DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, Maryland 20993

February 13, 2013

VIA HAND DELIVERY

Notification of Opportunity to Initiate a Voluntary Recall

Raymond J. Kasel, President
Kasel Associates Industries, Inc.
3315 Walnut St.
Denver, CO 80205

Dear Mr. Kasel:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 3501), as amended by the FDA Food Safety Modernization Act, the U.S. Food and Drug Administration (FDA) is providing your firm, Kasel Associates Industries, Inc. (Kasel), with an opportunity to voluntarily cease distribution and conduct a recall of pet treat products manufactured by your firm from April 20, 2012 through September 19, 2012. Section 423(a) of the FD&C Act provides in relevant part that if FDA "determines…that there is a reasonable probability that an article of human or animal food (other than infant formula) is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals," before taking further action under section 423 of the FD&C Act, FDA must offer the responsible party the opportunity to voluntarily cease distribution and recall such articles (21 U.S.C. 3501(a)).[1]

As discussed further below, FDA has determined that for those pet treats manufactured at your Denver facility from April 20, 2012 through September 19, 2012, which bear the lot codes BESTBY20APR2014 to BESTBY03OCT2014 for products with a two year expiry, or BESTBY20APR2013 to BESTBY03OCT2013 for products with a one year expiry (collectively, affected pet treats), there is a reasonable probability that such products are adulterated under section 402(a)(1)[2] and (a)(4)[3] of the FD&C Act (21 U.S.C. 342(a)(1) and (a)(4)) and a reasonable

[1] The term "responsible party" is defined in section 417 of the FD&C Act and refers to the person who submits the registration for a food facility that is required to register under section 415(a) of the FD&C Act (21 U.S.C. 350d), at which the food at issue is manufactured, processed, packed or held. On February 4, 2004, you registered Kasel with FDA pursuant to section 415(a) of the FD&C Act (21 U.S.C. 350d(a)). As such, this letter is directed to you as the responsible party.

[2] Under section 402(a)(1) of the FD&C Act, a food shall be deemed adulterated if "it bears or contains a poisonous or deleterious substance which may render it injurious to health."

probability that the use of or exposure to these products will cause serious adverse health consequences or death to humans or animals. If you do not voluntarily cease distribution and conduct a recall, FDA may, by order, require you to immediately cease distribution of the affected pet treats and also may require you to immediately give notice to other parties. If you elect to take the action requested in this letter, you should do so within the time frame and in the manner described below under "Opportunity to Initiate a Voluntary Recall" to avoid further regulatory action by FDA concerning the affected pet treats.

FDA's Determination

The basis for FDA's determination that there is a reasonable probability that the affected pet treats are adulterated under section 402(a)(1) and (a)(4) of the FD&C Act and that there is a reasonable probability that the use of or exposure to the pet treats will cause serious adverse health consequences or death to humans or animals is as follows:

- Multiple finished product samples of Kasel pet treats obtained by the State of Colorado's Department of Agriculture in September and October 2012, were tested and subsequently found to be positive for *Salmonella*.
- In response to the state of Colorado's *Salmonella*-positive results, FDA conducted an inspection of Kasel's manufacturing facility from September 19-28, 2012. During the inspection, the FDA investigators collected various samples for further testing, including bulk and finished product samples and numerous environmental samples. Many of these samples tested positive for *Salmonella*.
- *Salmonella* is a pathogenic organism that can cause serious adverse health consequences or death in humans and animals. The presence of *Salmonella* in pet food can pose a particularly acute health risk to children and people who are elderly or immunocompromised.
- Pet food contaminated with *Salmonella* is already a known vector of potential salmonellosis in humans. For example, the Centers for Disease Control and Prevention (CDC) reported that, from January 1, 2006 to October 31, 2008, 79 human cases of salmonellosis were linked by genetic evidence to *Salmonella* Schwarzengrund in dry dog food manufactured by a firm in the United States.
- Pet food, including pet treats, in which *Salmonella* is detected is considered adulterated under section 402(a)(1) of the FD&C Act.
- Pet food, including pet treats, which are prepared, packed, or held under conditions that could lead to contamination with *Salmonella* is considered adulterated under section 402(a)(4) of the FD&C Act.
- As discussed in detail below, evidence collected by FDA and the state of Colorado, including environmental and product samples collected and analyzed by Colorado and the FDA, and observations made by FDA during the inspection of your facility, establishes the following:
    - Pet treat products manufactured, processed, packed, or held by your facility from April 20, 2012, through September 19, 2012, are contaminated with *Salmonella*,

