at

AT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

UNITED STATES FOOD AND DRUG ADMINISTRATION

VIDEO TELECONFERENCE:

PROPOSED RULES ON BIOTERRORISM

Wednesday, May 7, 2003

1:00 p.m.

02N-0276 TR2

16071 Industrial Drive
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.
735 8th Street, S.E.
Washington, D.C. 20003-2802
(202) 546-6666

at

AT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

UNITED STATES FOOD AND DRUG ADMINISTRATION

VIDEO TELECONFERENCE:

PROPOSED RULES ON BIOTERRORISM

Wednesday, May 7, 2003

1:00 p.m.

02N-0276 TR2

16071 Industrial Drive
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.
735 8th Street, S.E.
Washington, D.C. 20003-2802
(202) 546-6666

at

1 P R O C E E D I N G S

2 MR. BARNETT: Welcome to this live video
3 teleconference. I'm Mark Barnett of the U.S. Food
4 and Drug Administration and I'll be serving as your
5 moderator this afternoon. This program represents
6 FDA's continuing commitment to keep people informed
7 and updated on proposed regulations being developed
8 under the Bioterrorism Act.
9 On January 29, we presented a program on
10 the rules for registration and prior notice. The
11 comment period for those two regulations is now
12 closed and FDA staff are in the process of
13 reviewing comments and preparing to draft the final
14 rules on registration and prior notice.
15 Today, we are going to discuss two new and
16 important regulations being proposed by the FDA
17 that will also help protect our nation against
18 bioterrorism. Both of those regulations concern
19 domestic and imported food and animal feeds that
20 are regulated by the FDA.
21 One of the regulations would require the
22 establishment, maintenance and retention of certain
23 records. The other regulation would allow for the
24 administrative detention of food products that may
25 pose a threat to public health.

1 Our show today is being broadcast live
2 throughout the United States, in Canada, Mexico,
3 the Caribbean and throughout South America. Our
4 broadcast audience includes manufacturers,
5 processors, distributors and transporters of food
6 and animal feeds. In addition, there are
7 importers, agents, brokers and representatives from
8 various embassies throughout the world that are
9 tuned in for this broadcast. This broadcast is
10 being simultaneously translated into Spanish and
11 French.
12 We have two basic goals in doing this
13 broadcast. First of all, we want to be sure that
14 you understand these proposals, why they were
15 proposed, what they provide for an what would be
16 expected of you in complying with them. So, in a
17 way, this broadcast will help to get you ready for
18 new requirements that are being mandated by U.S.
19 law.
20 Our second purpose is to encourage you to
21 comment on these regulations before they are made
22 final. That is very important. By sending us your
23 comments, you can help us to shape these
24 regulations while they are still being developed.
25 Here is how the comment system works.

at

1 Under U.S. law, proposed regulations are published
2 in a document called the Federal Register. This
3 provides a notice of what a government agency is
4 considering in a particular regulation and it
5 allows interested parties to submit comments or
6 suggestions to make the proposed regulation more
7 effective or less burdensome.
8 Comments on a proposed regulation are
9 accepted for a specified period of time. They are
10 carefully considered by the government agency
11 proposing the regulation and later they are
12 summarized and discussed in the preamble section of
13 the final regulation.
14 We encourage you to send your comments on
15 these two regulations to our Dockets Management
16 Branch, either electronically or by mail.
17 Throughout the broadcast today, we will giving you
18 information on how you can do that. You can also
19 find information on how to submit comments by going
20 to our Bioterrorism web page.
21 Now, let me talk a little bit about the
22 format for today's program. For each of the two
23 proposed rules, I will ask a panel of FDA experts
24 some questions that will draw out the information
25 you will need to know about these rules and then

1 you will have the opportunity to ask questions of
2 the panelists, either by phone or fax or e-mail.
3 The first panel is going to cover the
4 proposed rule on recordkeeping and the second panel
5 will cover administrative detention. In between
6 the two panels, we will have a ten-minute break
7 during which you will see some important
8 information on your screen about how to submit
9 comments on these two regulations to our Dockets
10 Management Branch.
11 Now, let me tell you how to submit your
12 comments to the panel. The phone number to call
13 today is 800-527-1401. The fax number is 888-361-
14 4011. The e-mail address is
15 tvquestions@cdrh.fda.gov. Those numbers are going
16 to be appearing on your screen right now and they
17 will continue to appear from time to time during
18 the broadcast.
19 If you choose to phone us, you have two
20 choices. You can ask your questions as panelists
21 directly on the air or you can leave your question
22 with the person answering the phone and it is going
23 to be given to us along with the faxes. I want to
24 clear up a point of possible confusion about your
25 questions during this broadcast. We are

1 encouraging you to ask questions of our panelists
2 to be sure that you understand the regulations, but
3 you cannot use your communication with the
4 panelists today as a means of submitting your
5 comments on the two regulations.
6 As I said earlier, you have to send those
7 comments, either electronically or by mail, to our
8 Dockets Management Branch and you will get
9 information on how to do that during the break.
10 Also, please remember that we are no
11 longer taking questions about the first two rules,
12 the ones on registration and prior notice. Those
13 were the ones we covered during our first broadcast
14 and the comment period on those two regulations is
15 closed.
16 I want to emphasize that we are going to
17 be covering a lot of information during this
18 broadcast. We are going to post the slides that we
19 use during today's broadcast on our website so you
20 can review what we discuss. In addition, you can
21 link to the full text of the proposals from our
22 website, and that website address will be posted at
23 the end of the first discussion and also during the
24 break.
25 Now, let me introduce our panelists. Bob

1 Lake is Director of the Office of Regulations and
2 Policy in FDA's Center for Food Safety and Applied
3 Nutrition. Leslye Fraser is Associate Director for
4 Regulations in that office. Steve Niedleman is
5 FDA's Assistant Commissioner for Regulatory
6 Affairs.
7 Bob, let's begin by talking about why FDA
8 is proposing this new system of records.
9 MR. LAKE: Mark, the answer to that really
10 has two parts. The most immediate answer is that
11 the Public Health security and Bioterrorism
12 Prepared and Response Act of 2002 requires the
13 Secretary of Health and Human Services to publish
14 final regulations by December 12 of 2003.
15 The other answer is really the underlying
16 reason why this is important. The purpose of these
17 regulations will be to require the establishment
18 and maintenance of records that will enable FDA--
19 and the records relate to the immediate prior
20 source of foods and ingredients as well as the
21 immediate subsequent recipient of these products,
22 these food products.
23 Let me just give you an example of what
24 that is important. We, from time to time,
25 encounter groupings or outbreaks of people who are

at

1 getting ill from a food. As we investigate, we may
2 find, for instance, that a particular ingredient in
3 that food is the source of the problem.
4 What we would then need to be able to do
5 is to trace back where that ingredient came from to
6 identify the source. Then, when we get to that
7 place, we may, then, discover that that
8 contaminated ingredient went to other places as
9 well, to other food companies. So then we can
10 trace forward if we have these kinds of records. We
11 believe, with this authority in place, it will
12 better enable FDA to do its job or protecting the
13 public.
14 MR. BARNETT: But companies already keep
15 records. Why is it that you need an additional
16 authority for this?
17 MR. LAKE: That is certainly true, Mark.
18 Companies do regularly keep records and many of
19 them cover much of the material that we are
20 interested in. However, we have found, in our
21 experience, that not all companies keep all of the
22 information we need and it is not always readily
23 available. That is why we need this.
24 MR. BARNETT: Of course, the ultimate goal
25 of all this is to help protect our nation against

1 bioterrorism. What connection can you make between
2 these records and that goal?
3 MR. LAKE: The goal is, certainly, firstly
4 to protect the public from bioterrorism. But,
5 also, it relates to other situations where, through
6 negligence, a food can become contaminated in a way
7 that poses a serious risk to the public. But we
8 believe that, as a result of having these records,
9 we will be in a much better position to do the
10 trace-back, the trace-forward, and, thus, better do
11 our job of protecting the public.
12 MR. BARNETT: Steve, there are other
13 requirements for keeping records as well. Are
14 companies going to be required to still fulfil
15 those obligations, too?
16 MR. NIEDLEMAN: Absolutely, Mark. The
17 regulations that are being proposed do not replace
18 any of the existing regulations that may apply to
19 the products that you manufacture such as the
20 specific requirements or regulations for infant
21 formula, animal feed, low-acid canned food or
22 bottled water.
23 MR. BARNETT: Leslye, let's start talking
24 now about who is going to have to establish and
25 maintain these records under the proposal.

