had not engaged in notice-and-comment rulemaking.

Current Alerts that impose country-wide (geographic) DWPEs have legal effects similar to the action level at issue in *CNI*. For example, Alert #24-01 provides for detention without physical examination of all bean curd from Hong Kong and the Peoples Republic of China, "except" shipments from firms listed that are "exempt" from DWPE.<sup>82</sup> Alert #16-02 provides for DWPE of all dried shark fins, dried fish maws, and dried shark cartilage powder derived from shark fins/maws from all countries—except those "exempt."<sup>83</sup> Like the action level in *CNI*, these types of Alerts imply that in the absence of an exemption, all products identified by the Alerts are adulterated. Therefore, like the actions in *CNI*, these Alerts are legislative rules and are vulnerable to legal challenge under the APA.

## V. THE EFFECT OF AN ALERT

The following illustration highlights the binding effect that an Alert has on subsequent importers.

### A. *Salmonella* in Lobster Tails

Suppose FDA collects a physical sample of lobster tails that a U.S. company, Importer A, imports. Those lobster tails originate from a French company, Producer F.

<sup>79</sup> *Id.* at 946.

<sup>80</sup> *Id.* at 947.

<sup>81</sup> 46 Fed. Reg. 747 (1981) (emphasis added).

<sup>82</sup> See Food and Drug Admin., Import Alert #24-01, Detention Without Physical Examination of Bean Curd From Hong Kong and the Peoples Republic of China (Apr. 13, 2000), available at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia2401.html](http://www.fda.gov/ora/fiars/ora_import_ia2401.html) (last visited Oct. 20, 2003).

<sup>83</sup> See Food and Drug Admin., Import Alert #16-02, Detention of All Dried Shark Fins, Dried Fish Maws and Shark Cartilage Powder Without Physical Examination (May 21, 1996, revised Aug. 14, 2003), available at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia1602.html](http://www.fda.gov/ora/fiars/ora_import_ia1602.html) (last visited Oct. 20, 2003).

FDA's sample identifies that the lobster tails are adulterated because the product contains salmonella and FDA refuses the lobster tails. As a result of that adjudication, FDA issues an Alert: "Lobster tails from French Producer F may be detained without physical examination because the lobster tails appear to be adulterated ... ."

### B. *Notice of the Alert*

Importer A has notice that FDA has determined that the lobster tails appear to be adulterated because Importer A receives an FDA Notice of Action that states the product is subject to refusal because it contains salmonella. Importer A, however, does not receive a copy of the Alert that FDA issues as a result of the violative sample. The Alert is available, however, on FDA's website.

### C. *Subsequent Importer*

Two weeks later, another U.S. company, Importer B, attempts to import Producer F's lobster tails. Because there is an Alert for Producer F's lobster tails, FDA DWPE's the product. Importer B does not have participation rights in FDA's decision to issue the Alert that leads to the DWPE of Importer B's entry. Although the Alert is available on FDA's website, the agency's procedures do not require, or even imply, that affected importers will receive notice of the Alert. It might take weeks, if not months, to actually post an Alert on the worldwide web. The effect of this is that, although the Alert eventually may be available on the web, the FDA may begin targeting Producer F immediately.

Ultimately, all that Importer B will receive is a "Notice of FDA Action" stating that the lobster tails are subject to refusal because they appear to be adulterated. The notice will *not* state why FDA believes the lobster tails appear to be adulterated because of the presence of salmonella.<sup>84</sup> Importer B has no information, therefore, to explain why FDA assumes that the product appears to be adulterated when there has been no physical examination of the lobster tails. Importer B, as well as any other similarly situated importer, is foreclosed from an opportunity to contend that the Alert is unlawful or unwise, or that an alternative policy should be adopted.

