

RECALLS OF HUMAN DRUGS AND MEDICAL DEVICES

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This paper describes the policies and procedures a firm should follow to prepare for and to execute a pharmaceutical or medical device recall. Part I briefly describes the legal framework governing drug and device recalls, as well as the relationship between recalls and other regulatory obligations under the Federal Food, Drug, and Cosmetic Act (FDCA). Part II describes how a firm should prepare in advance for recalls. Part III discusses the execution of recalls. The conclusion briefly describes some of the collateral consequences of a product recall.

The regulations addressing drug and device recalls are found at 21 C.F.R. §§ 7.40 through 7.59. The preambles to the proposed and final regulations should also be consulted. These can be found at 43 Fed. Reg. 26202 (June 16, 1978); 41 Fed. Reg. 26924 (June 30, 1974). Other key sources of information about FDA's expectations include chapter 7 of the Regulatory Procedures Manual, chapter 7 of the Investigations Operations Manual, and a March 2003 guidance for industry entitled "Product Recalls, Including Removals and Corrections."

I. Background

A recall is "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would [otherwise] initiate legal action."¹ The term does not extend to a "market withdrawal" or a "stock recovery."² A "market withdrawal" is the removal or correction of a distributed product involving a minor violation of the FDCA that would not be subject to legal action or involving no violation of the FDCA.³ A "stock recovery" is the removal or correction of a product that has not been marketed or that has not left the recalling firm's direct control.⁴

Section 518 of the FDCA gives FDA the authority to mandate a medical device recall if certain criteria are satisfied.⁵ Section 351 of the Public Health Service Act gives FDA the

¹ 21 C.F.R. § 7.3(g).

² *Id.*

³ 21 C.F.R. § 7.3(j). A company would initiate a market withdrawal, for example, in the event of product tampering where there was no evidence of manufacturing or distribution problems. Thus, for example, Johnson & Johnson announced a nationwide withdrawal of 31 million bottles of Tylenol after seven people died from taking cyanide-laced Extra-Strength Tylenol capsules. See Tamar Nordenberg, "Recalls: FDA, Industry Cooperate to Protect Consumers," at http://www.fda.gov/fdac/features/895_recalls.html.

⁴ 21 C.F.R. § 7.3(k).

⁵ 21 U.S.C. § 360h(e). Specifically, the Secretary must order the recall of a device intended for human use if he finds a reasonable probability that the device would cause "serious adverse health consequences or death."

authority to mandate recall of a biological product (including a biological product that is a “drug” for purposes of the FDCA) if certain criteria are met.⁶ These recalls are extremely rare,⁷ typically because the agency will use informal methods – including putting pressure on the company or issuing a press release – before resorting to a mandatory recall order. With the exceptions of recalls that meet the criteria in these two provisions of law, FDA has no authority under the FDCA to order a drug or device recall. The agency states that its recall policies and procedures are “founded upon the cooperation of firms and their willingness to remove violative products from the marketplace.”⁸ FDA’s recall regulations are “guidelines rather than enforceable requirements,”⁹ although in truth they are backed by the agency’s authority to seize violative products under section 304.¹⁰

There are two types of “voluntary” recall – FDA-requested recalls and firm-initiated recalls. FDA will request a recall only in an “urgent” situation.¹¹ And before doing so, it will have evidence capable of supporting seizure.¹² FDA-requested recalls are discussed in 21 C.F.R. § 7.45. Most recalls are initiated by the firm in question. These firm-initiated recalls are discussed in 21 C.F.R. § 7.46.

FDA places a recall in one of three classes. A Class I recall occurs when there is a reasonable probability that use of or exposure to a violative product will cause serious adverse health consequences or death. One lot of methotrexate for injection was recently the subject of a Class I recall due to chemical contamination (the presence of ethylene glycol). Several liquid-

⁶ 42 U.S.C. § 262(d). Specifically, the Secretary must order the recall of a batch, lot, or other quantity of a biologic licensed under the PHS Act that presents an “imminent or substantial hazard to the public health.”

⁷ I am not aware of any mandatory recalls of biological drugs, and there have been only a few mandatory device recalls. These include a 1992 recall of a ventilating system used with critically ill infants suffering from hyaline membrane disease and failing on conventional ventilation. Numerous software failures, humidification component failures, high intermittent pressures and high peak pressures, and pinch valve malfunctions were cited as reasons for the recall order. They also include a 1992 recall of a disinfecting solution for dialysis machines and hemodialyzers, because – when used as directed on the label – it was not an effective sterilant and not as effective as high level disinfectants.

⁸ 41 Fed. Reg. 26924, 29924 (June 30, 1974) (preamble to proposed recall regulations).

⁹ *Id.* Public interest groups periodically suggest, and members of Congress periodically introduce, legislation to give the agency authority to mandate recalls of any products within its purview. These proposals focus more often on food recalls than on drug recalls. There have also been legislative proposals to require FDA to notify patients and pharmacists of drug and device recalls.

¹⁰ 21 U.S.C. § 334.

¹¹ Regulatory Procedures Manual § 7-5-2.

¹² *Id.*

filled infant teething rings were the subject of a Class I recall in January because they were filled with *Pseudomonas aeruginosa* and *Pseudomonas putida*. A Class II recall occurs when 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. There was recently a Class II recall of a powered wheelchair because, when operated beyond a specific angle of incline, it could travel at an unsafe speed. A Class III recall occurs when use of or exposure to a violative product is not likely to cause adverse health consequences. Boston Scientific recently conducted a Class III recall of some of its Cilli II Cooled Ablation Catheters because they were mislabeled with the incorrect catheter curve description. Class I recalls are the least common, and Class II are the most common.¹³ The classification of a particular recall does not determine the ultimately recall strategy employed, but it communicates to the public the relative gravity of the hazard involved.¹⁴

II. Preparing for a Recall

FDA concludes its recall regulations by setting forth measures a “prudent firm” can take to minimize disruption in the event of a recall.¹⁵ First, FDA suggests preparing and maintaining a “current written contingency plan for use in initiating and effecting a recall in accordance with” agency guidelines.¹⁶ Second, FDA instructs companies to adequately code regulated products in order to make positive lot identification possible and to facilitate effective recall of all violative lots.¹⁷ Third, FDA encourages the maintenance of product distribution records necessary to assist in the location of a recalled product.¹⁸ These records should be kept for a period of time that exceeds the product’s shelf-life and expected use and that is at least as long as the retention period specified in other applicable regulations.¹⁹

The “written contingency plan” should be a Standard Operating Procedure (SOP) that specifies what steps must be taken, in what sequence, and by whom, as soon as a potential recall situation has been identified. These steps will typically include – in roughly this order – evaluating the information received, identifying the nature and source of the problem, determining its breadth and depth, evaluating the potential health consequences, deciding whether to recall, deciding whether FDA should be notified, developing a recall strategy, communicating that strategy to FDA and working with the agency as appropriate to shape it, implementing the recall, and conducting effectiveness checks. There will be roles for personnel

¹³ See FDA Enforcement Report Index (2006), available at <http://www.fda.gov/po/enforceindex/2006enforce.html>.

¹⁴ 41 Fed. Reg. at 26926.

¹⁵ 21 C.F.R. § 7.59.

¹⁶ 21 C.F.R. § 7.59(a).

¹⁷ 21 C.F.R. § 7.59(b).

¹⁸ 21 C.F.R. § 7.59(c).

¹⁹ *Id.*

from essentially every division of the company, with prominent roles for Quality Assurance, Regulatory Affairs, Legal Counsel, and Senior Management. It is usually helpful to identify a core team that will manage the recall and to assign key individuals decision-making authority at critical points in the process. It may be helpful to orchestrate a mock recall to test the effectiveness of the SOP. Finally, as suggested in section IV, it would be prudent for the firm to review its insurance coverage in the event of a recall.