at

1 MS. FRASER: Under the proposal, the rule
2 would apply to domestic persons that manufacture,
3 process, pack, hold, transport, distribute, receive
4 or import food for human or animal consumption
5 within the United States. As we use the term
6 "persons" here, it means more than individuals. It
7 also covers partnerships, cooperatives,
8 corporations, government entities such as schools
9 and so forth.
10 The rule also would apply to foreign
11 facilities that manufacture, process, pack or hold
12 food, again for human consumption in the United
13 States.
14 MR. BARNETT: You talked about domestic
15 persons and foreign facilities. Distinguish a
16 little bit about what those mean in this context.
17 MS. FRASER: Yes. The terms do mean
18 different things. The Section 306 of the
19 Bioterrorism Act, which we are implementing here,
20 gives FDA the authority to require records that
21 would require persons, domestic and foreign, again
22 that manufacture, process, pack, hold, distribute,
23 transport, receive or import food.
24 FDA is distinguishing the scope of
25 coverage domestically from foreign. On the

at

1 domestic side, we are generally applying the
2 requirements broadly to all persons that fit within
3 that category. On the foreign side, however, we
4 are limiting the coverage to just those facilities
5 that would be required to register with the FDA
6 under our registration rule that we proposed
7 earlier this year.
8 MR. BARNETT: There are some people who
9 are excluded from keeping these records; is that
10 right
11 MS. FRASER: Yes; there are. The proposed
12 rule contains a number of different exclusions. We
13 have both total exclusions and partial exclusions.
14 On the total exclusion side are farms, restaurants
15 that prepare and serve food directly to consumers,
16 firms regulated exclusively throughout the entire
17 facility by our United States Department of
18 Agriculture, also shortened and called USDA, and
19 then also excluded from all requirements are those
20 foreign facilities that would be excluded from
21 registering. Basically, those are foreign
22 facilities who prepare food for the United States
23 but the food leaves that facility and goes to
24 another foreign facility where further processing
25 and manufacturing or packaging occurs.

at

1 MR. BARNETT: Now, you said there were
2 partial exclusions, too.
3 MS. FRASER: Yes; there are. In the
4 partial exclusions, FDA started with fishing
5 vessels that do not process food or fish. We had
6 the authority to require fishing vessels to
7 register because they are not excluded in the
8 Bioterrorism Act. But, in the proposal, we are
9 limiting the coverage on fishing vessels, again, to
10 those that would be required to register.
11 Since, under the Registration Rule,
12 fishing vessels that do not process are exempt, we
13 are proposing to exclude them here. Also from the
14 requirement to establish and maintain records, they
15 would not be excluded from the Records Access
16 Authority.
17 Also, we have an existing rule that covers
18 BSE facilities that handle pet food and there is an
19 existing rule for BSE. BSE is commonly referred to
20 as mad cow disease. So pet-food entities that are
21 not subject to our BSE Rule would also be partially
22 excluded here from the requirement to establish and
23 maintain records.
24 MR. BARNETT: How about retail
25 MS. FRASER: In retail, we have two

at

1 exclusions that would apply there. There is one
2 that applies to all retail facilities that sell
3 food direction to consumers. The proposed rule
4 would exempt them from the requirement to establish
5 and maintain records governing the sales to
6 consumers. However, those facilities still would
7 have to keep records tracing the incoming food that
8 they receive and they also would remain subject to
9 the Records Access Provisions.
10 Then, lastly, retail facilities, and these
11 we tend to think of possibly as roadside stands
12 near a farm, that are selling unprocessed food--
13 that is, basically, food in its natural state--from
14 the farm would be, again, excluded. If they had
15 ten or fewer full-time employees, they would not
16 have to comply with any of these regulations.
17 This exclusion, also, would apply with
18 respect to any processed food like baked goods,
19 syrup, of all of the ingredients used came from the
20 farm. But, again, those facilities would remain
21 subject to the Records Access Provision.
22 MR. BARNETT: What about an entity that
23 has a mixture of activities; that is, it is a farm
24 but it also engages in processing at the same time
25 MS. FRASER: We do have those situations.

at

1 In that case, the facility or the entity would have
2 to keep records only with respect to those
3 activities that are covered by this rule. Again,
4 for an example, we may have a farm that is growing
5 oranges. On that same farm, they have a processing
6 plant in which they are taking the oranges, making
7 orange juice and selling the oranges into commerce.
8 In that case, the farming activity, the
9 growing of the oranges, is exempt and no
10 recordkeeping requirements would apply to that
11 activity. But the manufacturing and processing of
12 the oranges into orange juice to sell into commerce
13 is a covered activity and records would be required
14 for that aspect.
15 MR. BARNETT: We talked about who has to
16 keep these records. Now let's talk about what
17 kinds of foods would be applied here.
18 MS. FRASER: On the food side, we are
19 talking about all foods under FDA's jurisdiction.
20 We have an existing statute, the Federal Food, Drug
21 and Cosmetic Act, that contains a definition of
22 food in Section 201(f). That basically says food
23 is, "Articles used for food or drink, for man or
24 other animals, chewing gum and articles used for
25 components of any such article."

1 In the proposed rule, we include examples
2 of the types of foods that are covered so that
3 people would have an understanding of the breadth
4 and scope because we tend to think of food often as
5 hard ingredients and products and not necessarily
6 as drink, for example. Some of the items are
7 listed on the screen now. Food includes food and
8 food additives for man or animals. Food, under
9 FDA's jurisdiction includes dietary supplements and
10 dietary ingredients, infant formula, pet food.
11 We also regulate beverages including
12 alcoholic beverages and bottled water. We regulate
13 fruits and vegetables, fish and seafood, dairy
14 products and shell eggs, raw agricultural
15 commodities that are either used as food or as food
16 ingredients, canned foods, live food animals such
17 as hogs and lobster, and bakery goods, snack food
18 and candy.
19 MR. BARNETT: The foods that are regulated
20 by the Department of Agriculture, of course, are
21 not included.
22 MS. FRASER: Absolutely correct. The
23 foods that are excluded are those that are under
24 the Department of Agriculture's exclusive
25 jurisdiction. These tend to be meat products,

at

1 poultry products and egg products. However, there
2 may be a food product that is sold--for example, a
3 frozen dinner that you could heat up in the
4 microwave or your oven--that contains both products
5 regulated by FDA such as macaroni and cheese and
6 products that would be regulated by USDA such as
7 the meat product. In that case, since there is co-
8 jurisdiction, records would be required but only
9 with respect to those foods that FDA regulates.
10 MR. BARNETT: Steve, the proposed rule
11 distinguishes between transporters and
12 nontransporters. How do you define those terms in
13 the context of this rule.
14 MR. NIEDLEMAN: Mark, a transporter is a
15 person who has possession, custody or control of an
16 article of food for the sole purpose of
17 transporting it to the next consumer; for example,
18 a trucking company. A nontransporter, on the other
19 hand, is a person who owns food or who processes,
20 packs, distributes, imports the product or receives
21 it such as a manufacturer.
22 MR. BARNETT: Okay. Now, what records
23 would have to be established and maintained by the
24 nontransporter in order to identify the immediate
25 previous source of the food?

1 MR. NIEDLEMAN: We believe that, for a
2 nontransporter to develop a meaningful trace-back
3 system, they would have to establish and maintain
4 records to identify the nontransporter and
5 transporter immediate previous source of the foods
6 that they receive.
7 Those records must include the firm name,
8 including the responsible individual and contact
9 information, both domestic and foreign. They need
10 to include the description of the type of food that
11 was received, including the brand name and
12 specific variety; for example, romaine lettuce
13 versus just lettuce.
14 They would need to include the date the
15 food was received, the lot number or other
16 identifier if that is available, the quantity and
17 how the food is packaged--for example, in twenty-
18 five-pound cartons or in sixteen-ounce cans--and
19 the name of the responsible individual and contact
20 information of the transporters who brought the
21 food to you.
22 Records must include all information
23 reasonably available to you to identify the
24 specific source of each ingredient that was used to
25 make every lot of finished product.

1 MR. BARNETT: What does "reasonably
2 available" mean? "Reasonably available
3 information;" what is that?
4 MR. NIEDLEMAN: That will depend on each
5 particular case and each particular firm. What may
6 be reasonably available in one firm might not be in
7 another. We have two examples that we would like
8 to share with you that may clarify that.
9 In Example 1, we have a cookie
10 manufacturer who receives flour from three distinct
11 sources, Firm A, Firm B and Firm C. That flour is
12 commingled into a common storage bin that is drawn
13 upon by the manufacturer to make the cookies.
14 In that situation, information reasonably
15 is available to assure the identify of all the
16 potential sources of flour that was used in each
17 finished product. But they are unable to
18 distinguish between Firm A, B or C.
19 The other example, the same manufacturer
20 who manufactures cookies receives flour from three
21 distinct sources, Firm A, Firm B, Firm C. But they
22 store their flour in individual storage bins based
23 upon the receipt of the flour. The manufacturer
24 draws upon the specific flour to manufacture the
25 cookies.

1 In that situation, the information is
2 reasonably available to identify the specific
3 source of the flour for each finished product
4 because they know which storage bin that they draw
5 upon to manufacture the product.
6 MR. BARNETT: Now, what about the records
7 that these nontransporters are going to have to
8 maintain to identify what you call the immediate
9 subsequent recipient?
10 MR. NIEDLEMAN: Basically, it is the same
11 information that must be kept about the immediate
12 nontransporter recipients of all foods released and
13 the transporters who took the food to the
14 recipients; in other words, who received it, what
15 firm or firms, and how it got there, by what
16 transporter, what means, what company.
17 In this example, we show--this graphic
18 illustrates that a manufacturer must trace the
19 shipping mode, the transporter that transported the
20 product, whether it was directly to the next
21 nontransporter or not, as well as to the retail
22 store who would be considered the next transporter
23 of the goods. So the nontransporter must identify
24 both the transporter and nontransporter as the
25 recipients.