[3] Under section 402(a)(4) of the FD&C Act, a food shall be deemed adulterated if "it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

or are at risk for contamination with *Salmonella*, based on the conditions in your facility and multiple *Salmonella*-positive results from environmental samples, including positive results on food contact surfaces within your facility, and from samples of your finished product. Test results indicate there are more than a dozen different *Salmonella* serotypes in your firm's manufacturing facility and finished products. In addition, the test results indicate that various *Salmonella*-positive samples from finished products are serotype matches to, and in some cases share a Pulsed Field Gel Electrophoresis (PFGE) pattern with, other finished products and/or various environmental swabs taken at the facility during the September 2012 inspection.[4] Due to this widespread *Salmonella* contamination and/or risk of contamination, FDA has determined that there is a reasonable probability these products are adulterated under section 402 of the FD&C Act and there is a reasonable probability that the use of or exposure to these pet treats will cause serious adverse health consequences or death to humans or animals.

- Your facility created, caused or was otherwise responsible for this reasonable probability of adulteration under section 402 of the FD&C Act. Specifically, FDA has determined that the conditions within your facility (e.g., the presence of *Salmonella* in various locations throughout the facility and multiple sanitation deficiencies) that could lead to cross contamination between raw materials and finished products caused the reasonable probability.

Colorado's Testing of Finished Product Samples:

- On September 10, 2012, the Colorado Department of Agriculture collected unopened bags of Boots & Barkley American Beef Bully Sticks from Kasel's manufacturing facility as part of the State's routine inspection. This sample was tested and subsequently confirmed positive for *Salmonella* spp (species) by the State of Colorado's Department of Agriculture Biochemistry Laboratory.
- On September 14, 2012, an inspector for the State of Colorado collected seven samples of unopened bags of Boots & Barkley American Beef Bully Sticks from Target stores. Four of the seven samples tested, which consisted of products manufactured in April (BESTBY04APR2014DEN), June (BESTBY23JUN2014DEN) and September 2012 (BESTBY23SEPT2014DEN), were confirmed positive for *Salmonella* spp.
- On October 16, 2012, the State of Colorado informed Kasel that two additional products the firm manufactured on September 13, 2012 (Boots & Barkley American Pig Ears and Boots & Barkley American Variety Pack (BESTBY13SEP2014)) also tested positive for *Salmonella.*
- On October 25, 2012, the State of Colorado collected a sample of Nature's Deli Chicken Jerky Dog Treat products from Costco which were manufactured by Kasel on June 19, 2012 (BESTBY19JUNE2013DEN). On November 19, 2012, the State of Colorado notified FDA that this sample tested positive for *Salmonella* Tennessee.[5]
- Further laboratory analysis using PFGE technology has shown that *Salmonella* Tennessee isolates obtained from the Nature's Deli Chicken Jerky Dog Treats manufactured on June

[4] When a PFGE pattern of an isolate is indistinguishable from the pattern of another isolate from a common source, it is highly likely the two isolates are the same strain of *Salmonella.*

[5] FDA issued a warning to consumers regarding these dog treat products on December 6, 2012.

19, 2012 were indistinguishable (i.e., 100% match) from *Salmonella* isolates found on finished product samples of Kasel's pork femur, beef knuckle, and chicken jerky products manufactured in September 2012 and environmental samples collected by FDA during the September inspection.