III. Executing a Recall

A. Determining whether a recall is necessary

As noted above, a “recall” is the removal or correction of a marketed product that FDA considers to be in violation of the law and against which the agency would initiate legal action. When a firm becomes aware of a potential recall situation, it needs to determine whether the product violates the FDCA or PSHA and whether FDA would likely take legal action. The response to the first question typically turns on whether the product is “adulterated” or “misbranded.” The response to the second question is more complicated. Resource constraints mean that FDA would not take action against any number of minor violations, and indeed it is possible in some situations to persuade the agency that a particular violation is sufficiently minor to justify a “market withdrawal” rather than a “recall.” In other cases, however, even if FDA would not take legal action, the agency nevertheless will expect the company voluntarily to recall. Accordingly, the decision whether to recall when a minor violation presents no health hazard may be something of a business judgment.

The definition of adulteration can be found in section 501 of the FDCA. This provision applies to drugs, devices, and biological products licensed under the PSHA that meet the definition of “drug” under the FDCA. A drug is adulterated if consists in whole or in part of any filthy, putrid, or decomposed substance, or it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. A drug is also adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to current good manufacturing practice (GMP); if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; if it purports to be a drug recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in that compendium; if its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or if a substance has been mixed or packed with it so as to reduce its quality or strength.

A device is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. A device is also adulterated if it is subject to a performance standard established under section 514 of the FDCA and does not conform to the standard, or it is declared to be in conformity with a standard recognized by the Secretary under section 514(c) and fails to conform with that standard. A device is also adulterated if the methods used in, or

the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable GMP requirements.

The definition of misbranding can be found in section 502 of the FDCA. This provision, too, applies to drugs, devices, and biological products licensed under the PSHA that meet the definition of “drug” under the FDCA. A drug or device is misbranded if its labeling is false or misleading in any particular. A drug is also misbranded if its label does not include the established name and quantity (or proportion) of each active ingredient and the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package. A drug is misbranded if it purports to be a drug recognized in an official compendium, unless it is packaged and labeled as prescribed in that compendium. And it is misbranded if its container is made, formed, or filled so as to be misleading, or if its packaging or labeling violates an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

B. Notifying FDA

A firm has no legal obligation to notify FDA that it is planning or initiating a voluntary drug recall. FDA encourages companies to provide notification of recalls, however, and it expects to be involved in the planning of any Class I recall. There may be situations where it is reasonable not to notify the agency of a Class III recall, and some (fewer) situations where it is reasonable not to notify of a Class II recall. These are business judgments. It is possible, if one reports a recall, that FDA will decide the recall requires a higher classification or that the agency will request changes in the wording of the firm’s recall communications. Not reporting a recall, however, can affect the firm’s relationship with the agency. Seeking the agency’s input in the planning process can also prevent an enforcement action after the fact, if the agency concludes the recall lacked sufficient depth or breadth.

Pursuant to section 519(f) of the FDCA, FDA promulgated regulations in part 806 requiring manufacturers and importers to report promptly certain “corrections” and “removals” of medical devices. A report to FDA is required within 10 working days of initiating a correction or removal (1) to reduce a risk to health posed by the device, or (2) to remedy a violation of the FDCA where the device may present a risk to health.²⁰ A device poses a “risk to health” if (1) there is a “reasonable probability” that use of the device will cause serious adverse health consequences or death, or (2) use of the device may cause temporary or medically reversible adverse health consequences or an outcome where the probability of serious adverse health consequences is remote.²¹ This definition is the same as the definitions for Class I and Class II recalls in 21 C.F.R. § 7.3(m). As a practical matter, therefore, FDA will learn of Class I and Class II medical device recalls through its part 806 authority.

²⁰ 21 C.F.R. § 806.10.

²¹ 21 C.F.R. § 806.2.

If the firm decides to notify FDA, the Recall Coordinator in the district office where the firm's headquarters is located should be the first point of contact. FDA recommends that a firm notify the Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to issuing a press release or written notification to customers.

FDA's part 7 guidelines ask that a firm initiating a recall provide the agency with the following information: (1) the identity of the relevant product; (2) the reason for the recall and the date and circumstance under which the actual or potential deficiency was discovered; (3) an evaluation of the risks associated with the violative product; (4) the amount of the product produced and/or the timeframe of production; (5) the quantity of the product distributed; (6) distribution information, including the number and identity of those to whom the product has been distributed; (7) a copy of the recall communication or a proposed recall communication if none has issued; (8) a proposed recall strategy; and (9) the name and telephone number of designated firm contact person.²² Some of this information will not be complete at the time of first contact. The "recall communication" and "recall strategy" are discussed below. FDA may request some or all of this information in the event of an FDA-initiated recall.²³

The recall itself involves several distinct yet related steps, intended to ensure, to the extent required to protect public health, the orderly removal or remedy of violative products.²⁴ The steps of the recall process – described in the sections that follow – are: (1) evaluation of the health hazard associated with the product being recalled or being considered for recall; (2) development and implementation of a recall strategy; (3) communications to the firm's customers; (4) periodic reports on the progress of the recall; and (5) termination of the recall and proper disposition or correction of the violative products.²⁵

C. Evaluation of the health hazard

When faced with a potential recall, a firm must evaluate the health hazard presented by the product. The general purpose of a "health hazard evaluation" (also called a "health hazard assessment") is to identify and document (1) the nature of the risk presented by the product; (2) the population at risk; (3) any conditions that may exacerbate or attenuate the risk in this population; and (4) the likelihood of the risk occurring. Section 7.41 of the agency's regulations, and attachment D1 to the Regulatory Procedures Manual, provide guidance for a firm undertaking this evaluation.

An evaluation of the health hazard should take into account (1) whether any disease or injuries have already occurred from the use of the product; (2) whether any existing medical conditions could mask the risk from the product and whether products used to treat these

²² 21 C.F.R. § 7.46(a).

²³ 21 C.F.R. § 7.45(c).

²⁴ 41 Fed. Reg. at 26926.

²⁵ 41 Fed. Reg. at 26926.

conditions could contribute to (or lessen) the risk from the product; (3) the risk to various identifiable segments of the population, the relative frequency of use within each segment, and the risk to vulnerable groups like infants, children, elderly, pregnant women, and surgical patients; (4) the degree of seriousness of the hazard; (5) the likelihood of the occurrence of the hazard; and (6) short-term and long-term consequences of the hazard. The firm will want to consider the setting in which the product is used, the frequency of its use, the duration of its use, and how many users are under close medical supervision. It may be worth considering whether users could be brought under closer medical supervision and whether any medical interventions (for example, medical monitoring) could reduce the likelihood of harm. A hazard is “life threatening” if death could occur, “severe” if it could result in permanent significant disability, “moderate” if it could result in transient but significant disability or permanent minor disability, and “limited” if it could result in transient minor disability or annoying complaints. When determining the likelihood of harm occurring, the firm will want to look at how frequently the injury in question has already occurred, its frequency in relation to total product exposure, and the robustness of the documentation to date.

D. Development and implementation of recall strategy

A “recall strategy” is the “planned specific course of action to be taken in conducting a specific recall, which addresses the depth of the recall, need for public warnings, and extent of effectiveness checks for the recall.”²⁶ Each recall is unique and requires its own recall strategy. In the case of an FDA-requested recall, the agency will develop the recall strategy.²⁷ In the case of a firm-initiated recall, the recalling firm will develop the recall strategy.²⁸ The strategy must “suit the individual circumstances of the particular recall” and must take into account among other relevant factors: (1) the results of the health hazard evaluation; (2) the ease in identifying, isolating, and removing the violative product; (3) the degree to which the product’s deficiency is obvious to the consumer or user; (4) the amount of product remaining on the market; and (5) the need for continued availability of essential product.²⁹

FDA part 7 guidelines identify three elements essential to any recall strategy.³⁰ First, a strategy should discuss the “depth of the recall.”³¹ In other words, it must identify the appropriate level in the distribution chain (consumer/user, retail, or wholesale) to which the recall should extend, in light of the risk of harm posed by and the extent of distribution of the product.³² If a recall extends only to the wholesaler and distributor level, the firm should be

²⁶ Investigations Operations Manual, § 7.1.1.4.