### D. *Notice and Hearing*

Future importers of Producer F's lobster tails, like Importer B, also will have their lobster tails DWPE and will exhaust costly administrative remedies (testimony and hearing at which time the importer will need to overcome the assumed appearance of a violation). The practical consequence is that this process may be costly and protracted, and affected importers, like Importer B, have no fair opportunity to challenge the Alert before FDA applies it. Importer B will have to demonstrate to FDA, during the informal notice and hearing period, that the lobster tails it offers for entry from Producer F do not contain salmonella. It will be difficult for Importer B to know *how* to overcome this

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<sup>84</sup> Neither the detention notice nor the refusal notice will state why FDA believes Importer B's lobster tails "appear" to be adulterated. Even if Importer B knew the Alert was on FDA's website, the Alert would not identify important information including, for example, the shipper of previous lobster tails from Producer F. Such information may be critical because a shipper could contaminate product just as easily as a producer of lobster tails. The point is that Importer B would not have important facts necessary to demonstrate that the lobster tails Importer B offered are different than Importer A's lobster tails, which gave rise to the Alert.

“appearance” of adulteration because Importer B will not have any “guidance” or regulation to look to in order to understand how to demonstrate that the Alert, and thus the “appearance” of adulteration, does *not apply* to Importer B’s lobster tails.

## VI. ALERTS ARE BINDING RULES

FDA incorrectly labels Alerts as “guidance.” The exceptions to notice and comment under the APA carry many labels, including “guidance.” In fact, courts tend to treat interpretative rules, policy statements, and guidelines virtually the same.<sup>85</sup> According to the label, “guidance,” Alerts *should* be exempt from the APA provisions requiring notice and comment. To conclude as much, however, is simply incorrect. In order to clarify the point, it is necessary to analyze why Alerts are rules but *not* the kind of rules (i.e., policy statements, interpretative rules, or guidance) that are exempt from the APA’s notice-and-comment requirements.

Alerts cannot fall within the definition of guidance, policy statements, or interpretative rules because Alerts *are* binding. The above illustration is not a theoretical example—rather it is a very real situation that occurs daily. As a consequence of Importer A’s importation of lobster tails and the subsequent Alert, Importer B now has an obligation to overcome the appearance of adulteration if Importer B wants to get the product cleared into the United States. Thus, Alerts are binding as a practical matter because they impose obligations on similarly situated importers. FDA treats Alerts as an independent basis for action in matters that determine the rights and obligations of any importer that offers, for entry into the United States, products listed on an Alert. The Alert is dispositive, therefore, of the issue it addresses—DWPE. When a product is detained, it is subject to refusal, so *but for* the Alert, Importer B’s product would not be DWPE and Importer B would not have to overcome the appearance of a violation.

### A. Alerts Are Not General Statements of Policy

Policy statements fall within the category of agency actions that are “rules” within the APA’s definition because they constitute “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or describe law or policy.”<sup>86</sup> A general statement of policy is a nonlegislative rule because it does not establish a binding norm and it is not finally determinative of the issues or rights that it addresses. An agency cannot apply or rely upon a general statement of policy as law because it announces only what the agency seeks to establish as policy.<sup>87</sup>

It seems plausible that Alerts could be general statements of policy. After all, Alerts do state that they are not binding on FDA or the public. Furthermore, Alerts merely state that FDA field staff *may* DWPE particular products because they appear to violate the FDCA. If Alerts are truly policy statements, however, then they must not impose obligations on the importing industry. The illustration in Part V demonstrates that Alerts do impose significant obligations on similarly situated importers that attempt to bring a product, identified in an Alert, into the United States. Affected importers will have their product detained on the spot and then will bear the obligation of demonstrating that the product is not in violation.

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<sup>85</sup> See *Community Nutrition Inst. v. Young*, 818 F.2d 943, 945 (D.C. Cir. 1987).

<sup>86</sup> See 5 U.S.C. § 551(4).

<sup>87</sup> *Id.*

### B. Alerts Are Not "Guidance"

Although FDA contends that Alerts are "guidance," and many Alerts do state that FDA field staff *may* DWPE particular products because they appear to violate the FDCA, an Alert is not "guidance." Furthermore, by labeling Alerts as "guidance," FDA effectively misbrands Alerts.