FDA's Testing of Product and Environmental Samples:

- During the September 19-28, 2012, inspection at your firm's manufacturing facility, the FDA investigators collected various samples for further testing, including: three bulk (unpackaged) product samples; four retail-packaged finished product samples; and 87 environmental swabs.
    - **Bulk product samples**: One of the bulk product samples (5 inch bully beef sticks) tested positive for *Salmonella*. One culture of this sample tested positive for *Salmonella* Anatum, which reflects a serotype match with the finished product sample of Boots & Barkley American 5 inch bully beef sticks (BESTBY23SEP2014DEN) collected by the State of Colorado. A second culture of the bulk 5 inch bully beef sticks sample tested positive for *Salmonella* Infantis, which matches several of the environmental swabs taken by FDA (Sample No. 730799, subs 22, 49 and 54) in areas of your facility that handle product that has already undergone a kill step to rid it of harmful pathogens such as *Salmonella* that may have been present in the raw ingredients.
    - **Retail-packaged product samples**: Because *Salmonella* is often unevenly distributed through an article of food or a food product lot, laboratory testing may not always yield a positive result even though some portions of a product or product lot may contain *Salmonella*. All four of the retail-packaged finished product samples FDA investigators collected during the inspection (Nature's Deli Chicken Jerky Dog Treats with Best By date of 091913DEN; Boots & Barkley American Pig Ears with Best By date of 03OCT2014DEN; Boots & Barkley American Pork Femur with Best By date of 03OCT2014DEN; and Boots & Barkley American Beef Knuckles with Best By date of 03OCT2014DEN) tested positive for *Salmonella*. Given the typically uneven distribution of *Salmonella* in articles of food, the fact that all of the finished product samples collected were positive indicates a pervasive level of *Salmonella* contamination. In addition, analysis using PFGE showed that *Salmonella* Tennessee isolates obtained from three of the positive finished product samples (Nature's Deli Chicken Jerky Dog Treats - BESTBY19SEP2013DEN; Boots & Barkley American Pork Femur - BESTBY03OCT2014DEN; and Boots & Barkley American Beef Knuckle - BESTBY03OCT2014DEN (which was also positive for *Salmonella* Agona)) were a 100% match with isolates obtained from a finished product sample of Nature's Deli Chicken Jerky Dog Treats (Colorado sample) manufactured on June 19, 2012 (BESTBY19JUN2013DEN). Those same finished product samples were also a 100% PFGE match with multiple environmental swabs that tested positive for *Salmonella* Tennessee, including some taken on food contact surfaces within the facility (product conveyor belt #2 and bucket). When a PFGE pattern of an isolate is indistinguishable from the pattern of another isolate from a common source, it is highly likely the two isolates are the same strain of *Salmonella* Tennessee.

- **Environmental swabs**: As part of our inspection, FDA collected environmental samples from different areas of your facility, including the Packaging Room, Bulk Storage Room, Processing Products/Cooling Room, Band-Saw Room and the Loading Dock. Some of these areas are in the portions of your facility that handle pet treat products that have already undergone a kill step. Forty eight (48) of the environmental swabs FDA collected were confirmed positive for *Salmonella*. As previously discussed, multiple swabs collected during FDA's September 2012 inspection that tested positive for *Salmonella* Tennessee (Sample 730799, subs 13, 14, 16, 19, 20, 21, 24, 29, 34, 35, 36, 38, 39 and 41) were determined by further laboratory analysis to have a PFGE pattern that is indistinguishable from the pattern of several of the finished product samples, including products manufactured as early as June 2012. Laboratory testing of the environmental swabs also revealed contamination of the facility with *Salmonella* Mbandaka (Sample 730799, sub 31), which matches the serotype of *Salmonella* detected in pet treat products Kasel manufactured in April 2012 (Boots & Barkley American 5 inch Bully Beef Sticks -- BESTBY20APRIL2014DEN). In addition, a finished product sample of Boots & Barkley American 5 inch Bully Beef Sticks manufactured in June 2012 (BESTBY01JUN2014DEN) (Colorado sample); a finished product sample of Boots & Barkley American Pig Ears manufactured in September 2012 (BESTBY03OCT2014DEN) (FDA sample); and environmental samples (44, 46, 47, 48 and 51) collected by FDA in September are all a match for *Salmonella* Derby. These results indicate a continuous contamination issue.