1 MR. BARNETT: Let's turn our attention now
2 to the transporters, what are the requirements on
3 record keeping for the transporters. You gave the
4 example of a shipping company, for example.
5 MR. NIEDLEMAN: Right. The requirements
6 for transporters are essentially the same as for
7 nontransporters in that the records would have to
8 include the firm name, including the responsible
9 individual and contact information, whether it is
10 domestic or foreign, of the person who had the food
11 immediately before you as well as the person who
12 had the food immediately after you delivered it.
13 It needs to describe the type of food,
14 including the brand name and specific variety, the
15 dates the food was received and delivered, the lot
16 number or other identifier, if that is available,
17 again, the quantity and how the food is packaged,
18 twenty-five-pound cartons or sixteen-pound tins,
19 No. 16 cans, or whatever, identification of each
20 and every mode of transportation and responsible
21 individuals throughout the transport if the same
22 transportation company was being used during the
23 various legs of travel from the original
24 manufacturer to the final destination.
25 MR. BARNETT: Let me interrupt this

1 discussion for a moment, and talk to our audience.
2 You don't have to wait until the end of this panel
3 discussion to send your questions in. So you can
4 telephone us or e-mail us or send us a fax as
5 questions occur to you. So you don't have to wait
6 until the end. We are looking forward to hearing
7 from you. We have got a few faxes already and we
8 would like to see more.
9 Leslye, let's turn now to another
10 question. What if the same transportation company
11 uses several modes of transportation for one
12 shipment, a truck, a plane, a train, and so on?
13 What about records there
14 MS. FRASER: The proposed rule does
15 distinguish between what one transportation company
16 has within its ability to move food and another
17 transportation company that uses different
18 vehicles. In this example, we have the same
19 manufacturer delivering a product to a retail store
20 but it is one transportation company here. One
21 company owns the first truck that picks up the food
22 product from the manufacturing facility. That same
23 company owns the airplane that the truck delivers
24 the food to.
25 They also own the second truck that picks

1 up the food in the destination city and takes it to
2 the retail store. Here, the proposed rule would
3 require that transportation company to identify
4 each of those legs. They would have to tell us how
5 long the food was with the truck, the plane and the
6 second truck, when the food was received and
7 released and who the responsible individual was at
8 each step of the way as part of their
9 recordkeeping.
10 MR. BARNETT: Let's take a totally
11 different example and turn it around and say that
12 it is one shipment, but it involves several
13 different transportation companies
14 MS. FRASER: Yes. Here the recordkeeping
15 requirement would apply differently because there
16 are different transportation companies involved.
17 Basically, the rule would not require anyone to
18 keep records of transactions to which they are not
19 a party. So, in this case, the first truck is
20 owned by Company A. The plane is owned by Company
21 B. And the second truck is owned by Company C.
22 Each transportation company would only
23 have to keep records of the person or the facility
24 from which they received the food. So, in Company
25 A, they would only have to say the manufacturer and

1 the person or facility to whom they delivered the
2 food. In this case, for Company A, it would be
3 Company B. So it is one up, one back. They would
4 not have an obligation to keep track of Company A
5 to B to C nor would the manufacturer.
6 In this example, the manufacturer would
7 have to both keep records, as Steve said earlier,
8 that the nontransporter source was the retail store
9 and the transportation source was Company A or, in
10 the previous slide, it was that purple
11 transportation company.
12 MR. BARNETT: When must these records be
13 created
14 MS. FRASER: The records must be created
15 at the time the activity occurs.
16 MR. BARNETT: Okay. Now, if I am already
17 keeping records that contain the same information,
18 or some of the same information, that you are
19 requiring, can I use those records or do I have to
20 do the whole thing again
21 MS. FRASER: No; absolutely you could use
22 those records. FDA was well aware that many of the
23 people that would be subject to these requirements
24 are currently keeping records to comply with other
25 federal, state, local or even local laws or even as

at

1 a matter of good business practice. We fully
2 envision that they would be able to use those
3 records.
4 What they need to examine for themselves,
5 though, is that those records contain all of the
6 information that would be required by this rule.
7 To the extent that it does not, or they do not,
8 then they would just have to supplement their
9 existing records with the information that is
10 required by this rule to make sure that they are in
11 full compliance with everything.
12 MR. BARNETT: Do these records have to be
13 kept in a specific format that the FDA specifies,
14 or can you use your own format?
15 MS. FRASER: You can absolutely use your
16 own format. We were interested in allowing covered
17 entities to be able to use existing records as much
18 as possible. So the proposed rule does specify
19 that records can be maintained in any format,
20 either paper or electronic. It is up to that
21 person who has to keep the records to decide which
22 format works best for them.
23 But, again, the records do need to contain
24 all the required information. We also included an
25 exemption from our existing regulation contained at

1 21, The Code of Federal Regulations, Part 11. That
2 provision specifies criteria under which FDA
3 generally will accept electronic records.
4 So, to the extent that records are being
5 created electronically just for this rule, Part 11
6 would not apply. However, if those records are
7 being used in compliance with another requirement,
8 then Part 11 would still apply.
9 MR. BARNETT: How long do I have to keep
10 these records if I am establishing them?
11 MS. FRASER: That would depend on the type
12 of food you have and the form the food is in. The
13 proposed rule would require all records to be
14 maintained for one year if they relate to
15 perishable foods that are not used in nonperishable
16 end products. So, for example, this would be fresh
17 fruits and vegetables that are eaten in their raw
18 state.
19 We also would require records to be
20 maintained and retained for one year that relates
21 to all animal food including pet food, and then all
22 other records would have to be retained for up to
23 two years. FDA chose these time frames because we
24 found, in past trace-back and trace-forward
25 experiences, that often we are not finding out

at

1 about a public-health emergency relating to food
2 until several months to a year after the food has
3 been released into commerce. We also received
4 input during our early comment period that some of
5 these food products may stay in the stream of
6 commerce for two or three years.
7 MR. BARNETT: Where do the records have to
8 be kept?
9 MS. FRASER: The proposed rule would
10 require the records to be maintained at the site
11 where the activity occurred or in a reasonably
12 accessible location. For example, if you had
13 electronic records that are housed off-site in a
14 computer, as long as you could access them from on-
15 site via a computer terminal, we would count that
16 as on-site.
17 Also, if you keep paper records and they
18 become too voluminous to keep on site, and you
19 store them somewhere else, as long as they can be
20 retrieved at that on-site location within the time
21 frames required in the proposed rule, FDA would
22 consider that acceptable.
23 MR. BARNETT: Steve, Leslye talked about
24 experience in which the FDA has not been able to
25 access records quickly. With respect to this rule,

at

1 how quickly would the records have to be made
2 available to the FDA if the FDA asked to see them?
3 MR. NIEDLEMAN: Mark, under the proposed
4 rule, the required records or other information
5 must be made available to FDA or FDA's
6 representatives within four hours as long as that
7 request is made between 8:00 a.m. and 6:00 p.m.,
8 Monday through Friday. If our request is made at
9 another time, the firm has up to eight hours to
10 produce the records.
11 MR. BARNETT: So it is relatively quick.
12 So the next question gets to be can the FDA simply,
13 in an arbitrary way, just ask for records or does
14 there have to be some criteria before they ask--
15 fulfilling some criteria before they ask for those?
16 MR. NIEDLEMAN: The Bioterrorism Act
17 placed restrictions on FDA's ability to get these
18 records. We can only require access to the records
19 when there is a reasonable belief that the article
20 of food is adulterated and that it presents a
21 threat of serious adverse health consequences or
22 death to humans or animals.
23 MR. BARNETT: Now, there is some kind of
24 information that can be, in fact, excluded from
25 this recordkeeping; is that right?

at

1 MR. NIEDLEMAN: That is correct. Certain
2 records will be excluded from the proposed
3 regulations and those are recipes--that is, the
4 quantitative formula or how much of each ingredient
5 is actually used in manufacturing product, but not
6 the individual ingredients. Any financial data,
7 pricing data, personnel data, research data or
8 sales data other than shipment data regarding
9 sales.
10 MR. BARNETT: You said that the
11 quantitative formula is excluded but not the
12 ingredients. What do you mean by that?
13 MR. NIEDLEMAN: What we are proposing is
14 define a recipe as the quantitative formula of each
15 ingredient used in the manufacture of a product.
16 So, basically, we would be entitled to know what
17 ingredients were being used, just not how much.
18 MR. BARNETT: So, not the amount, but the
19 name of the ingredients.
20 MR. NIEDLEMAN: Of the actual ingredients
21 that are being used.
22 MS. FRASER: Mark, just to clarify, when
23 we are saying they are excluded, they are excluded
24 from FDA's access authority.
25 MR. NIEDLEMAN: Right

at

1 MS. FRASER: Those records that were
2 listed on the slide, FDA would not have access to.
3 MR. BARNETT: Steve, what would happen if
4 the FDA requested to see the records and found out,
5 in fact, that those records had not been
6 established and maintained?
7 MR. NIEDLEMAN: The Bioterrorism Act
8 created several new prohibited acts. Failure to
9 establish and maintain the required records or make
10 them available to FDA would be one of those new
11 prohibited acts. The FDA has the option, if they
12 so saw fit, to pursue civil actions in the form of
13 an injunction or proceed with criminal actions in
14 the form of a prosecution in federal court to those
15 individuals who commit prohibited acts.
16 MR. BARNETT: When is the industry going
17 to have to comply with these regulations?
18 MR. NIEDLEMAN: It is important for
19 everybody to understand that this is currently a
20 proposal and there is no requirement for industry
21 to comply at this point. Under the proposal, all
22 businesses except smaller and very small businesses
23 must comply within six months from the publication
24 in the Federal Register.
25 Larger businesses, or typical businesses,