In February 1997, FDA published a set of guidelines entitled *Good Guidance Practices* (GGPs) in the *Federal Register*.<sup>88</sup> The GGPs establish FDA's policies and procedures for the issuance and use of "guidance documents." According to FDA, "guidance documents" clarify statutes and substantive rules in order to provide implementation that is "effective, fair, and consistent."<sup>89</sup> "Guidance" documents are not binding on the public or FDA.<sup>90</sup> FDA's guidance documents state:

This guidance document represents the agency's current thinking on \* \* \*. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.<sup>91</sup>

Alerts, however, do not clarify statutes and substantive rules as "guidance documents." It is not clear, therefore, why FDA labels Alerts as "guidance." Presumably, FDA is signaling the belief that notice and comment is not necessary. According to the GGPs, however, Alerts are Level I<sup>92</sup> documents that allow for an opportunity for some type of notice and comment in the *Federal Register* before implementation. Therefore, it *seems* that GGPs would provide for public notice and comment, but that opportunity is not the same as the APA provides. Also, FDA fails to follow GGPs when it issues Alerts.<sup>93</sup> Out of the hundreds of Alerts issued since 1994, only eight have been published in the *Federal Register*.

Even if FDA provides for notice and comment, current Alerts fail to explain FDA's authority to DWPE. Current Alerts, labeled as "guidance," do not provide for implementation that is "effective, fair, and consistent."<sup>94</sup> Because Alerts are not "guidance," Alerts are binding.

### C. Alerts Are Not Interpretative Rules

Alerts do not interpret any language in a statute or regulation. In issuing an interpretive rule, "an agency can declare its understanding of what a statute requires without

<sup>88</sup> See Good Guidance Practices, 62 Fed. Reg. 8967 (1997).

<sup>89</sup> *Id.*

<sup>90</sup> See *id.* at 8967, 8969.

<sup>91</sup> *Id.* at 8969.

<sup>92</sup> *Id.* at 8972; see also 21 C.F.R. § 10.115(c) (Level 1 guidance documents include guidance documents that: (i) set forth initial interpretations of statutory or regulatory requirements; (ii) set forth changes in interpretation or policy that are of more than a minor nature; (iii) include complex scientific issues; or (iv) Cover highly controversial issues. Level I guidance documents must be published in the *Federal Register*).

<sup>93</sup> See 62 Fed. Reg. at 8967. Out of a total of 143 Alerts, only eight have been published in the *Federal Register*. See, e.g., Guidance for Industry and for FDA Employees on Import Alert #66-66, 65 Fed. Reg. 75,718 (Dec. 4, 2000); Draft Guidance for Industry on Surveillance and Detention Without Physical Examination of Condoms, 65 Fed. Reg. 49,585 (Aug. 14, 2000); Medical Devices; Draft Guidance for Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves, 65 Fed. Reg. 45,991 (July 26, 2000); Actions Regarding Family Planning Service Projects, Transplantation of Human Fetal Tissue, and Importation of the Drug Mifepristone, 58 Fed. Reg. 7468 (Feb. 5, 1993); Reimportation of Prescription Drugs for Human Use, 53 Fed. Reg. 28,069 (July 26, 1988); Detention of Noncertified Television Receivers Labeled for Export, 52 Fed. Reg. 37,373 (Oct. 6, 1987); Soy Drinks and Other Beverages That Purport to Be Infant Formulas or Milk Substitutes, 52 Fed. Reg. 25,636 (July 8, 1987); Automatic Detention and/or Examination of Imported Soft Cheese, 52 Fed. Reg. 21,998 (June 10, 1987).

<sup>94</sup> 21 C.F.R. § 10.115; 65 Fed. Reg. 56,468 (Sept. 19, 2000).

providing notice and comment, but an agency cannot go beyond the text of a statute ... [and the interpretive rule] does not create any new right or duty but merely provides an interpretation of [the statute].”<sup>95</sup> Alerts, on their face, only imply some interpretation of section 801. Even so, the court in *Syncor* noted that when the statute that is being interpreted is very general, and FDA’s interpretation provides all of the guidance, then the interpretation likely is a substantive regulation because FDA’s rule gives content to a general term.<sup>96</sup> FDA’s Alerts give content to the vague terms “otherwise” and “appearance” in section 801.<sup>97</sup> An Alert creates a new duty for the importer—the duty, or obligation, to overcome the appearance of a violation.