²⁷ 21 C.F.R. § 7.42(a)(1).

²⁸ 21 C.F.R. § 7.42(a)(1).

²⁹ 21 C.F.R. § 7.42(a)(1); 41 Fed. Reg. at 26927.

³⁰ 21 C.F.R. § 7.42(b).

³¹ 21 C.F.R. § 7.42(b)(1).

³² 21 C.F.R. § 7.42(b)(1).

prepared to explain its rationale for not recalling to retail and pharmacy level.³³ Second, the recall strategy should specify whether a “public warning” is required, and if so whether that warning will issue through generalized or special news media.³⁴ A “public warning” is appropriate in “urgent situations” where a recalled product “presents a serious hazard to health.”³⁵ FDA will typically issue the public warning itself.³⁶ Third, the strategy should identify the methods to be used for “effectiveness checks,” which are intended to verify that recipients of the recalled product have received notice of the recall and have taken appropriate action in response.³⁷ FDA’s part 7 guidelines specify five levels of effectiveness checks.³⁸

E. Recall communications

A recalling firm is responsible for promptly notifying each of its affect direct accounts about any recall it initiates. This is the “recall communication,” and it is discussed in section 7.49 of the agency’s regulations. The format, content, and extent of a recall communication depend on the product, the hazard, and the nature of the direct accounts. Generally, however, it should convey (1) that the product is subject to a recall; (2) that further distribution or use of the product should stop immediately; (3) when appropriate, that the recipient should in turn notify the next party in the chain of distribution of the recall; and (4) what to do with the product.³⁹ Section 7.49(d) states that direct consignees who receive a recall communication should “immediately carry out the instructions” in the communication and, where necessary, extend the recall to those to whom it has distributed the recalled product.⁴⁰ FDA recommends that the firm include a self-addressed stamped card for the recipient to complete and return, when the instructions have been followed.

³³ Investigations Operation Manual, § 7.1.1.4.

³⁴ 21 C.F.R. § 7.42(b)(2).

³⁵ *Id.*

³⁶ FDA also publishes in the *FDA Enforcement Report* a “descriptive listing of each new recall according to its classification; whether it was [FDA]-requested or firm-initiated, and the specific action being taken by the recalling firm.” 21 C.F.R. § 7.50.

³⁷ 21 C.F.R. § 7.42(b)(3); *see* 41 Fed. Reg. at 26927. Normally, the recalling firm is charged with conducting these checks, but, where necessary and appropriate, FDA will assist. 21 C.F.R. § 7.42(b)(3). FDA will also conduct “audit checks,” which essentially verify the firm’s effectiveness checks.

³⁸ 21 C.F.R. § 7.42(b)(3). The levels range from “Level A” in which 100 percent of consignees are contacted to “Level E” in which none of the consignees are contacted. *Id.* A “consignee” is anyone who received, purchased, or used the product being recalled. 21 C.F.R. § 7.3(n).

³⁹ 21 C.F.R. § 7.49(a).

⁴⁰ 21 C.F.R. § 7.49(d).

The “format, content, and extent” of recall communication should be appropriate in light of the hazard posed by the product being recalled and the ultimate recall strategy.⁴¹ For example, if a consumer-level recall is warranted given the health hazard, but the risk to patients from abrupt interruption of therapy is greater than the risk associated with the health hazard, it may be appropriate to communicate the recall in a way that encourages consumers to immediately consult their health care practitioners. A firm may also need to consider bilingual or multilingual recall notifications. FDA recommends that Recall Notifications be flagged with large bold print (“**URGENT: DRUG RECALL**” or “**URGENT: MEDICAL DEVICE RECALL.**”) Envelopes should be similarly flagged. FDA has issued sample notifications.

A press release may also be warranted. FDA has explained that where a product may pose a “significant health hazard” and the recalled product “is in the hands of consumers,” a press release “is usually appropriate.” Further, it is FDA policy “that press releases issue for Class I recalls, unless specific circumstances indicate that a press release would not be beneficial to the public.”⁴² FDA has issued a model press release. The agency also recommends that a firm consult with the Recall Coordinator before issuing any press release. The agency may also ask that the firm permit the District Office to review all recall correspondence and press releases prior to use. While the company is not legally required to agree, if FDA believes the firm’s communications and press releases are inadequate, it may release its own. In some situations, a joint press release may be helpful.

F. Reports to FDA

FDA expects a recalling firm to provide periodic status reports regarding the progress of the recall.⁴³ Status reports are described in section 7.53 of the agency’s regulations. The frequency of the reports should depend on the urgency of the recall, but generally the agency will suggest a report every two to four weeks.⁴⁴ Typically they are to be submitted to the local Recall Coordinator. Unless otherwise specified by the agency or inappropriate for the recall in question, a status report should state: (1) the number of recipients of the product notified of the recall and the method of notification; (2) the number of recipients responding to the recall and the number of products each recipient had in its possession upon receipt of the recall notification; (3) the number of recipients that did not respond; (4) the number of products returned pursuant to the recall; (5) the number and results of effectiveness checks conducted by the firm; and (6) the estimated completion date for the recall.⁴⁵

⁴¹ 21 C.F.R. § 7.49.

⁴² Regulatory Procedures Manual, § 7-7-3.

⁴³ 21 C.F.R. § 7.53; *see* 41 Fed. Reg. at 26927.

⁴⁴ 21 C.F.R. § 7.53(a).

⁴⁵ 21 C.F.R. § 7.53(b).

G. Termination of the recall

Termination of a recall is described in section 7.55 of the agency's regulations. A recall may be terminated when "all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy" and it is rational to assume that "the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product."⁴⁶ FDA's determination that this standard has been met may be based upon information provided in recall status reports, FDA inspections, or a written request from the recalling firm.⁴⁷ In a Class I recall situation, once the monitoring district determines the recall has been effective, a recall termination is prepared for the review and approval of the Center Director.⁴⁸ Prior approval by the Center is not required for termination of a Class II or III recall.⁴⁹ In every case, written notification that a recall is terminated will be issued by the appropriate District office to the recalling firm.⁵⁰ FDA will not terminate a recall until the firm has brought the product into compliance or disposed of it in an acceptable manner.

IV. Conclusion

A product recall will have several collateral consequences, and the relationship between these consequences and decisions the firm must make during the recall can be complicated. Most of these issues are beyond the scope of this paper, but should be considered by a firm as it prepares its recall SOP and as it implements recalls. For example, a recall may be very expensive – due to out-of-pocket costs to implement the recall, costs of replacing the products, any downturn in sales during a period of uncertainty, and the cost of reestablishing the firm's reputation.⁵¹ Many of the expenses may not be covered by the firm's commercial general liability (CGL) insurance, although they might be covered by a separate recall insurance policy. The firm's SEC counsel should be consulted to determine whether there may be disclosure obligations associated with the recall. Also, there could be considerable media attention. How a firm conducts a highly-publicized class I recall, in particular, can have significant consequences

⁴⁶ 21 C.F.R. § 7.55(a).

⁴⁷ 41 Fed. Reg. at 26927; *see* 21 C.F.R. § 7.53(b).

⁴⁸ Regulatory Procedures Manual, § 7-9.

⁴⁹ *Id.*.