at

1 that are greater than 500 employees, or equal to
2 500 employees, must comply within six months.
3 Smaller businesses, those with eleven to 499
4 employees, must comply within twelve months. Very
5 small businesses, with less than or equal to ten
6 employees, must comply within eighteen months.
7 MR. BARNETT: Bob, when can we expect to
8 see these regulations appear in their final form?
9 MR. LAKE: Of course, the first step is to
10 publish them as a proposal. In this case, this
11 proposal was put on display on Monday of this week.
12 It will be published on Friday of this week, May 9.
13 Then, after FDA has received all the comments and
14 reviewed them, we, then, we have to prepare the
15 final regulation. The statute requires that the
16 final regulation be published by December 12 of
17 2003.
18 MR. BARNETT: We have obligations in the
19 FDA under the World Trade Organization, under
20 NAFTA. What is the relationship between this
21 regulation and those obligations?
22 MR. LAKE: You are absolutely right, Mark,
23 that we do have those obligations. Nothing in the
24 statute changes those obligations. We are fully
25 cognizant of them and believe that we are in

at

1 compliance with them. We are notifying the World
2 Trade Organization of these proposals simultaneous
3 with publication so that the international
4 community will be able to comment on them as well
5 as those in the U.S.
6 In addition to that, this proposal and the
7 next one that we are going to talk about as well,
8 really apply every bit as much to domestic
9 producers as to those abroad; in fact, really more
10 so to domestic companies.
11 MR. BARNETT: What are the next steps,
12 now, in getting these regulations finalized?
13 MR. LAKE: There are actually a series of
14 things. One, the most important thing next is for
15 those who have an interest to review the proposed
16 regs, to then comment on them to the Food and Drug
17 Administration. Then it would be up to FDA to deal
18 with each and every issue that is raised in the
19 comments and prepare the final regulation.
20 MR. BARNETT: If I want to submit
21 comments, how can I go about doing that?
22 MR. LAKE: There are a couple of ways of
23 doing that. The first and most traditional way is
24 to submit comments to our Dockets Management
25 Branch. The address for that is now on the screen.

at

1 Again, it is very important to include the docket
2 number which, in this case, is 02N-0277, to be sure
3 that the comment goes into the right file.
4 MR. BARNETT: Also, you can do this
5 electronically?
6 MR. LAKE: That is correct. The slide is
7 now on the screen as well. This is the way that
8 you can submit your comments electronically. Here,
9 again, it is very important that you include the
10 docket number.
11 MR. BARNETT: You can also get updated
12 information on the progress of the regulation from
13 time to time.
14 MR. LAKE: That is correct, Mark. Updates
15 are available on FDA's website and the slide
16 showing how to access that is now on the screen.
17 As information becomes available, we will be
18 putting it on that website.
19 MR. BARNETT: We have some faxes and I
20 hear that more are coming in momentarily, but let
21 me begin with the ones that have already come in.
22 This first one says, "In following raw agricultural
23 products through the chain of custody, wouldn't it
24 be more appropriate to trace these bulk products in
25 such as way as to limit the number of potential

at

1 sources of contamination rather than just listing
2 all of the suppliers?"
3 MR. LAKE: Mark, shall I take that one? I
4 think there may be two questions lurking there.
5 One seems to have the notion that limiting the
6 number of people who handle the food limits the
7 potential risk of contamination. That is certainly
8 a factor but it is not a part of this rulemaking,
9 beyond the scope of this rulemaking.
10 The other issue that I see lurking in that
11 question is the notion of preserving the identity
12 of a food from the farm and maintaining all the
13 ingredients that relate--that came from that farm
14 all the way through the entire system.
15 This is done voluntarily, for instance, in
16 the case of organic foods. But we felt that that,
17 too, was beyond the scope of what we wanted to do
18 in this proposal. So this is not about identity
19 preservation. It is about recordkeeping and access
20 to facilitate trace-back and track-forward.
21 MR. BARNETT: This one says, "Does the
22 recordkeeping requirement apply to customs brokers
23 and freight-forwarders who 'facilitate'," and that
24 is in quotes, "who 'facilitate' and/or arrange the
25 import and transportation of these covered goods?"

at

1 Leslye, do you want to handle that

2 MS. FRASER: Yes; it does. The statute

3 and the proposed rule on the domestic side does

4 apply to persons who import food along with those

5 who manufacture, process, pack, hold, distribute,

6 transport or receive. On the foreign side, with

7 respect to exporters, it would also apply basically

8 to the last foreign facility who did a major

9 manufacturing, processing or packaging activity

10 with respect to that food as well as to any other

11 foreign facility that did some of the minor type of

12 activity, what we call a de minimis activity, such

13 as putting on a label.

14 MR. BARNETT: This one says, "Does the

15 recordkeeping rule apply to manufacturers of food-

16 packaging materials?"

17 MS. FRASER: No; it does not. We are

18 proposing not to--although we did have the

19 authority in the Bioterrorism Act to require

20 records for those who also handle food-packaging

21 materials, because the Act specifies records of

22 foods and its packaging, in the proposed rule, FDA

23 did not require records of packaging materials.

24 But we did take comment on that approach.

25 MR. BARNETT: This one says, "Will the

at

1 bills of lading commonly used by trucking companies
2 suffice for the transporter recordkeeping
3 requirements?"
4 MS. FRASER: It could. It would be for
5 the transporter to make sure that what is contained
6 in their bill of lading contains all of the
7 required information in the proposed rule. We
8 could envision that there are some bills of lading
9 that do meet those requirements and there may be
10 others that do not. But it would be for the
11 transporter to make sure that, if that is the
12 mechanism they want to use as their recordkeeping,
13 that they supplement and deficiencies in their
14 record-keeping ability.
15 MR. BARNETT: Okay. This one says, "The
16 regulation establishes different recordkeeping for
17 transporters and nontransporters. Why the
18 difference? Why the distinction between the two?"
19 MR. NIEDLEMAN: Basically, a
20 nontransporter is anybody other than a shipping
21 company in very simplistic terms. A transporter
22 just is responsible for the delivery of the
23 product. They need to know from whom they received
24 it and to whom they delivered it. They can't
25 necessarily be responsible for who or where each

at

1 ingredient came from when that manufacturer
2 received those ingredients and only the
3 manufacturer would be able to put that story
4 together and be able to trace the legacy or the
5 history of that product.
6 So the nontransporter has additional
7 responsibilities than the transporter
8 MS. FRASER: In addition to that, part of
9 our philosophy was we wanted to be able to quickly
10 isolate any potentially contaminated food that met
11 the standard of being adulterated or evidence of
12 being adulterated with a serious adverse health
13 consequence to humans or animals. So it would be
14 easier to go through sort of the buyer-seller chain
15 quickly and figure out where the food had gone down
16 the chain and, once we found the source, to go back
17 out and figure out where all the other similarly
18 contaminated food had gone separately from going
19 through each step of the way.
20 If we go back to that example where we had
21 the manufacturer going to a truck to a plane to a
22 truck to the retail store, it would be easier for
23 us to say, "retail store to the manufacturer," if
24 that is where the contamination occurred.
25 It also could have occurred during

at

1 transportation and then we would go separately
2 through that leg. But we were looking at what
3 would be the quickest way we could respond in a
4 public-health emergency related to food, and that
5 was our proposed approach. But, again, we did ask
6 for comment on having nontransporters having
7 basically to keep two tracks of records.
8 MR. BARNETT: We have about twelve more
9 minutes in this section. We have a lot of faxes
10 coming in so I am going to go a little faster now
11 and ask you to keep your answers brief. Okay.
12 "Are there any recordkeeping requirements," we are
13 probably going to go too fast, now. "Are there any
14 recordkeeping requirements for foreign
15 transporters? It is not mentioned under foreign
16 facilities."
17 MS. FRASER: No.
18 MR. BARNETT: There are not. Okay. That
19 was brief. We are going to be through too soon.
20 "One transportation company example. What
21 about when the product is shipped to a retail
22 store's central warehouse and then, from there, to
23 retail stores. Where does the responsibility for
24 recordkeeping lie?" Is that clear?
25 MR. LAKE: Well, I think there are a

at

1 couple of different possibilities there. The
2 central warehousing facility may be servicing
3 several stores owned by the same company. So, from
4 that point forward, it is really the responsibility
5 of that company that is receiving the food to keep
6 records and also to keep records of the transporter
7 that delivered it to them.
8 The transporter has to know where they
9 pick their stuff up and, of course, where they drop
10 it off.
11 MR. BARNETT: Okay. This one says, "Are
12 transportation companies required to verify the
13 accuracy of contents reported by the
14 nontransporting shipping company?"
15 MS. FRASER: We did not specify that one
16 way or the other in the rule. So we would invite
17 comment on that. Our approach was that we needed a
18 record of how much was picked up and how much was
19 delivered so that we could make sure, again, in a
20 trace-back, we had accounted for all goods. We did
21 not speak to verification at all.
22 MR. BARNETT: Okay. Here are two of them,
23 from one caller, or one faxer, who says, "We are a
24 nonprofit service provider for persons with mental
25 retardation and developmental disabilities. We