## VII. PROCEDURAL FAIRNESS

### A. Fair Notice

Importers have *potential* notice of Alerts because they are available on FDA’s website. It does not follow, however, that affected importers have *actual* notice of the legal norms that FDA applies to them when their product is on an Alert. Indeed, importers affected by an Alert (those importers that experience having their product DWPE because of an Alert) will have the opportunity to challenge a detention. That opportunity exists whether or not the importer’s product was DWPE or detained because FDA physically examined the product. Affected importers do not enjoy procedural fairness, however, at the time the DWPE occurs. The importer only receives notice that the product is subject to refusal because it violates the FDCA. The importer does not know why the appearance exists and FDA should not expect the importer to know without more notice—only FDA knows why the product appears to be violative.

FDA has no rules or guidance for these affected importers as to how to avoid application of DWPE to their product. Fair notice of DWPE—including agency-created rules like Alerts—is essential in order to give affected importers a reasonable opportunity to meet the obligations that an Alert imposes.

### B. Notice and Comment

Notice-and-comment rulemaking is one of the “greatest inventions of modern government.”<sup>98</sup> There are many reasons why interested importers should have a meaningful opportunity to contribute to FDA’s process for DWPE through the issuance of Alerts. FDA has the opportunity to gather “the information, facts, and probabilities which are necessary to fair and intelligent action.”<sup>99</sup> Importers are in a much better position than FDA to provide the specific information necessary to formulate a fair DWPE rule that FDA will apply through Alerts.

The APA notice-and-comment provisions exist, in part, for the purpose of ensuring public participation. An opportunity for public participation facilitates the representation of otherwise unrepresented interests and helps agencies obtain the fairest and most complete presentation of opposing views. The result is a more balanced and informed agency decision. A judicial check ensures that the administrative action is not arbitrary, capricious, or an abuse of discretion,<sup>100</sup> and that the government’s regulatory

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<sup>95</sup> *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991).

<sup>96</sup> *Syncor*, 127 F.3d at 93-94.

<sup>97</sup> See 21 U.S.C. § 381 (FDCA § 801).

<sup>98</sup> 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 1:7, at 488 (1st ed. 1958).

<sup>99</sup> *Nat’l Petroleum Refiners Ass’n v. FTC*, 482 F.2d 672, 683 (D.C. Cir. 1973).

<sup>100</sup> 5 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 28:8, at 290 (2d ed. 1984).

authority serves the American people in the best possible way.<sup>101</sup> Coordinated review of agency rulemaking ensures that regulations are consistent with Congress' statutory law making delegation.<sup>102</sup>

The APA establishes a presumption in favor of reviewability stating that judicial review is available "except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law."<sup>103</sup> The drafters of the APA did not delineate clearly, however, the "committed to agency discretion" exception.<sup>104</sup> FDA may argue, therefore, that Alerts fall within this exception.

### VIII. COMMITTED TO AGENCY DISCRETION

In *Sugarman v. Forbragd*,<sup>105</sup> FDA refused a shipment of adulterated coffee beans that it found to be "unfit for food."<sup>106</sup> The importer sought review of the agency's decision on grounds that the APA required agency notice, a hearing, and judicial review. The Ninth Circuit Court of Appeals held that FDA's refusal of the coffee beans was committed to agency discretion by law, and, therefore, was unreviewable under section 702(a)(2) of the APA.<sup>107</sup>

Under the APA, however, the availability of substantive judicial review is *distinct* from the question of whether the basic rulemaking strictures of notice and comment apply.<sup>108</sup> The APA's procedural requirements are enforceable apart from the reviewability of the underlying action, and support several important functions wholly distinct from judicial review. Therefore, *Sugarman's* holding is not so broad as to apply to Alerts.<sup>109</sup>