⁵⁰ *Id.*

⁵¹ Coca-Cola lost almost 10 percent of its stock value between the time Belgian consumers became ill after drinking its product and the day the company chairman apologized in full page ads in European newspapers. Direct costs of withdrawing Perrier products from shelves worldwide in 1990, after a benzene contamination was found, may have been as much as \$30 million. The cost of Johnson & Johnson's recall is generally thought to have been around \$100 million. *See* Daniel T. Torpey, "Are You Ready for Total Recall? A Guide to Product Recalls and the Insurance that Covers Them," IRMI.com (November 2000).

for the reputation of its brand. Even a well-executed recall, however, can attract the attention of product liability lawyers, and it may not always be possible to exclude documentation relating to the recall from litigation. This possibility should be assessed and may influence decisions in the SOP relating to use of email, other documentation practices, and involvement of counsel. A market withdrawal or stock recovery may attract less attention than a recall, but the firm's insurance policy may cover only recalls and not market withdrawals and stock recoveries. Indeed, the company should expect closer scrutiny in general after a recall. FDA will inspect the firm in the case of a Class I recall or a significant Class II recall, although the inspection is usually limited to the product at issue. A full-blown GMP inspection may result, however, depending on the findings of the initial inspection. FDA may also notify state and/or local officials about the recall, as well as Canadian regulatory authorities, and foreign and military consignees. This may prompt other inquiries, inspections, and even breach of contract disputes. A highly-publicized recall may also attract Congressional attention, although typically members of Congress will focus more on the adequacy of the agency's authority and response than on the firm's conduct.⁵² Although uncommon, criminal investigations, civil suits, and shareholder litigation can follow in some cases. While these collateral consequences should not drive the decision whether to recall and how to implement the recall, they may influence decisions at the margins and, in any case, may trigger a cascade of additional decisions.

⁵² For example, Congressmen Stark and Waxman asked FDA to respond to a series of questions relating to the agency's handling of a 1994 recall by Ethicon of its Vicryl disposable sutures. See, e.g., "Reps Stark and Waxman Question FDA's Ability to Supervise Recalls," *The Gray Sheet* (June 28, 1999).

THE LEGAL BACKGROUND FOR FDA MEDICAL DEVICE AND DRUG RECALLS

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Properly Executed Recalls

- FDA does not expect a company to be “recall free,” but it does expect a company’s recalls to be conducted properly.
- Properly executed recalls:
 - Facilitate protection of the public health.
 - Potentially reduce a company’s product liability exposure.

Properly Executed Recalls

- They also:
 - Instill in FDA a perception that the company can and will take effective remedial action when needed.
 - Avoid FDA legal and/or administrative actions based on untimely or inappropriate recalls or other field actions.

Focus of Discussion

- Legal background for recalls involving medical devices and drugs regulated by FDA.
- FDA's mandatory recall and related authority.
- Potential consequences of not initiating a recall when necessary.

Focus of Discussion

- The interaction of recalls and the good manufacturing practice obligation to take timely and appropriate corrective and preventive actions.
- The possible need to obtain premarket approval, licensure or clearance to effectuate a recall.

LEGAL BACKGROUND

“Part 7” Recalls

- FDA does not have authority to mandate compliance with Part 7; Part 7 is not law.
- A firm may wish to voluntarily comply with some or all of Part 7 as an alternative to FDA taking legal action.
- Part 7 defines key terms, establishes a recall classification scheme, and provides guidance on conducting a recall.

Definitions

- “Recall”
 - A firm’s removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.
 - “Recall” does not include a “market withdrawal” or “stock recovery.”
 - 21 C.F.R. § 7.3(g).

Definitions

- “Correction”
 - The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.
 - 21 C.F.R. § 7.3(h).

Definitions

- “Market withdrawal”
 - A firm’s removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
 - 21 C.F.R. § 7.3(j).

Definitions

- “Stock recovery”
 - 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).

Recall Classification Scheme

- Class I Recall – A situation in which there is a reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death.
– 21 C.F.R. § 7.3(m)(1).

Recall Classification Scheme

- Class II Recall – A situation 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.
– 21 C.F.R. § 7.3(m)(2).

Recall Classification Scheme

- Class III Recall – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
 - 21 C.F.R. § 7.3(m)(3).

Part 7 Recall Guidance

- Describes how FDA will conduct its Health Hazard Evaluation (HHE) and classify the recall.
- Describes specific considerations for FDA-requested and firm-initiated recalls.

Part 7 Recall Guidance

- Describes factors for determining a recall strategy and its elements.
 - Depth of recall.
 - Need for public warning.
 - Extent of effectiveness checks.

Part 7 Recall Guidance

- Discusses recall communications (form and content).
- Discusses public notification of recalls by FDA.
- Discusses FDA's expectations for recall status reports and recall termination requests to the agency.
- Discusses steps a firm can take to prepare in advance for a voluntary recall.

Other Guidance Documents

- “Methods for Conducting Recall Effectiveness Checks” (June 16, 1978).
- “Guidance for Industry: Product Recalls, Including Removals and Corrections” (November 3, 2003).

Mandatory Recall and Related Authority

Mandatory Recall Authorities

- Infant formula
 - 21 U.S.C. § 350a(e)-(g); 21 C.F.R. Part 107, Subpart E.
- Medical devices
 - 21 U.S.C. § 360h(e); 21 C.F.R. Part 810.

Mandatory Recall Authorities

- Human biological products
 - 42 U.S.C. § 262(d).
- Human cell and tissue products
 - 21 C.F.R. §§ 1270.43 and 1271.440.

Mandatory Device Recall Process

- If FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, it may issue an order regarding cessation of use of the device to the appropriate persons.
 - 21 U.S.C. § 360h(e)(1); 21 C.F.R. Part 810.

Order

- At this stage, the order does not require recall of the device.
- It does require appropriate persons (including manufacturers, importers, distributors, or retailers of the device) to:

Order

- Immediately cease distribution of such device;
- Immediately notify health professionals and device user facilities of the order; and
- Instruct such professionals and facilities to cease use of such device.

Hearing on the Order

- Opportunity for informal hearing to determine if adequate grounds exist for the issuance of the order.
- Request hearing within 10 days of issuance.

Hearing Actions

- If inadequate grounds, order to be vacated.
- Otherwise, order may be amended to include the mandatory recall of the device and:

Hearing Actions

- To specify a timetable for the recall;
- To require periodic reports to the agency on recall status and progress;
and
- Provisions for notification to individuals subject to the risks associated with use of the device.

Mandatory Biological Product Recalls

- If FDA determines that a batch, lot or other quantity of a licensed biological product presents an immediate or substantial hazard to the public health, FDA shall issue an order immediately requiring the recall of such batch, lot or other quantity of such product.
– 42 U.S.C. § 262(d)(1).

Mandatory Biological Product Recalls

- Opportunity for hearing before the agency pursuant to 5 U.S.C. § 554.
- Potential civil penalty of \$100,000/day for each violation.

Mandatory Recalls Under Part 1270

- Applies to “human tissue for transplantation” recovered before May 25, 2005.
- If FDA finds that tissue may be in violation of 21 C.F.R. Part 1270, it can order a tissue establishment to recall the tissue.
- An establishment must request a hearing on the order within five working days of receipt of order.

Mandatory Recalls Under Part 1271

- Applies to “human cells, tissues and cellular and tissue-based products” (HCT/P) regulated under 21 C.F.R. Part 1271.

Mandatory Recalls Under Part 1271

- Upon an agency finding that there are reasonable grounds to believe that an HCT/P is violative because it was manufactured in violation of Part 1271, it was infected or contaminated, or the relevant HCT/P establishment is otherwise in violation of Part 1271.
- FDA may, among other things, order the HCT/P establishment to recall the product.

