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.[53] 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."[54]

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

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.[57] 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.[58]

In 1985, a district court ordered the re-exportation, in lieu of destruction, of unapproved animal drugs offered for import.[59] 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."[60] 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."[61]

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

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[53] *See* 57 Fed. Reg. 47,314, 47,316 (1992); 65 Fed. Reg. 56,468 (2000).

[54] *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).

[55] *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).

[56] *Id.*

[57] *See* Bellarno Int'l, Ltd. v. Food & Drug Admin., 678 F. Supp. 410 (E.D.N.Y. 1988); s*ee 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).

[58] *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."

[59] *See* United States v. Articles of Drug, 634 F. Supp. 435 (N.D. Ill. 1985).

[60] *Id.* at 455.

[61] *Id.*

[62] 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[63] when the importer could not supply a complete chain of custody.[64] The court disagreed with FDA's contention that FDA enjoys "plenary authority"[65] to automatically detain a product.[66] 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."[67]

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.[68] 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.[69]

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.[70]

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.[71]

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.[72]

Some recent FDA Alerts have been identical to the Alert struck down in *Bellarno*.[73] 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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[63] *Id*. at 415.

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

[65] *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.).

[66] *See Bellarno,* 678 F. Supp. at 411-13.

[67] *Id*.

[68] *Id*. at 413.

[69] *Id*.

[70] *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).

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

[72] *Bellarno,* 678 F. Supp. at 414-16.

[73] *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 (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 …".