Additionally, the refusal of coffee beans in *Sugarman* was based on an FDA analysis of an actual physical sample that confirmed adulteration. In contrast, Alerts do not require physical examination of the imported product. Alerts automatically presume adulteration and provide for DWPE, without any physical examination or sample. DWPE through Alerts is the type of "arbitrary refusal," referred to by the court in *Sugarman*,<sup>110</sup> that is an appropriate subject for judicial review.<sup>111</sup>

### IX. RECOMMENDATIONS

#### A. Issue a DWPE Rule

"When a statute does not impose a duty on the persons subject to it but instead authorizes (or requires—it makes no difference) an agency to impose a duty, the formu-

<sup>101</sup> See Exec. Order 12,866, 58 Fed. Reg. 51,735 (1993) ("Coordinated review of agency rulemaking is necessary to insure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive Order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency.").

<sup>102</sup> *Id.*

<sup>103</sup> See 5 U.S.C. § 701(a).

<sup>104</sup> See 5 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 28:1, at 255 (2d ed. 1984); S. REP. NO. 752, 79th Cong., 1st Sess. 38 (1945) (App. B), reprinted in ADMINISTRATIVE PROCEDURE ACT: LEGISLATIVE HISTORY, S. DOC. NO. 248, at 406-07 (79th Cong., 2d Sess. 1946).

<sup>105</sup> 405 F.2d 1189, (9th Cir. Cal. 1968).

<sup>106</sup> *Id.* at 1190.

<sup>107</sup> *Id.*

<sup>108</sup> See *Lincoln v. Vigil*, 113 S. Ct. 2024, 2033 (1993) (addressing the question, "quite apart from the matter of substantive reviewability," of whether the agency "was required to abide by the familiar notice and comment provisions of the APA").

<sup>109</sup> *Sugarman* was heard four years prior to FDA's development of Alerts.

<sup>110</sup> *Sugarman*, 405 F.2d at 1190.

<sup>111</sup> *Id.*

lation of that duty becomes a legislative task entrusted to the agency.”<sup>112</sup> The plain language of section 701 authorizes FDA and the Secretary of Treasury to promulgate regulations. Specifically, section 701 provides that FDA and the Secretary of the Treasury shall “jointly prescribe” regulations for the efficient enforcement of section 801 of the FDCA.<sup>113</sup> There is no prohibition against FDA’s authority to interpret its regulations and to conclude that section 801 is a congressional grant of authority to DWPE products that appear to be in violation of the FDCA. But the APA does prohibit FDA from implementing DWPE through Alerts without following APA procedures. In addition, constitutional requirements of due process require fair notice of FDA’s actions and how the importer may respond.

By labeling Alerts as “guidance,” FDA subverts the notice-and-comment procedures of the APA. Thus, Alerts (which are rules) mean whatever FDA says they mean, and FDA effectively “has the power of self-interpretation.”<sup>114</sup> This sort of action permits FDA to “supply the meaning of regulatory gaps or ambiguities of its own making and seemingly relieves the Agency of the cost of the imprecision that it creates.”<sup>115</sup> The ambiguity rears its ugly head in countless ways.

Both the underlying purpose of Alerts and the message that the Alerts deliver to importers are ambiguous. Although Alerts are intended to protect the public from unsafe products,<sup>116</sup> they do not really accomplish this goal. Rather, Alerts impose burdens on both U.S. importers and foreign processors that are not based upon *solutions* to potential health risks, but instead are based on presumptions that an arbitrary amount of “clean” shipments signifies that a product may no longer be unsafe. Public protection is not achieved by treating symptoms alone.

Imposing liability on importers without adequate notice also is economically inefficient.<sup>117</sup> Each time FDA issues an Alert that affects an importer who was not a party to the prior adjudication, FDA imposes liabilities on individuals without adequate notice. “Even a law that may be inefficient as a matter of social welfare may be ‘efficient’ if it is well-specified and known in advance.”<sup>118</sup> “At the very least, such a law permits the parties to arrange their affairs accordingly, and maximizes social welfare within the constraints of the law.”<sup>119</sup> By contrast, punishing importers without notice imposes economic costs on society by undermining principles of predictability, or the ability to rely on expectations.