When Part 1271 Order is Effective

- When there are reasonable grounds to believe there is a danger to health, such an order will be effective immediately.

When Part 1271 Order is Effective

- In other cases:
 - Passage of five working days from the establishment's receipt of the order; or
 - If the establishment requests a Part 16 hearing, a decision in favor of the order in accordance with those proceedings.

Medical Device Reports of Corrections and Removals

- Required for any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device which may present a risk to health.
 - Even if event was caused by user error.
- 21 U.S.C. § 360i(f); 21 C.F.R. Part 806.

Reports Not Required

- If the information has already been provided to FDA under:
 - 21 C.F.R. Part 803 (MDR);
 - 21 C.F.R. Part 1004 (Purchase, Repairs, or Replacement of Electronic Products); or
 - 21 C.F.R. Part 810 (Mandatory Device Recalls).

Reports Not Required

- Manufacturers and importers must keep records of those corrections or removals that are not required to be reported to FDA.
 - 21 C.F.R. § 806.20.

“Risk to Health”

- Definition in Part 806 tracks the definitions of Class I and Class II recalls under 21 C.F.R. § 7.3(m).
- Part 806 does not require reporting recalls categorized as Class III under Part 7.

Actions Exempt from Reporting Under Part 806

- Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the FDC Act caused by the device;
- Market withdrawals;
- Routine servicing; and
- Stock recoveries.

FDA's "Other Avenues"

- Condemnation and seizure under 21 U.S.C. § 334.
- Court-ordered injunction under 21 U.S.C. § 332.
- Prosecution under 21 U.S.C. § 333(a) or 42 U.S.C. § 262(f).
- Civil money penalties for device violations under 21 U.S.C. § 333(g).

FDA's "Other Avenues"

- Warning Letters.
- Ordered repair, replacement, or refund of devices. 21 U.S.C. § 360h(b).
- Other enforcement tools exist as well.

Linkage to Manufacturing Practices

- Medical devices, drugs, and biological products – subject to cGMPs.
- Requirement to take corrective or preventive actions to address non-conforming product and other quality problems may involve the conduct of a voluntary recall.
- Failure to do so may implicate prohibited acts under the FDC Act.

Linkage to Premarket Approval

- Many recalls involve corrections.
- Corrections may require premarket approval, licensure or clearance.
- If required, not obtaining adulterates and/or misbrands the product, or otherwise makes it violative, exposing the firm to FDA enforcement action.

Questions?

Neil F. O'Flaherty, Esq.

THE LEGAL BACKGROUND FOR FDA MEDICAL DEVICE AND DRUG RECALLS

BY

Neil F. O'Flaherty

INTRODUCTION

Recalls will occur. Even the most compliant company at some point in time will be faced with the need to remove or correct a product in the field due to a design, composition, contamination, manufacturing, labeling, or other problem. The U.S. Food and Drug Administration (FDA) realizes that such actions will occur and does not expect companies to be “recall free.” However, FDA does expect recalls, and other types of field actions, to be executed in a timely and appropriate fashion when needed. Timely and proper execution of necessary recalls and other field actions can greatly facilitate protection of the public health. It also can potentially reduce a company’s product liability exposure. Finally, it can instill in FDA a perception that the company can and will take effective remedial action when needed, and help a firm to avoid FDA legal and/or administrative actions based on untimely or inappropriate recalls or other field actions.

This paper will discuss and explore the legal background for recalls involving medical devices and drugs regulated by FDA, including FDA’s mandatory recall and related authority. It will also discuss the potential consequences of not initiating a recall when necessary. Finally, it

will explore the interaction of recalls and the good manufacturing practice obligation to take timely and appropriate corrective and preventive actions with respect to FDA-regulated products, as well as the possible need to obtain premarket approval, licensure or clearance to effectuate a corrective action under certain circumstances.

LEGAL BACKGROUND

1. FDA's Recall Guidelines

When one talks about recalls, one most often is referring to voluntary recall actions undertaken by FDA-regulated firms – for our purposes – medical device and drug product firms. The starting point for understanding FDA's expectations and guidance for such voluntary recalls is 21 C.F.R. Part 7 ("Part 7") (attached). Because FDA's voluntary recall provisions are found in the Code of Federal Regulations, one might think that the provisions are regulations with the force and effect of law. In actuality, they are not. Except in some rare circumstances which are discussed below, FDA cannot mandate a product recall. It also cannot require a firm to follow the Part 7 recall provisions. As FDA acknowledged in its preamble to the final recall guidelines:

The Commissioner acknowledged in the preamble to the proposed regulations that product recall is a voluntary action requiring the cooperation and willingness of a firm to carry it out. Accordingly, it is not the purpose of this document to establish enforceable

recall requirements. Instead, the provisions of this final rule are being issued as guidelines . . . and they are intended solely to define FDA's recall policies and procedures and to provide guidance to firms so they may more effectively discharge their recall responsibilities.

See Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibilities. 43 Fed. Reg. 26202 (June 16, 1978).

Having said this, FDA looks at conducting voluntary recalls pursuant to Part 7 as an alternative to the agency's taking legal action, e.g., seizure, under the Federal Food, Drug, and Cosmetic (FDC) Act, to address the product problem in question. As FDA states in Part 7:

Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall

responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

21 C.F.R. § 7.40(a).

2. Definition of "Recall" and Classification Scheme

Part 7 defines what FDA considers to be a recall and establishes a recall classification scheme. FDA defines "recall" in Part 7 as a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. 21 C.F.R. § 7.3(g). "Recall" does not include a "market withdrawal" or "stock recovery." Id. Under Part 7, "correction" means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location. 21 C.F.R. § 7.3(h). A "market withdrawal" means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. 21 C.F.R. § 7.3(j). A "stock recovery" means 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).

There are three classes of recalls under Part 7 which are based on risk to the public health:

- Class I recall – A situation in which there is a reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II recall – A situation 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.
- Class III recall – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

21 C.F.R. § 7.3(m)(1)-(3). FDA will assign a recall a classification (i.e., Class I, Class II, or Class III) to indicate the relative degree of health hazard of the product being recalled. 21 C.F.R. § 7.41(b).

3. FDA's Expectations and Guidance

In Part 7, FDA also provides its expectations and guidance on how to plan and execute a voluntary recall and how to interact with the agency on a recall. Many aspects of a voluntary recall are covered. Section 7.41 describes how FDA will conduct a health hazard evaluation of a violative product subject to recall in furtherance of classifying the recall into Class I, II, or III. Oftentimes, firms will conduct their own health hazard evaluation to support a determination of the appropriate classification of a recall. As discussed below, a device firm's determination in this regard can be critical when it is deciding whether it has an obligation to submit a mandatory report of device correction or removal under 21 C.F.R. Part 806. Of course, FDA can disagree with a firm's classification determination.

Section 7.42 discusses the factors for determining a recall strategy and the elements involved in a recall strategy, including the depth of the recall (consumer/user level, retail level or wholesale level), the need for a public warning (above and beyond the recall communication to consignees), and the extent of necessary recall effectiveness checks. Section 7.45 deals with FDA-requested recalls, including factors to be considered by the agency in determining whether to request a voluntary recall and what information should be requested of a firm. Section 7.46 deals with firm-initiated recalls, and, among other things, describes the information that should be submitted to FDA about the voluntary recall. Section 7.49 provides guidance on recall communications, including format and content, among other things. Section 7.50 describes how FDA will notify the public of recalls through its published enforcement reports. Sections 7.53

and 7.55 provide FDA's expectations and guidance on submitting recall status reports and recall termination requests to the agency. Finally, in Section 7.59, FDA provides general guidance for firms in terms of steps that they can take to prepare for voluntary recalls in advance, including (1) preparing and maintaining a written contingency plan for initiating and effecting a recall, (2) using sufficient coding of products to make possible positive identification of product and to facilitate effective recall of all violative lots, and (3) maintaining such product distribution records as are necessary to facilitate location of products that are being recalled.