1 purchase, transport and prepare food for the
2 individuals we serve. Does the Act require that we
3 keep records for all food purchases for two years?"
4 MR. LAKE: I can take that one. The
5 answer is that they have to keep records of where
6 they got their food but, to the extent that they
7 would qualify as a retailer, they would not have to
8 keep records on their customers.
9 MR. BARNETT: Okay. And then, quickly,
10 the second part of this, "Do the recordkeeping
11 requirements of the Act apply to residential
12 service providers such as nursing homes, group
13 homes, and so on?"
14 MR. LAKE: Yes.
15 MR. BARNETT: They do.
16 MR. LAKE: In the same way.
17 MR. BARNETT: Okay. This one says, "How
18 would a bottled-water processor identify the
19 nontransporter previous source as to the name and
20 responsible individual, address, telephone, fax,
21 and so on?"
22 MR. NIEDLEMAN: They would be identifying
23 the source of the water that they are using in
24 their bottling facility. If it is a spring, then
25 that is the source of the water. If they are

at

1 purchasing the water from another company, then
2 they would have to identify that and how they
3 received it.
4 MR. BARNETT: Okay. "FDA was given
5 record-review authority when the Bioterrorism Act
6 was signed last June. Has the FDA exercised its
7 new authority to date, record-review authority?"
8 MS. FRASER: Access.
9 MR. LAKE: Yes; I think it really means
10 records-access authority. We have not exercised it
11 so far. But the question is based on the reality.
12 We already have access authority granted by the new
13 law. This relates to what records have to be kept.
14 MR. BARNETT: Okay. This one says, "The
15 legislation refers to food for human consumption.
16 Packaging materials are not intended for human
17 consumption. Why are you including food-packaging
18 materials in the rule?"
19 MR. NIEDLEMAN: I think we covered that
20 MS. FRASER: We are not including them.
21 MR. BARNETT: We are not including it;
22 okay
23 MS. FRASER: But the Act gave us the
24 authority to include it, but we chose not to but
25 are taking comment on it.

at

1 MR. BARNETT: Okay. This says, "Would
2 grain elevators under the jurisdiction of the U.S.
3 Warehouse Act be required to keep records?"
4 MR. LAKE: The answer to that is yes.
5 MR. NIEDLEMAN: Yes.
6 MR. BARNETT: Okay. "Does a domestic
7 company have to keep records if they only export
8 products not to be consumed in the U.S.?"
9 MR. LAKE: That one, to me, sounds like
10 one we would like to have some comment on it.
11 MR. BARNETT: Okay.
12 MS. FRASER: But the requirement is for
13 food for consumption in the U.S., so I agree with
14 Bob. We would want comment on whether any of their
15 ingredients, or what are they actually moving and
16 doing.
17 MR. BARNETT: Okay. That is a good point,
18 then, something that you want to hear from people
19 about.
20 MR. NIEDLEMAN: Right; that is something
21 we want to hear more about.
22 MR. BARNETT: Good. Okay. I would
23 mention to our audience, we have about six more
24 minutes. I have two more faxes. If you hurry, we
25 might be able to get another question or two in

at

1 here. Okay. "What steps are being taken to avoid
2 the duplication of recordkeeping requirements with
3 U.S. Customs or ATF?"
4 MS. FRASER: We don't envision that there
5 should be duplication per se because existing
6 records that are kept for any other reason, whether
7 it is in compliance with a federal law such as U.S.
8 Customs or USDA or as a matter of business
9 practices, those records can be used. To the
10 extent the we are requiring additional information
11 so that we can do an effective trace-back, which is
12 a different purpose than why Customs would require
13 records, then only those additional elements would
14 have to be added to existing records. But it does
15 not require a second set of duplicative records.
16 MR. BARNETT: This is my last one, here.
17 It says, "If a manufacturer makes canned beans with
18 meat with more than 2 percent of meat, he therefore
19 would be under USDA jurisdiction. Must he keep
20 records of the ingredients other than the meat?"
21 MR. LAKE: Well, the ingredients, other
22 than the meat, would almost certainly be FDA-
23 regulated ingredients. So the answer is yes.
24 MR. BARNETT: Okay. Our viewers took me
25 up on my last offer. We have three more. We will

at

1 do it and we will do it fairly quickly. We will be
2 okay. It says, "Are there penalties for
3 unintentional errors," and unintentional is
4 underlined, "in the recordkeeping?"
5 MR. NIEDLEMAN: That is tough to judge. I
6 mean, what is unintentional? Is it one in 100, or
7 is it one in 100 that you are complying with? I
8 think, again, there is going to be a learning curve
9 associated with this and it is going to be
10 different for any specific situation. It is tough
11 to just make a blanket statement like that or give
12 a blanket response. We are going to have to
13 evaluate the situation.
14 MR. LAKE: But I would also say this is
15 another area where I think we would be interested
16 in comments, what do our viewers and others think
17 about this.
18 MR. BARNETT: Okay. It says, "Your
19 description of the definition of food did not
20 mention 'packaging' or food-contact sources where
21 migration occurs." This is another packaging
22 question. "The two previous proposed regulations
23 did describe food to include packaging and
24 migration sources. Are you intending to interpret
25 the meaning of food differently than you have

at

1 before?

2 MS. FRASER: No; we are not choosing to

3 interpret or selecting to interpret food

4 differently. The definition of food remains the

5 same. The application of the two requirements is

6 what differs. The Bioterrorism Act in Section 306

7 said that FDA may issue regulations, or must issue

8 regulations by December 12 that would require

9 records for immediate previous source and immediate

10 subsequent recipients of food and its packaging.

11 It gave us discretion to decide what food

12 to regulate. We chose, in the proposal, not to

13 regulate packaging just as we chose not to regulate

14 all pet-food entities and we are taking comment on

15 that.

16 MR. BARNETT: Okay. "Does the nonedible

17 chicken parts from a USDA chicken-processing

18 facility fall under this rule of the nonedible

19 parts are intended to be used for pet food?"

20 MS. FRASER: If that entity is currently

21 subject to FDA's BSE rule, they would be subject to

22 this rule. I don't know the specifics to answer

23 that question directly. But if they are not

24 subject to FDA's BSE rule, they would be exempt

25 from this rule.

at

1 MR. BARNETT: Okay. "Will FDA recognize
2 systems and regulations in place and administered
3 by a foreign country's government as being
4 equivalent to the requirements in the proposed
5 rule?"
6 MR. LAKE: Let me respond to that.
7 Before, at least in my limited understanding of the
8 way the WTO agreements work, first, we have to
9 establish a requirement. Then we can begin
10 discussions about whether that requirement can be
11 met by equivalent requirements in other countries.
12 Again, the purpose here is to assure that we have
13 the ability to trace food and we are, as we talked
14 earlier, open to any system of records that already
15 exists.
16 So, if another government requires
17 adequate records for trace-back, then the companies
18 complying with the requirement would probably be in
19 compliance with their own as well.
20 MR. BARNETT: Okay. Well, it is time to
21 end this part of the discussion. This is the one
22 on recordkeeping. It is time for a ten-minute
23 break. When we come back, we are going to discuss
24 the second proposed rule, the one on administrative
25 detention.

at

1 Now, during the break, we are going to be
2 showing some important information on your screen.
3 You will see the electronic and mail addresses you
4 should use to submit your comments to our Dockets
5 Management Branch and you will see the internet
6 address for FDA's Bioterrorism web page. On that
7 web page, you will find a link to all of the
8 comments received by FDA on the proposed rules,
9 updated information on future satellite downlinks,
10 and a wide variety of topics on FDA's activities
11 involving bioterrorism.
12 So we will see you back here in just a few
13 minutes.
14 [Break.]
15 MR. BARNETT: We are back live and ready
16 to discuss the proposed regulation on
17 administrative detention. So, Bob Lake, let's
18 begin by asking what it is. What is administrative
19 detention?
20 MR. LAKE: Well, Mark, the new
21 Bioterrorism Law provides authority for FDA to
22 detain products in domestic commerce if they
23 present a threat of serious adverse-health
24 consequences or death to humans or animals. The
25 authority that has been provided is currently in

at

1 effect and could be used even now.

2 MR. BARNETT: Why did you need it?

3 MR. LAKE: We have lacked authority to

4 hold a food in place, as it were, in the past.

5 This new authority gives us the ability to do that

6 in order to allow us to go into federal court and

7 file a seizure action.

8 MR. BARNETT: While the food is being

9 held.

10 MR. LAKE: While it is being held in

11 place; that's correct.

12 MR. BARNETT: Do you envision that this

13 will be used more for domestic or imported foods?

14 MR. LAKE: It could be used for either

15 but, as a practical matter, we already have

16 authority for detaining foreign products coming

17 into the U.S. that violate U.S. law. And we have

18 been exercising that authority to simply keep those

19 foods out of the U.S. for many, many years.

20 What this new authority does is allow us

21 to detain product that is in the United States.

22 This, therefore, will apply mainly, I believe, to

23 domestic producers. But it could apply to an

24 imported food that was originally allowed into the

25 U.S. and then found out to be contaminated at some

at

1 later time.