Insanitary Conditions at Kasel's Manufacturing Plant:

- During FDA's inspection, our investigators also observed serious problems with sanitation, cleanliness, and record-keeping practices for food and clean-up procedures in your facility's food production environment. These problems were noted in the Form FDA-483 provided to your firm at the close of the inspection. These conditions, along with the widespread presence of multiple strains of *Salmonella*, cause your products to be adulterated within the meaning of section 402(a)(4) of the FD&C Act, in that the foods have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Further, the conditions and practices observed at your firm create a reasonable probability that finished product that is manufactured, processed, packed, and held by your facility is contaminated with *Salmonella*, and therefore that there is a reasonable probability of that finished product causing serious adverse health consequences or death to humans or animals.
- Specifically, our investigators observed the following:
  - Evidence of pest infestation throughout the facility including evidence of cockroaches, beetles, moths, flies and rodents.
  - Building, fixtures and physical facilities were in disrepair throughout the building, including broken light fixtures, leaking pipes and sinks, out of service faucets at hand sinks, holes in the wall, cracks in floors, and ceiling tiles that were broken, wet and missing.
  - Manufacturing equipment, including band saws, belt conveyors, crates, and fork lifts, were in various states of disrepair.

- Employees did not wash their hands after leaving the restroom, after leaving the lunchroom and before donning new gloves.
- Inadequate or lack of documentation of which products were cooked and packaged at what time.
- A number of conditions and practices in your facility likely resulted in the spread of *Salmonella* throughout the facility and further *Salmonella* contamination of multiple products. Specifically:
    - Food-contact surfaces and equipment, including surfaces of utensils, belt conveyors, hoppers, packaging equipment, and bulk storage totes, were not cleaned and sanitized throughout the facility. Our investigators observed dirty surfaces, filth and product build-up on food-contact surfaces and equipment in the facility where finished product is processed, packed and held.
    - Failure to protect finished product from potential contamination from raw ingredients, including lack of warewashing facilities for equipment that may be used for both raw and finished products.
    - Storage of finished product under conditions that may lead to contamination by microbial or physical agents. For example, bins of bulk product were observed to have plastic, cardboard, gloves and other objects nested in the finished product. In addition, bulk product bins were stored in direct contact with the floor and were uncovered
    - Failure to handle work in progress in a manner that protects against contamination including contamination by foam foot sanitizer on raw ingredients. For example, it was observed that a pallet of raw ingredients was sprayed by a foam foot sanitizer and uncovered raw ingredients were stored on the loading dock with the doors open.

Based upon the results of extensive product and environmental testing, and the condition of the facility as observed by FDA investigators during the September 2012 inspection, FDA believes there is a reasonable probability that all pet treat products manufactured at your firm's Denver facility during the time period from April 20 through September 19, 2012, are adulterated under sections 402(a)(1) and (a)(4) of the FD&C Act and that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences or death to humans or animals. We acknowledge your written response to the Form FDA 483 that was issued at the end of our inspection of your facility, which was received by FDA on October 25, 2012. In your response, you indicate that a number of corrective actions were taken following the inspection in response to FDA's observations. It will be necessary for FDA to evaluate the completed corrective actions on site to assure their adequacy. However, because the affected products were produced prior to these corrective actions being taken, your response has no bearing on the legal determination described in this letter.