4. Other FDA Recall Guidance

Over the years, FDA has issued certain additional guidance documents to provide further recommendations and suggestions on conducting recalls. For instance, FDA issued an additional guidance on conducting effectiveness checks, entitled "Methods for Conducting Recall Effectiveness Checks" (June 16, 1978). More recently in 2003, FDA issued its "Guidance for Industry: Product Recalls, Including Removals and Corrections" (Nov. 3, 2003). Among other things, this guidance takes account of FDA's mandatory recall authority and elaborates on its policies and procedures under Part 7. The guidance states:

This guidance is intended to assist those members of industry regulated by the Food and Drug Administration (FDA) in handling all aspects of a product recall, including all corrections and removals. The guidance includes a checklist of documentation

and information that FDA utilizes to evaluate, classify, monitor and audit product recalls. Various statutory provisions and regulations, described below, authorize FDA to require recalls of certain products in particular circumstances. Additionally, Subpart C of Part 7 of FDA regulations (21 C.F.R. §§ 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own or at FDA's request. This guidance provides more specific recommendations and applies to both mandatory and voluntary recalls of all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical and radiological devices; cosmetics; human biological products, including blood; and human tissue.)

The guidance was issued by the FDA Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Management and Operations.

5. FDA Mandatory Recall and Related Authority

As the November 2003 guidance points out, certain statutory provisions within the FDC Act and the Public Health Service (PHS) Act authorize mandatory recalls of infant formula (21 U.S.C. § 350a(e)-(g)), medical devices (21 U.S.C. § 360h(e)), and human biological products

(42 U.S.C. § 262(d)). Additionally, FDA statutes and regulations set forth specific requirements for mandatory infant formula recalls (21 C.F.R. Part 107, Subpart E), mandatory reporting of and recordkeeping on certain medical device corrections and removals (21 U.S.C. § 360i(f); 21 C.F.R. Part 806), and mandatory human cell and tissue product recalls (21 C.F.R. §§ 1270.43 and 1271.440). This paper will focus on medical device and biological product mandatory recall authority (as most biological products are technically drugs),² as well as the mandatory reporting and recordkeeping requirements for certain medical device corrections and removals. It will also briefly discuss human cell and tissue product mandatory recalls as these products are an emerging area of FDA regulation.

a. Medical Device Mandatory Recall Authority

Congress provided FDA with mandatory recall authority relative to medical devices at 21 U.S.C. § 360h(e). Pursuant to this section, if FDA finds there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, it shall issue an order requiring the appropriate persons (including the manufacturers, importers,

² The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clauses (A), (B) or (C). While biological products are regulated under the Public Health Service Act, 42 U.S.C. §§ 262-263, the FDC Act applies to biological products subject to regulation under 42 U.S.C. § 262. 42 U.S.C. § 262(g). Thus, for example, biological products are subject to the

distributors, or retailers of the device) to immediately cease distribution of such device, to immediately notify health professionals and device user facilities of the order, and to instruct such professionals and facilities to cease use of such device. The order shall provide the person subject to it with an opportunity for an informal hearing, to be held not later than 10 days after issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such devices.

If, after providing an opportunity for such a hearing, FDA determines that inadequate grounds exist to support the actions required by the order, the agency is required to vacate the order. If, after providing an opportunity for an informal hearing, the agency determines that the order should be amended to include a recall of the device, FDA shall amend the order to require a recall. FDA shall specify a timetable in which the device recall will occur and shall require periodic reports to be submitted to the agency describing the progress of the recall. An amended order shall not include recall of the device from individuals, and shall not include recall of the device from device user facilities if the FDA determines that the risk of recalling such devices from such facilities presents a greater health risk than the health risk of not recalling the device from use. The amended order shall also provide for notice to individuals subject to the risks associated with use of the device. FDA may utilize the assistance of health professionals who prescribe or use the device in notifying the individuals. If a significant number of such individuals cannot be identified, FDA shall notify such individuals by public dissemination of

same seizure and injunction authority as conventional drugs and medical devices under 21 U.S.C. §§ 332 and 334.

information pursuant to 21 U.S.C. § 375(b). The regulations at 21 C.F.R. Part 810 implement the statutory provision of Section 360h(e).

Very few mandatory device recalls have been ordered. One example is the Medline Dynafed enteral pump in 1991. According to FDA, these pumps had a number of design defects apparently caused by an initially flawed design and/or lack of validation and inability to comply with good manufacturing practices. According to CDRH, there have been many instances where it has been prepared to issue a mandatory recall order. However, the firms decided to conduct the recall voluntarily, although they initially did not want to conduct a recall. In practice, according to CDRH, if FDA feels a product presents a significant safety issue to the public health and the firm is resistant to disclose the problem to the public, the agency normally will issue a press release. This action has been sufficient to convince firms that they need to conduct a recall in most cases, according to CDRH.

b. Biological Product Mandatory Recall Authority

As for biological products, mandatory recall authority is found at 42 U.S.C. § 262(d). Under § 262(d), upon a determination that a batch, lot or other quantity of a licensed biological product presents an immediate or substantial hazard to the public health, FDA shall issue an order immediately requiring the recall of such batch, lot or other quantity of such product. The order shall be issued in accordance with 5 U.S.C. § 554. Section 554 requires an opportunity for an evidentiary hearing before the agency on the record. Any violation of a § 262(d) recall order

shall subject the violator to a civil penalty of up to \$100,000 per day per violation. When asked, FDA was not aware of a case where this mandatory recall authority was used.

c. Human Cell and Tissue Product Mandatory Recall Authority

For “human tissue for transplantation” recovered before May 25, 2005, if FDA finds that the tissue may be in violation of 21 C.F.R. Part 1270, it can order a tissue establishment to recall the tissue, among other things. 21 C.F.R. § 1270.43(a). The written order will ordinarily provide that the human tissue be recalled within five working days from the date of receipt of the order and will state with particularity the facts that justify the order. 21 C.F.R. § 1270.43(b). Within five working days of receipt of a written order, the recipient must request a hearing on the matter in accordance with 21 C.F.R. Part 16 in order to challenge the action.

There are now similar provisions for “human cells, tissues and cellular and tissue-based products” (HCT/P) regulated under 21 C.F.R. Part 1271. Upon an agency finding that there are reasonable grounds to believe that an HCT/P is violative because it was manufactured in violation of Part 1271, it was infected or contaminated, or the relevant HCT/P establishment is otherwise in violation of Part 1271, FDA may, among other things, order the HCT/P establishment to recall the product. 21 C.F.R. § 1271.440(a).

When FDA determines that there are reasonable grounds to believe there is a danger to health, such an order will be effective immediately. 21 C.F.R. § 1271.440(a)(3). In other situations, such order will be effective only after the later of the following:

- Passage of five working days from the establishment's receipt of the order; or
- If the establishment requests a Part 16 hearing, a decision in favor of the order in accordance with those proceedings.

Again, the order should state with particularity the facts that justify the order and ordinarily will provide that the HCT/P be recalled within five working days from the date of receipt of the order (unless the action is challenged). 21 C.F.R. § 1271.440(c)(3).