2 MR. BARNETT: Leslye, let me ask you a

3 similar question to the one I gave you on

4 recordkeeping and that is what kinds of foods are

5 going to be subject to administrative detention.

6 MS. FRASER: Again, it is the same foods,

7 foods under FDA's jurisdiction. The difference

8 here from records is that records was limited to

9 foods that were intended for consumption by humans

10 or animals in the United States. By comparison,

11 administrative detention would apply to all foods,

12 whether or not they were going to be consumed in

13 the United States, that currently are under our

14 authority.

15 Again, we have the definition of the

16 Federal Food, Drug and Cosmetic Act that applies

17 and the same examples that we went through

18 previously as the types of food that we regulate.

19 Again, it is food and food additives for man or

20 animals, dietary supplements and dietary

21 ingredients, infant formula, pet food including

22 alcoholic beverages and bottled water, fruits and

23 vegetables, fish and seafood, dairy products and

24 shell eggs, raw agriculture commodities used as

25 food or components of food, canned food, live food

1 animals, bakery good, snack food and candy.

2 MR. BARNETT: Again, a parallel question

3 to what I asked you about recordkeeping. What food

4 is not subject to administrative detention by FDA

5 MS. FRASER: It also is the same, that

6 foods that are under the exclusive jurisdiction of

7 the U.S. Department of Agriculture would not be

8 subject to administrative detention. That, again,

9 is meat products, poultry products and egg

10 products. If there is a product out there, though,

11 that contains food that is both subject to our

12 jurisdiction along with food subject to USDA's

13 jurisdiction in one package, such as, again, a

14 frozen dinner that is intended to be heated up in a

15 microwave, we could detain that food because we

16 would have jurisdiction over the FDA food.

17 MR. BARNETT: Bob, the statute only

18 requires the FDA to set standards for perishable

19 foods. Yet, it is interesting that in the proposed

20 rule, you are going beyond that. Why are you doing

21 that?

22 MR. LAKE: Mark, the reason for that is

23 that--first, you are right. We are only required

24 to do the rulemaking for perishables but we decided

25 that, while we were at it, we would include all

1 foods. The advantage is that this enables us to be
2 sure that we have procedures in place that will
3 allow us to meet the statutory time frames and, in
4 particular, we felt that it was important to spell
5 out the details of how the appeal process would
6 work. That process is really the same for both.
7 It is the timing that is different between the
8 perishable and nonperishable.
9 MR. BARNETT: Okay. Leslye, in the
10 context of this rule, what is perishable? What
11 does that mean?
12 MS. FRASER: FDA has included a proposed
13 definition for perishable food in this rule and in
14 the recordkeeping rule. They are both the same
15 definition. It is taken from our current
16 definition of perishable commodity in our
17 Regulatory Procedures Manual. That definition is,
18 "Food that is not heat treated, not frozen, and not
19 otherwise preserved in a manner as to prevent the
20 quality of food from being adversely affected if it
21 is held longer than seven days under the normal
22 shipping and storage conditions for that food."
23 We are taking comment on that definition.
24 In this rule, it impacts which appeals process and
25 the timing for appeals would apply. In the

1 recordkeeping rule, it affects the retention times.
2 So, in both rules, we are taking comment.
3 MR. BARNETT: Steve, the administrative
4 detention is not new to the FDA. The are
5 administrative detentions in other FDA regulations.
6 What are they?
7 MR. NIEDLEMAN: The proposed rule is
8 modeled after the Medical Device Administrative
9 Detention Authorities that exist in 21, Code of
10 Federal Regulations, 800.55. We believe that the
11 device detention process has been effective and
12 efficient and should equally be as efficient for
13 foods, and it has been modified moderately to
14 accompany that.
15 This is useful because using the device
16 model as a model for the field, they are familiar
17 with the process. It will reduce the amount of
18 time we need to train our field staff as to how to
19 properly implement the new Food Detention
20 Authorities.
21 I would also like to note that the
22 administrative detention requirements that are
23 being proposed and as required by the Bioterrorism
24 Act require us to provide an opportunity for an
25 informal hearing as part of the appeal process if

at

1 an appeal is filed and that 21, Code of Federal
2 Regulations, again Title 21, Part 16, sets out the
3 FDA's informal hearing process that will be
4 followed when the administrative detention is put
5 in place.
6 MR. BARNETT: Steve, just in a general
7 way, how do you think the detention process is
8 going to work?
9 MR. NIEDLEMAN: Mark, once the standard is
10 met to impose a detention, we will consider whether
11 or not that is the most efficient way for us to
12 proceed. But, assuming that it is, we will be able
13 to temporarily place and prevent further
14 distribution of that product in commerce as well as
15 further sale of that product for up to thirty days
16 while it is being detained.
17 During that time, the agency can proceed
18 with final agency action to remove the product from
19 commerce and we anticipate that the final agency
20 action would be a seizure. Seizures are in rem
21 processes which basically just affect product and
22 do not affect individuals. They do not include
23 individuals.
24 For those who are not familiar with the
25 term "seizure," what we mean by it, basically, FDA

at

1 would seek, through the Assistant U.S. Attorney's
2 Office, the ability to control or arrest the
3 product and segregate it from nonviolative product
4 and prevent it from entering commerce.
5 MR. BARNETT: That is an interesting
6 comparison. It is the arrest of a product as
7 opposed to arrest of a person.
8 MR. NIEDLEMAN: Individual; that's
9 correct.
10 MR. BARNETT: Who is authorized, Leslye,
11 to order one of these administrative detentions
12 MS. FRASER: An officer or qualified
13 employee of FDA may order an administrative
14 detention. Those are people like investigators,
15 inspectors or other employees of other federal
16 agencies that we have commissioned to assist us
17 with investigations or inspections.
18 MR. BARNETT: I am assuming that, before
19 you detain a product in this way, that you have
20 certain criteria you use that have to be met before
21 you can take this kind of action.
22 MS. FRASER: Yes; we do. The statute,
23 both the statute and the proposed rule, specify
24 that a detention may be ordered if, during an
25 inspection, an investigation or an examination, an

at

1 officer or qualified employee has credible evidence
2 or information that an article of food presents a
3 threat of serious adverse-health consequences or
4 death to humans or animals. So that standard would
5 first have to be met, the serious adverse-health
6 consequences, before and administrative detention
7 could be ordered on an article of food.
8 MR. BARNETT: But, before it is ordered,
9 someone else in the FDA has to also approve it; is
10 that right
11 MS. FRASER: Absolutely right. The FDA
12 district director with responsibility for the
13 geographical location where the food is located
14 would have to approve the detention or someone
15 senior to that person. That approval can be
16 obtained in writing or it may be obtained orally
17 with a written confirmation to follow.
18 For example, if someone is in a remote
19 part of town and doing an investigation and finds
20 food, or has a reasonable belief that there is this
21 article of food presenting the serious threat, they
22 can call and obtain oral approval if there isn't a
23 fax machine rather than have to drive and obtain
24 that approval. But then the approval would have to
25 be followed up with a written confirmation.

at

1 MR. BARNETT: Talk about the detention
2 order, itself. It has to include certain--the FDA,
3 now. Not the other person. I am changing things
4 around here. The FDA has to include certain
5 information in that detention order. What is that
6 information?
7 MS. FRASER: FDA specified a number of
8 elements that must be contained in the detention
9 order in the proposed rule. And we do invite
10 comment on that. What we proposed is that the
11 detention order must include the detention-order
12 number, the hour and date of the order, the
13 identification of the detained article of food, the
14 detention period of time, a statement that the food
15 cannot be--or how long the food is going to be
16 detained for.
17 The order also has to include general
18 reasons, or a general statement, giving the reasons
19 for the detention, the address and location where
20 the food is to be detained and any appropriate
21 storage conditions to maintain the quality of the
22 food, any applicable conditions of transportation;
23 for example, if FDA determines it appropriate to
24 move the food to secure storage or to a cooled
25 storage, we would have to specify the

1 transportation of that, and a statement that the
2 food may not be consumed, moved, altered or
3 tampered with in any manner during the detention
4 period unless we have given written approval and
5 permission to do that.
6 MR. BARNETT: Steve, how long can the FDA
7 detail--oh; did you want to add something? Go
8 ahead.
9 MS. FRASER: Sorry. Yes; there is some
10 more. The order also has to include information
11 regarding how to appeal the detention and the name
12 and contact information of the district director in
13 whose district the food is located. Again, this is
14 the person that generally has approved the order.
15 And, then, lastly, how that approval was obtained;
16 was it orally or was it in writing.
17 MR. BARNETT: So, Steve, how long can the
18 FDA detain an article of food?
19 MR. NIEDLEMAN: Well, Mark, we detain
20 products for a reasonable period, generally up to
21 twenty days, unless a greater period, not to exceed
22 thirty days, is needed to enable us to take a more
23 permanent action or more final regulatory action
24 against the violative product.
25 MR. BARNETT: Where is the detained

1 article of food held and under what conditions?

2 MR. NIEDLEMAN: The detained product needs

3 to be detained in place at the location and under

4 the conditions that we identify in our detention

5 order. We must also order, if appropriate, the

6 removal of the product to secure storage if that is

7 indicated or not already located in secure storage.