The procedures for removal from Alerts are ambiguous. The *Regulatory Procedures Manual* contains arbitrary and capricious procedures for overcoming the appearance of a violation. One example is FDA’s acceptance of a specific number of commercial entries.<sup>120</sup> According to the *Regulatory Procedures Manual*, a product may be removed

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<sup>112</sup> *Hocor v. U.S. Dep’t of Agriculture*, 82 F.3d 165, 169-70 (7th Cir. 1996).

<sup>113</sup> See 21 U.S.C. § 371(a) (FDCA § 701(a)).

<sup>114</sup> *Regulatory Fair Warning Act of 1998: Hearing on H.R. 4049 Before the House Comm. on Commercial and Administrative Law*, 103rd Cong. (1998) (testimony of Daniel E. Troy, Associate Scholar of Legal Studies, American Enterprise Institute for Public Policy, and Partner, Wiley, Rein & Fielding).

<sup>115</sup> *Id.*

<sup>116</sup> See Off. of Regulatory Aff., Food and Drug Admin., Import Program System Information (last updated Feb. 20, 2003), at [http://www.fda.gov/ora/import/ora\\_import\\_system.html](http://www.fda.gov/ora/import/ora_import_system.html) (last visited Oct. 20, 2003); see also FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. Import Information Directives.

<sup>117</sup> See Troy Testimony, *supra* note 114 (citing Gregory Sidak & Daniel F. Spulber, *Deregulatory Takings and Breach of the Regulatory Contract*, 71 N.Y.U. L. REV. 851, 865 (1996)).

<sup>118</sup> See Troy Testimony, *supra* note 114.

<sup>119</sup> *Id.*

<sup>120</sup> See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions*.

from an Alert if there are consecutive nonviolative commercial shipments of a given product type. This procedure does not embody the current regulations that FDA applies to domestic manufacturers. To the contrary, FDA requires domestic manufacturers to explain how they will resolve noncompliance with FDA rules and regulations.<sup>121</sup> In other words, domestic manufacturers must investigate, to FDA's satisfaction, the cause of the nonconformance and explain how the manufacturer plans to eliminate future noncompliance with FDA rules and regulations.

There also is ambiguity in the manner in which FDA handles Alerts internally. Federal laws and regulations must provide clear standards to regulators to prevent arbitrary and subjective enforcement.<sup>122</sup> FDA field staff is under no absolute mandate to recommend that an Alert issue for a product that is refused because it violates the FDCA. FDA field staff in various ports can, and will, recommend Alerts inconsistently, thereby compromising uniform enforcement against products that "appear" to be in violation of the FDCA. The consequence of inconsistent issuance of Alerts is inefficient use of limited resources. When FDA has evidence that a particular product "appears" to violate the FDCA, and ultimately is refused entry, FDA should not allow the product to enter U.S. commerce until that appearance is overcome. As currently formulated, the procedures in the *Regulatory Procedures Manual* give FDA virtually unlimited discretion to decide on an *ad hoc* basis when to issue, and when to apply, an Alert. FDA's ostensible solution to the vagueness of section 801 is to label Alerts as "guidance." This approach is not practical unless FDA's procedures for interpreting and applying Alerts are reasonably clear.

There is ambiguity in the message that FDA announces to the public. FDA's own administrative procedures, which it fails to follow consistently,<sup>123</sup> require Alerts to undergo notice and comment prior to implementation. Yet only eight Alerts, out of hundreds, underwent notice and comment in the *Federal Register*. These specific documents identify FDA's own administrative procedures<sup>124</sup> as the basis for *Federal Register* publication.<sup>125</sup> By labeling Alerts as "guidance," FDA places an extra burden on itself by subjecting *all* Alerts to the administrative procedures in 21 C.F.R. § 10.115. Issuance of a DWPE rule will allow FDA to withstand judicial review of Alerts as rules via case-by-case adjudications. Moreover, FDA's own GGP publication rules would not apply to each and every Alert. FDA needs to act quickly to protect consumers from imported products that may cause harm. It is unimaginable to assume that there will be effective protection of the U.S. public, if the procedure involves months, maybe a year or more, of time for submission via notice and comment in the *Federal Register* for every single Alert that is issued.