FDA has implemented its Part 1270 "human tissue" mandatory recall authority multiple times. For example, in 1994, FDA ordered product recalls under Part 1270 of human skin and bone products for lack of proper communicable disease testing documentation, among other reasons. An example of FDA's use of its authority under 21 C.F.R. § 1271.440 occurred on January 31, 2006, when FDA ordered an HCT/P manufacturer to cease manufacturing and to retain HCT/Ps without further distribution due to serious Part 1271 violations. The firm had already conducted recalls. While this order was not a mandatory recall order, it shows the agency's willingness to issue orders pursuant to 21 C.F.R. § 1271.440.

d. Mandatory Reporting of Device Corrections and Removals

Under 21 U.S.C. § 360i(f) (with implementing regulations promulgated by FDA at 21 C.F.R. Part 806), medical device manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device or remedy a violation of the FDC Act caused by the device which may present a risk to health. A report must be made even if the event was caused by user error.

A report is not required, however, if the information has already been provided to FDA under the medical device reporting regulations (21 C.F.R. Part 803), under the “repurchase, repair, or replacement of electronic product” regulations (21 C.F.R. Part 1004), or under the medical device mandatory recall authority regulations (21 C.F.R. Part 810). Under 21 C.F.R. § 806.20(a), manufacturers and importers must keep records of those corrections or removals that are not required to be reported to FDA. However, if a report is not required under Part 806, the firm still may voluntarily report under 21 C.F.R. Part 7 as discussed above.

The definition of “risk to health” under 21 C.F.R. Part 806 tracks the definitions of Class I and Class II recalls under 21 C.F.R. § 7.3(m). Therefore, reports of device corrections and removals are required for Class I and II device recalls. Under Part 806, manufacturers and

importers need not report events categorized as Class III recalls under 21 C.F.R. Part 7; only the “correction and removal” recordkeeping requirements would apply under § 806.20(b).

The following actions are exempt from the Part 806 reporting requirements: (1) actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device; (2) market withdrawals; (3) routine servicing; and (4) stock recoveries. 21 C.F.R. § 806.1(b).

e. Other Enforcement Tools

Besides mandatory recall authority, FDA also has other avenues open to it to affect the removal or correction of product in the field. FDA has the ability to seek condemnation and seizure of violative product in court under 21 U.S.C. § 334. Any article that is adulterated or misbranded when introduced into interstate commerce shall be liable to be proceeded against on libel of information and condemned in any district court of the United States or any United States court of a Territory within the jurisdiction of which the article is found. In addition, FDA can also seek an injunction in court under 21 U.S.C. § 332 to force a company to take a particular action or to cease particular action. In this regard, FDA could seek a court-ordered recall of product.

Besides seizure and injunction authorities to address violative product in the field, FDA also has other enforcement tools at its disposal to address violations of the FDC Act. While a firm could face a seizure or injunction action based upon not taking a voluntary recall action when appropriate, the agency more generally could use some of its other enforcement tools to address the violations. For instance, FDA has the authority, through the Department of Justice, to prosecute violators under 21 U.S.C. § 333(a), as well as theoretically under 42 U.S.C. § 262(f) (for biological products). In the context of medical devices, FDA also can seek civil monetary penalties under 21 U.S.C. § 333(g). It also has the more often used, but less severe, enforcement tools of issuing Warning Letters and untitled compliance letters. There also are other more rarely used enforcement authorities such as the agency's ability to order the repair, replacement, or refund of devices. See 21 U.S.C. § 360h(b).

CURRENT GOOD MANUFACTURING PRACTICE AND PREMARKET APPROVAL CONSIDERATIONS FOR RECALLS

It is also worth noting that there is often a link between recalls and a firm's current good manufacturing practice (cGMP) obligation to take appropriate corrective action. This paper will use the device model to make this point, although similar concepts apply to drugs and biological products. FDA's Quality System Regulation (QSR), 21 C.F.R. Part 820, covers cGMPs for medical devices. Under 21 C.F.R. § 820.100, among other things, a device firm has the obligation to take actions needed to correct and prevent recurrences of nonconforming product and other quality problems. In some cases, this necessary action may involve the conduct of a

voluntary recall. As such, if FDA thought a recall was necessary to remove or correct nonconforming product or product with a quality problem, and a firm did not undertake such a recall, FDA theoretically could argue a violation of § 820.100 has occurred. Lack of compliance with QSR requirements adulterates a medical device under 21 U.S.C. § 351(h), and it is illegal to introduce into interstate commerce any adulterated or misbranded device under 21 U.S.C. § 331(a). Such a violation of the QSR and commission of a prohibited act, all generated potentially from not conducting a voluntary recall, trigger FDA's enforcement authorities. As discussed above, FDA has a vast array of enforcement possibilities at its disposal – seizure, injunction, Warning Letter, etc.

Many voluntary recalls will involve “corrections” to product. For example, a recall may involve relabeling of a product or repair, adjustment or modification of a product. Many such actions, depending on the significance of the change, may require premarket approval, licensure or clearance before the “corrected” product with the change can be placed into interstate commerce or used. For example, in the context of medical devices, a Class III medical device, originally authorized for marketing through the premarket approval application process, requires a PMA supplement approval prior to institution of any change which affects the safety or effectiveness of the device. 21 C.F.R. § 814.39. Other medical devices, cleared for marketing through the premarket notification (510(k)) submission process, need a new 510(k) clearance before they can be marketed with a change which could significantly affect their safety or effectiveness. 21 C.F.R. § 807.81(a)(3). Similar provisions exist for drug and biological products. See, e.g., 21 C.F.R. §§ 314.70(b) and 601.12(b).

As part of planning for a recall, firms must consider whether there will be a need for premarket approval, licensure, or clearance of a “correction” in order to carry out the recall. Introducing modified products, without the requisite approval, licensure or clearance, adulterates and/or misbrands the products or otherwise renders them violative. 21 U.S.C. §§ 351-52; 42 U.S.C. § 262. It is illegal to introduce adulterated, misbranded or otherwise violative products into interstate commerce. 21 U.S.C. § 331(a); 42 U.S.C. § 262. FDA has the authority to take legal and/or administrative enforcement action to address such prohibited introduction.

CONCLUSION

Recalls will happen. The key is conducting them in a way which minimizes FDA and other liabilities. Thinking through relevant considerations (type of field action, classification, applicability of Part 806, compliance with Part 7 guidelines, etc.) before initiating a recall or other field action can greatly increase the efficiency of the action and its acceptability to FDA.

Food and Drug Administration, HHS

§ 7.3

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Southwest Import District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

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Pacific Regional Laboratory, SW: 19701 Fairchild, Irvine, CA 92612.

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PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

- Sec.
- 7.1 Scope.
- 7.3 Definitions.
- 7.12 Guaranty.
- 7.13 Suggested forms of guaranty.

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

- 7.40 Recall policy.
- 7.41 Health hazard evaluation and recall classification.
- 7.42 Recall strategy.
- 7.45 Food and Drug Administration-requested recall.
- 7.46 Firm-initiated recall.
- 7.49 Recall communications.
- 7.50 Public notification of recall.
- 7.53 Recall status reports.
- 7.55 Termination of a recall.
- 7.59 General industry guidance.

Subpart D [Reserved]

Subpart E—Criminal Violations

- 7.84 Opportunity for presentation of views before report of criminal violation.
- 7.85 Conduct of a presentation of views before report of criminal violation.

7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 241, 262, 263b-263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for

human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.

(h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) *Recalling firm* means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) *Market withdrawal* means 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 Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) *Stock recovery* means 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.

(l) *Recall strategy* means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) *Recall classification* means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation 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.

(2) Class II is a situation 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.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) *Consignee* means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

§7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

§7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

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(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

SOURCE: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and

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Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where 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.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(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

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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.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§7.42 Recall strategy.

(a) *General.* (1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market-place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy.* A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall.* Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any

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intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) *Public warning.* The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks.* The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

(i) Level A—100 percent of the total number of consignees to be contacted;

(ii) Level B—Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C—10 percent of the total number of consignees to be contacted;

(iv) Level D—2 percent of the total number of consignees to be contacted; or

(v) Level E—No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

§ 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following 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 the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's

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determination of the need for the recall or how the recall should be conducted.