8 MR. BARNETT: Can the detained article be

9 delivered to somebody else or maybe transferred to

10 another location by the owner?

11 MR. NIEDLEMAN: An article of food that

12 has already been detained may not be further

13 distributed to the next person in line. It may not

14 be distributed to the importer or to another owner

15 or to another consignee. It may not be transferred

16 from the place where it has been ordered detained

17 or from the secure-storage facility where it is

18 currently being held until a FDA-authorized

19 representative releases the article or the

20 detention period expires, whichever occurs first.

21 MR. BARNETT: But there are certain

22 circumstances where the food can be moved to

23 another location; is that right?

24 MR. NIEDLEMAN: That is correct. With FDA

25 approval, we may allow limited conditional release

1 of a detained article. Some of those conditions
2 for release would be moving the detained article to
3 a secure facility, moving it so that it maintains
4 or preserves the integrity or the quality of the
5 product, as Leslye said, perhaps to a refrigerated
6 warehouse so that the product maintains its
7 integrity or for any other appropriate purpose that
8 we feel is appropriate.
9 MR. BARNETT: Leslye, can the FDA require
10 that the detained food be labeled or marked in some
11 way to distinguish it?
12 MS. FRASER: Yes; we can. Both the
13 Bioterrorism Act and the proposed rule specify that
14 FDA could require marking or labeling that the food
15 is detained. This needs to be distinguished from--
16 some people are familiar with Section 308 of the
17 Bioterrorism Act which requires marking of food
18 that has been refused entry. That is imported
19 food. This is not that kind of marking. This is
20 simply a marking or a label that would indicate the
21 food has been detained, the conditions of the
22 detention, and then also an indication that the
23 food may not be moved or consumed or the label be
24 removed without written permission of FDA.
25 If the detention order is terminated, then

1 the labels or the markings would be removed so that
2 we don't envision this--if the food turns out not
3 to present that serious threat, we don't envision
4 this as something that would inhibit the ability to
5 sell the product elsewhere or where it was intended
6 to go.
7 MR. BARNETT: Who actually receives the
8 detention order?
9 MS. FRASER: The proposed rule would
10 require, at minimum, the agent operator or owner of
11 the facility or place where the food is being
12 detained to receive a copy of the order. If the
13 person that owns the food isn't one of those three
14 entities, FDA also would provide a copy of the
15 detention order to that party if that person's
16 identity could be reasonably determined.
17 And then, if the food is detained on a
18 carrier or other transportation vehicle, we also
19 would provide a copy of the detention order both to
20 the person that is transporting the food as well as
21 the shipper of record, again if we could reasonably
22 determine their identities.
23 MR. BARNETT: Okay. Let me interrupt for
24 a moment and say to our audience, we already have
25 received several faxes. We would certainly like to

at

1 see more. You don't have to wait until the end to
2 start sending your question. So fax us or phone us
3 or e-mail us and you can start doing that at any
4 time, starting now.
5 Steve, what procedures apply when the FDA
6 initiates a seizure action against a detained,
7 nonperishable food? We have a nonperishable and it
8 has been detained and now the FDA wants to seize
9 it. How does that work?
10 MR. NIEDLEMAN: FDA would follow its
11 already-in-place procedures that are already
12 stipulated in our Regulatory Procedures Manual.
13 These are long-established procedures for how to
14 effect a seizure. We certainly fully support
15 expeditious and speedy handling and processing of
16 seizure actions. However, there is no specific
17 time frame included in the RPM to file a seizure
18 action with the Assistant U.S. Attorney at the
19 jurisdiction where the product is located.
20 Basically, agency policy is we would not
21 like to take a seizure action based on evidence
22 that is older than sixty days, which is way beyond
23 the detention period. So that should not apply as
24 a factor in a detained product.
25 MR. BARNETT: Now, what about the

1 perishable foods? Any difference there in terms of
2 seizure?
3 MR. NIEDLEMAN: Yes. As required by the
4 Bioterrorism legislation, by the Bioterrorism Act,
5 we have implemented expedited procedures for
6 seizure of a perishable product. If we decide to
7 initiate seizure action against a perishable food,
8 we will send that seizure recommendation to the
9 Department of Justice within four calendar days of
10 the filing of the detention unless certain
11 extenuating circumstances exist.
12 Extending circumstances could be awaiting
13 laboratory analysis or other conditions for which
14 we have no control.
15 MR. BARNETT: Now, Leslye, can an FDA
16 detention order be appealed? Suppose the person
17 getting the order doesn't agree with it?
18 MS. FRASER: Yes. That person may appeal
19 the detention order and the way in which you would
20 appeal would be specified on the detention order.
21 The appeals would go to the FDA district director
22 in which the food is located, where the food is
23 located.
24 MR. BARNETT: Talk about how this would
25 work when we are dealing with a seizure or a

at

1 detention of a nonperishable food.

2 MS. FRASER: For a nonperishable food, and

3 actually let me back up a minute with respect to

4 who can appeal. The person who can appeal is the

5 person that would be able to file an action or to

6 appeal if we brought a seizure action. So whoever

7 could claim the food, if it were seized, is the one

8 that is authorized to actually appeal. So it is

9 not everyone who gets the detention order can

10 appeal.

11 With that, if we have a nonperishable

12 food, a person can choose to appeal with the

13 request for an informal hearing or just to appeal

14 where written materials would be reviewed. If they

15 want an informal hearing in a nonperishable food,

16 they would have to let us know with four days of

17 receiving the detention order that they were

18 requesting the hearing and indicating that they

19 were going to appeal.

20 Then we would have to receive the appeal,

21 itself, within ten days of their receiving the

22 detention order. After that, FDA, the time when we

23 receive the appeal, that triggers the clock for us

24 holding the hearing if one was requested. We would

25 have to hold the hearing within three days of

at

1 receiving the appeal.

2 MR. BARNETT: How does that differ, now,

3 if we are talking about a perishable food

4 MS. FRASER: For a perishable food and,

5 again, this is one that we basically said would

6 lose its quality within seven days, the timing is

7 similar but faster. We do not have an intent to

8 request the hearing that has to be filed. You

9 would have to file the appeal with or without the

10 request for hearing within two days of receiving

11 the detention order and then FDA would have to hold

12 the hearing within two days.

13 Again, the comparison, if you assume that

14 someone would appeal on the first day that they

15 received a detention order, then the timing for a

16 perishable and a nonperishable food really would

17 differ by just a day. But, for a nonperishable

18 food, the party, at their choosing, can take longer

19 to choose to appeal, but that is the difference in

20 the timing.

21 MR. BARNETT: The FDA does have a limit on

22 it in terms of responding or issuing a decision on

23 an appeal. They can't just delay this for a long

24 time

25 MS. FRASER: Correct. FDA is required by

at

1 the Bioterrorism Act for both nonperishable and
2 perishable foods to issue a decision within five
3 days of receiving an appeal. That, again, is in
4 part why we develop regulations or propose
5 regulations that address the timing so that we can
6 insure that we meet that five-day time frame.
7 As part of the appeal which would be heard
8 by a regional food and drug director at the FDA,
9 that person who was the hearing officer, that is
10 the person that would hear or review the materials
11 if it is just in writing or preside over the
12 informal hearing. They also would render the
13 decision. But they could require the hearing to be
14 held within one day, to be held and completed
15 within one day. Again, that is to make sure we can
16 render a decision within five days of receiving the
17 appeal as required by the Act.
18 MR. BARNETT: You mentioned the five-day
19 limit several times. Is that five calendar days
20 including weekends, or not including weekends? How
21 does that work
22 MS. FRASER: It is five calendar days
23 including weekends and holidays.
24 MR. BARNETT: Bob, how is the FDA going to
25 handle classified information when you have an

1 informal hearing and the company, obviously,
2 doesn't want this information to be released?
3 MR. LAKE: Certainly, in this environment
4 where we have to be concerned about possible
5 terrorist actions, it is certainly possible that
6 our information is coming from classified
7 documents. They are classified for national-
8 security reasons and we could not disclose those
9 documents. On the other hand, we certainly do
10 recognize the need to have a fair and proper
11 hearing.
12 So to the extent that we can, it is our
13 belief that the hearing officer should be able, in
14 most cases, to at least reveal the general nature
15 of the information and offer an opportunity for the
16 person who is concerned about the goods, the food,
17 to present evidence to contradict that information.
18 The other point with regard to use of
19 classified information is that if we make a
20 decision that is based on classified information,
21 that will be noted in the decision, itself.
22 MR. BARNETT: Steve, when does a detention
23 order terminate?
24 MR. NIEDLEMAN: Mark, an authorized FDA
25 representative will issue a detention-termination

at

1 notice releasing the detained articles either once
2 we are satisfied that the product no longer needs
3 to be detained or the detention has expired, the
4 detention period has run its course.
5 If FDA fails to issue a detention-
6 termination notice by the time the detention does
7 expire, the goods are automatically deemed to be no
8 longer detained. We generally will issue the
9 detention-termination notice to the same individual
10 that we issued the detention notice to or to their
11 representative. As Leslye mentioned earlier, we
12 would also either authorize or ourselves remove any
13 tags or markings that may have been placed on the
14 goods so that the product can return to commerce
15 unblemished and ready to be sold.
16 MR. BARNETT: Bob, this, of course, is a
17 proposed regulation. So what are the next steps in
18 carrying it on and getting it through.
19 MR. LAKE: First, again, we have to
20 actually publish the proposal and, as with records,
21 this will occur on this Friday, May 9. The next
22 step after that is that we receive comments and,
23 again, in both of these cases, the comments will be
24 due by July 8.
25 MR. BARNETT: If someone out there wants