Opportunity to Initiate a Voluntary Recall

As discussed above, in accordance with section 423(a) of the FD&C Act, we are providing you with an opportunity to voluntarily cease distribution and conduct a recall of the affected pet treats. If you elect to voluntarily cease distribution and conduct a recall of these products, you should do so in the following time and manner:

- Within two (2) business days of your receipt of this letter, cease distribution and initiate a recall of all pet treat products manufactured at your firm's Denver facility from April 20, 2012 through September 19, 2012 which bear the lot codes BESTBY20APR2014 to BESTBY03OCT2014 for products with a two year expiry, or BESTBY20APR2013 to BESTBY03OCT2013 for products with a one year expiry, except for those pet treats that have already been recalled by your firm. This includes all pet treat products manufactured, processed, packed or held by your firm during the relevant time period, including but not limited to: Nature's Deli Chicken Jerky Dog Treats; Boots & Barkley American Bully Beef Sticks; Boots & Barkley American Pig Ears; Boots & Barkley American Pork Femur; Boots & Barkley American Beef Knuckle; Boots and Barkley Variety Pack.
- Notify all direct consignees and request that those who further distributed these products conduct a sub-recall to the retail level and, if known, to the consumer level.
- Conduct your recall(s) of these products in coordination with the FDA Denver District Recall Coordinator
- Follow the procedures for recalls found in FDA's regulations at 21 CFR Part 7 to the extent appropriate. A copy of these regulations is enclosed.

If you do not voluntarily cease distribution and conduct a recall in the time and manner described in this section, FDA may, by order, require you to immediately cease distribution of the affected pet treats. Additionally, FDA may, by order require you to immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling the affected pet treats to immediately cease distribution of such articles; and to immediately notify all persons to which such articles have been distributed, transported, or sold, to immediately cease distribution of the affected pet treats.

Please respond to this letter by contacting Ms. LaTonya M. Mitchell, District Director, at telephone number (303) 236-3016 or via email at latonya.mitchell@fda.hhs.gov, as soon as possible. If a response is not received from you within two (2) business days of your receipt of this letter, FDA may by order require you to immediately cease distribution and notify applicable parties, as explained above.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine

Enclosure: 21 CFR Part 7

Laboratory Branch.
Southeast Regional Laboratory, Atlanta, GA.
Chemistry Branch I.
Microbiology Branch.
Atlanta Center for Nutrient Analysis.
Chemistry Branch II.
Regional Field Office, Southwest Region.
District Office, Dallas, TX.
Compliance Branch.
Investigations Branch.
District Office, Kansas City, MO.
Compliance Branch.
Investigations Branch.
Science Operations Branch.
Total Diet and Pesticide Research Center.
District Office, Denver, CO.
Compliance Branch.
Investigations Branch.
Laboratory Branch.
Arkansas Regional Laboratory.
General Chemistry Branch.
Pesticide Chemistry Branch.
Microbiology Branch.
Southwest Import District Office, Dallas, TX.
Compliance Branch.
Investigations Branch.

§5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993.

§5.1110 FDA public information offices.

(a) *Division of Dockets Management.* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301–827–6860.

(b) *Division of Freedom of Information.* The Division of Freedom of Information public room is located in rm. 1050, Element Bldg., 12420 Parklawn Dr., Rockville, MD 20857, Telephone: 301–796–3900.

(c) *Press Relations Staff.* Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740, Telephone: 301–436–2335.

PART 7—ENFORCEMENT POLICY

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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]

EFFECTIVE DATE NOTE: At 77 FR 5176, Feb. 2, 2012, § 7.3 was amended by revising the first sentence of paragraph (f), effective Apr. 2, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 7.3 Definitions.

* * * * *

(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, any tobacco product intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. * * *

* * * * *

§ 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.

(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 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 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 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 that 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 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 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 quatity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding 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.

(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 Adminstration 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 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 12168, 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 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

Sec.

Subpart B—General Administrative Procedures

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