[43 FR 26218, June 16, 1978, as amended at 69 FR 17290, Apr. 2, 2004]

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

- (1) Identity of the product involved.
- (2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
- (3) Evaluation of the risk associated with the deficiency or possible deficiency.
- (4) Total amount of such products produced and/or the timespan of the production.
- (5) Total amount of such products estimated to be in distribution channels.
- (6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
- (7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
- (8) Proposed strategy for conducting the recall.
- (9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not

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delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

- (1) That the product in question is subject to a recall.
- (2) That further distribution or use of any remaining product should cease immediately.
- (3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- (4) Instructions regarding what to do with the product.

(b) *Implementation.* A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "DRUG [or FOOD, BIOLOGIC, etc.] RECALL [or CORRECTION]". The letter and the envelope should be also marked: "URGENT" for class I and class

II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents.* (1) A recall communication should be written in accordance with the following guidelines:

- (i) Be brief and to the point;
- (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
- (iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

(d) *Responsibility of recipient.* Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay 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. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

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(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration 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 proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the

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product and is at least the length of time specified in other applicable regulations concerning records retention.

Subpart D [Reserved]

Subpart E—Criminal Violations

§7.84 Opportunity for presentation of views before report of criminal violation.

(a)(1) Except as provided in paragraph (a) (2) and (3) of this section, a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

(2) Notice and opportunity need not be provided if the Commissioner has reason to believe that they may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution.

(3) Notice and opportunity need not be provided if the Commissioner contemplates recommending further investigation by the Department of Justice.

(b) If a statute enforced by the Commissioner does not contain a provision for an opportunity to present views, the Commissioner need not, but may in the Commissioner's discretion, provide notice and an opportunity to present views.

(c) If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views will include all violations.

(d) Notice of an opportunity to present views may be by letter, standard form, or other document(s) identifying the products and/or conduct alleged to violate the law. The notice shall—

(1) Be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication;

(2) Specify the time and place where those named may present their views;

(3) Summarize the violations that constitute the basis of the contemplated prosecution;

(4) Describe the purpose and procedure of the presentation; and

(5) Furnish a form on which the legal status of any person named in the notice may be designated.

(e) If more than one person is named in a notice, a separate opportunity for presentation of views shall be scheduled on request. Otherwise, the time and place specified in a notice may be changed only upon a showing of reasonable grounds. A request for any change shall be addressed to the Food and Drug Administration office that issued the notice and shall be received in that office at least 3 working days before the date set in the notice.

(f) A person who has received a notice is under no legal obligation to appear or answer in any manner. A person choosing to respond may appear personally, with or without a representative, or may designate a representative to appear for him or her. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled, the Commissioner will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the information available.

(g) If a respondent chooses to appear solely by designated representative, that representative shall present a signed statement of authorization. If a representative appears for more than one respondent, the representative shall submit independent documentation of authority to act for each respondent. If a representative appears without written authorization, the opportunity to present views with respect to that respondent may be provided at that time only if the authenticity of the representative's authority is first verified by telephone or other appropriate means.

[44 FR 12167, Mar. 6, 1979]

§ 7.85 Conduct of a presentation of views before report of criminal violation.

(a) The presentation of views shall be heard by a designated Food and Drug Administration employee. Other Food and Drug Administration employees may be present.

(b) A presentation of views shall not be open to the public. The agency employee designated to receive views will permit participation of other persons only if they appear with the respondent or the respondent's designated representative, and at the request of, and on behalf of, the respondent.

(c) A respondent may present any information of any kind bearing on the Commissioner's determination to recommend prosecution. Information may include statements of persons appearing on the respondent's behalf, letters, documents, laboratory analyses, if applicable, or other relevant information or arguments. The opportunity to present views shall be informal. The rules of evidence shall not apply. Any information given by a respondent, including statements by the respondent, shall become part of the agency's records concerning the matter and may be used for any official purpose. The Food and Drug Administration is under no obligation to present evidence or witnesses.

(d) If the respondent holds a "guaranty or undertaking" as described in section 303(c) of the act (21 U.S.C. 333(c)) that is applicable to the notice, that document, or a verified copy of it, may be presented by the respondent.

(e) A respondent may have an oral presentation recorded and transcribed at his or her expense, in which case a copy of the transcription shall be furnished to the Food and Drug Administration office from which the notice issued. The employee designated to receive views may order a presentation of views recorded and transcribed at agency expense, in which case a copy of such transcription shall be provided to each respondent.

(f) If an oral presentation is not recorded and transcribed, the agency employee designated to receive views shall dictate a written summary of the presentation. A copy of the summary shall be provided to each respondent.

(g) A respondent may comment on the summary or may supplement any response by additional written or documentary evidence. Any comment or addition shall be furnished to the Food and Drug Administration office where the respondent's views were presented. If materials are submitted within 10 calendar days after receipt of the copy of the summary or transcription of the presentation, as applicable, they will be considered before a final decision as to whether or not to recommend prosecution. Any materials received after the supplemental response period generally will be considered only if the final agency decision has not yet been made.

(h)(1) When consideration of a criminal prosecution recommendation involving the same violations is closed by the Commissioner with respect to all persons named in the notice, the Commissioner will so notify each person in writing.

(2) When it is determined that a person named in a notice will not be included in the Commissioner's recommendation for criminal prosecution, the Commissioner will so notify that person, if and when the Commissioner concludes that notification will not prejudice the prosecution of any other person.

(3) When a United States attorney informs the agency that no persons recommended will be prosecuted, the Commissioner will so notify each person in writing, unless the United States attorney has already done so.

(4) When a United States attorney informs the agency of intent to prosecute some, but not all, persons who had been provided an opportunity to present views and were subsequently named in the Commissioner's recommendation for criminal prosecution, the Commissioner, after being advised by the United States attorney that the notification will not prejudice the prosecution of any other person, will so notify those persons eliminated from further consideration, unless the United States attorney has already done so.

[44 FR 12166, Mar. 6, 1979]

§ 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

(a) Records related to a section 305 opportunity for presentation of views constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memorandums.

(1) Notwithstanding the rule established in § 20.21 of this chapter, no record related to a section 305 presentation is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in § 20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise, in accordance with § 20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in subpart D of part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and § 7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that

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would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305 presentation of views before public disclosure only under §20.32 of this chapter.

[44 FR 12168, Mar. 6, 1979]

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart A—General Provisions

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- 10.25 Initiation of administrative proceedings.
- 10.30 Citizen petition.
- 10.33 Administrative reconsideration of action.
- 10.35 Administrative stay of action.
- 10.40 Promulgation of regulations for the efficient enforcement of the law.
- 10.45 Court review of final administrative action; exhaustion of administrative remedies.
- 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.
- 10.55 Separation of functions; ex parte communications.
- 10.60 Referral by court.
- 10.65 Meetings and correspondence.
- 10.70 Documentation of significant decisions in administrative file.
- 10.75 Internal agency review of decisions.
- 10.80 Dissemination of draft Federal Register notices and regulations.
- 10.85 Advisory opinions.
- 10.90 Food and Drug Administration regulations, recommendations, and agreements.
- 10.95 Participation in outside standard-setting activities.

- 10.100 Public calendar.
- 10.105 Representation by an organization.
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- 10.115 Good guidance practices.

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

- 10.200 Scope.
- 10.203 Definitions.
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- 10.205 Electronic media coverage of public administrative proceedings.
- 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

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SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 10 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

(b) If a requirement in another part of title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) References in this part and parts 12, 13, 14, 15, and 16 to *publication*, or to the day or date of publication, or use of the phrase *to publish*, refer to publication in the FEDERAL REGISTER unless otherwise noted.

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