### B. Issue Good Guidance Practices (GGPs)

Once a DWPE rule issues, importers need to understand how to "overcome" an appearance of a violation. FDA must provide true "guidance" to both the public and

<sup>121</sup> See FDA INVESTIGATIONS OPERATIONS MANUAL, *supra* note 23, ch. 4, *Establishment Inspections*.

<sup>122</sup> See, e.g., *Kolender v. Lawson*, 461 U.S. 352, 357 (1983).

<sup>123</sup> See *supra* note 93.

<sup>124</sup> 21 C.F.R. § 10.115.

<sup>125</sup> See 65 Fed. Reg. 75,718 (Dec. 4, 2000) (stating that "This Level 1 guidance is being issued consistent with FDA's good guidance regulation. The guidance represents the agency's current thinking on the detention without physical examination of API's that appear to be misbranded under 502(f)(1) of the act because they do not meet the requirements for the labeling exemptions in § 201.122. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.") [Guidance for Industry and for FDA Employees on Import Alert #66-66]. See also 65 Fed. Reg. 56,468 (Sept. 19, 2000) (codified as amended at 21 § C.F.R. 10.115). The eight Alerts published under FDA's Administrative Procedures and Practices regulation make it unclear as to why all Alerts are not published in the *Federal Register*.

FDA personnel as to what actions may establish that an appearance of a violation no longer exists.<sup>126</sup> Issuing a GGP documents *could* provide public protection because it would allow importers and foreign processors to engage in dialogue with both FDA and the industry regarding the best way to handle health and safety problems. A DWPE rule that includes best practices, by example for the industry or industry sector, could be applied uniformly and consistently to achieve public protection.

DWPE through Alerts places the burden on importers to demonstrate that the products they are offering into the United States comply with FDA rules and regulations.<sup>127</sup> FDA, however, fails to provide importers with the procedural fairness necessary to handle the burden that an Alert carries. It must be possible for the importing community to perceive the principles that guide FDA's procedures for obtaining removal under Alerts. Accordingly, FDA could identify and incorporate principles of good manufacturing practices into that guidance to ensure solutions for noncompliant products versus arbitrary numbers of future shipments that do not address the root cause of non-compliance.

## X. CONCLUSION

FDA is responsible for protecting all U.S. consumers from imported products that pose potential harm to the health and welfare of American citizens. This is an incredible challenge that FDA continually faces. The concept of Alerts is well founded on the effort to ensure uniform import coverage and to provide the highest level of protection for consumers in the United States. In order for FDA to achieve the goal that Alerts provide efficient and uniform enforcement at the U.S. border, however, FDA must reassess the way it labels and issues Alerts.

FDA misbrands Alerts by labeling them as "guidance." The effect on the importing community is a lack of procedural fairness that significantly affects an importer's ability to import FDA-regulated products into the United States. Just as FDA requires the products under FDA's jurisdiction to be labeled properly, so must FDA correctly label Alerts so that the protections embodied in the APA may provide the procedural fairness due the regulated importing community. By doing so, FDA will achieve the highest level of protection for consumers in the United States because U.S. importers, who are also U.S. consumers, will better understand *how* to help ensure that the FDA regulated-products they import for commercial U.S. consumption are safe.

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<sup>126</sup> See *K & K Merchandise Group v. Shalala*, 1996 U.S. Dist. LEXIS 4880 (S.D.N.Y. Apr. 15, 1996). An importer's multisystems had been detained and refused clearance due to failure to meet federal performance standards for radiation emission. The court held that the Compliance Program "may be justified according to the wide discretionary power FDA enjoys to determine the factors regarding its decision to grant or refuse admission of imported goods." *Id.* at 23.

<sup>127</sup> See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. *Automatic Detentions* ("Automatic detention properly places the responsibility for ensuring compliance with the law on the importer.").