at

1 to comment, how do they do that? First of all, how
2 do they get a copy of the proposed rule?
3 MR. LAKE: All right. Now, on the screen
4 is an indication as to how one can get a copy of
5 our proposed rules. This can be obtained
6 electronically or you can write to the Dockets
7 Management Branch at the address on the screen.
8 MR. BARNETT: And then, once you have it,
9 how do you get the comments in?
10 MR. LAKE: Again, there are two ways of
11 doing this. One can either submit the comments
12 electronically or they can be submitted in written
13 form in the traditional way to the Dockets
14 Management Branch at the address that is shown on
15 the screen, and then the e-mail address, or the
16 electronic address, is also on the screen for how
17 the comments can be submitted electronically.
18 MR. BARNETT: Now, people can also get
19 updated information on all the FDA bioterrorism
20 activities including these proposed rules. And
21 they can do that how?
22 MR. LAKE: That is correct, Mark. Again,
23 the screen is now showing the website for obtaining
24 up-to-date information on our bioterrorism
25 activities which include the proposals we published

at

1 before as well as these proposals and we will have
2 other information as it develops.
3 MR. BARNETT: We have a nice pile of faxes
4 here. Folks, you can keep sending them in. We
5 have almost half an hour left. We have plenty of
6 faxes, but we can use more. So keep sending us
7 your questions.
8 This one says, "When and if a product is
9 detained and needs to be moved to a secured
10 warehouse, can any trucker be used?"
11 MR. NIEDLEMAN: I don't think the
12 regulations specify what type of trucker can be
13 used but, generally speaking, we would expect, in
14 concert with security issues, we probably would
15 want a bonded trucker who can be assured that the
16 product will reach its final destination.
17 MR. BARNETT: Okay. "Will the detention
18 proposal change the relationship between state and
19 federal enforcement?"
20 MR. LAKE: It may, to some degree.
21 Historically, FDA has. When we wanted to seize and
22 were concerned that it might move away from us
23 before we could get the papers filed in court, we
24 have turned to state authorities. States typically
25 have what they call embargo authority which is

at

1 essentially the same kind of authority to hold it
2 in place until FDA could pursue its seizure action.
3 There may still be situations where we
4 follow that similar process. But now that we have
5 our own specific authority, we may be using that
6 much more often--well, obviously more than we have
7 in the past.
8 MR. BARNETT: Right. This one says, "Do
9 either of the proposals discussed today apply to
10 foods that are not in interstate commerce?"
11 Leslye, do you want to take that one
12 MS. FRASER: I guess I would turn that
13 question around and say the proposals apply to all
14 foods whether or not they are in interstate
15 commerce.
16 MR. LAKE: Let me just, on that--we are
17 specifically inviting comment on that issue, also
18 on the question on secure transportation. That
19 also sounds to me like an area where it would be
20 useful to submit comments to the FDA.
21 MR. BARNETT: All right. This one says,
22 "Will FDA increase personnel to handle all of these
23 proposed changes?"
24 MR. LAKE: It depends on the Congress and
25 whether they give us more budget.

at

1 MR. BARNETT: Okay. "The Bioterrorism Act
2 immediately gave FDA its detention authority. Has
3 FDA used this authority to date?"
4 MR. NIEDLEMAN: Not for foods. We have
5 not used the detention authority although it is
6 available to us.
7 MR. BARNETT: Okay. "Will the
8 administrative detention authority be used to
9 detain food for which no prior notice was
10 submitted?"
11 MR. LAKE: Let me answer that. This, I
12 think, is not the way we will deal with failures to
13 adhere to the prior-notice requirement. Again, the
14 prior-notice provision of the law has built into it
15 a requirement that, if the prior notice is not
16 submitted in a timely way, then FDA is to refuse
17 entry. So the food would not be allowed in the
18 U.S. but it would be based on the prior-notice law
19 rather than on this detention authority.
20 Let me come back to my remark about the
21 Congress to note that, separate from the
22 Bioterrorism Law but as part of the budgetary
23 process last year, we did get significant new
24 authority to hire a large number of people. Those
25 people are all now in place. Whether we get people

at

1 beyond that would depend on future budget
2 considerations.
3 MR. NIEDLEMAN: Mark, can I just go back
4 to that question and further elaborate a little bit
5 on whether or not we would use it for prior notice.
6 The standard for using or implementing an
7 administrative detention is when the agency has
8 credible evidence or information that the food
9 product presents a threat of serious adverse-health
10 consequences or death to humans or animals. Just
11 not filing a prior notice, unless there is absent
12 other information, would not raise to the standard
13 for implementing an administrative detention.
14 MR. BARNETT: Okay. This one says, "If a
15 product is detained for a period of time in which
16 the product is no longer fit for consumption, then
17 gets released, what responsibility falls on FDA?"
18 MR. LAKE: The procedures are designed to
19 assure that there is care exercised by FDA and the
20 statute provides some of that. Our proposed rule
21 is providing additional safeguards. And, of
22 course, one of the things, as Steve has just
23 pointed out, is that the standard for using the
24 authority is a pretty high standard.
25 But if the standard is met and we have

at

1 followed the procedures, then, obviously, we
2 believe that that food is a problem. We do not
3 bear the responsibility of what happens to the food
4 in that situation. It would be on the owner. This
5 is not unlike what already exists with regard to
6 seizures or with products that are refused entry
7 into the U.S. because they are not in compliance
8 with the U.S. law.
9 MR. NIEDLEMAN: Just to further elaborate,
10 again, we are sensitive to the fact that if a
11 product is labeled as requiring refrigeration, or
12 requiring certain storage conditions, that we would
13 certainly assure that all effort is made to
14 maintain those products and store them so that
15 spoilage or deterioration is minimized
16 MS. FRASER: I guess, just to tag along, I
17 think the other part of it is that the appeal
18 process is designed to be as rapid as possible and
19 FDA does recognize that there is a potential impact
20 on foods. So we would look to be moving as quickly
21 and as expeditiously as possible any time we did
22 detain a food both to protect the public health if
23 the food really did have that serious adverse-
24 health consequence and then, conversely, to release
25 a product as quickly as we could if it did not.

at

1 MR. BARNETT: This one says, "Does FDA
2 have warehouses? Will the FDA use customs
3 facilities for storing detained goods?"
4 MS. FRASER: It would depend on the
5 circumstances. We would use facilities that we
6 deem appropriate. It might be customs warehouses.
7 It might be a warehouse where the food already
8 exists if we think that is a secure facility and
9 there is no danger of the food getting into
10 commerce. So it really would be a case-by-case
11 basis on where we would detain the food and that
12 would be specified in the detention order, itself.
13 MR. LAKE: I want to add to that a little
14 bit. FDA does not, itself, own warehouses so it
15 wouldn't be in an FDA warehouse. But it would
16 depend. Again, most of the situations, I believe,
17 are going to happen where the product is found
18 somewhere in the United States, not necessarily--in
19 fact, I think generally not--at the border.
20 So it would be with whatever warehouse is
21 available in the area so long as we can be assured
22 that the product is not going to be further
23 distributed to consumers.
24 MR. BARNETT: Okay. This one says, "How
25 does the FDA plan to draw a distinction between an

at

1 order of detention for a suspected act of
2 bioterrorism and an historically more routine
3 reason; for example, plant or supplier indirect
4 accidental adulteration, and so on?"
5 MR. NIEDLEMAN: Again, it is the standard
6 by which we can implement the administrative
7 detention authority, and that is credible evidence
8 or information that the product poses a threat of
9 serious adverse-health consequences or death. That
10 is the standard that we would use to impose an
11 administrative detention. That is what Congress
12 gave us to use and that is what we would live by.
13 MR. BARNETT: So your answer essentially
14 is that you are not drawing a distinction between--
15 MR. NIEDLEMAN: Right.
16 MR. LAKE: Let me just add on to that. It
17 is not going to be uncommon that we, through an
18 analysis or otherwise, know that the product is
19 dangerous or hazardous to people or animals long
20 before we understand why it got hazardous. So the
21 point is to keep it from getting to consumers. So
22 we would not make the distinction as to how it got
23 contaminated so long as, as Steve points out, the
24 statutory standard is met.
25 MR. BARNETT: Okay. This one says, "Has

at

1 FDA considered the economic impact of this
2 proposal?"
3 MS. FRASER: Yes; we have and there is an
4 extensive economic analysis for each of the rules
5 that we have proposed and we do invite comments on
6 those aspects of the proposal as well. In
7 particular, to the extent that reviewers disagree
8 with our assumptions or our analyses, we invite
9 comment on that but what would be most helpful is
10 accompanying data that supports the new analyses or
11 the approaches that are offered.
12 MR. BARNETT: Okay. This one says, "Can
13 the administrative detention or other provisions of
14 the bioterrorism regulations be used for non-
15 terrorist contaminations such as insects, bacteria
16 and chemicals?" I think you touched on that.
17 MR. NIEDLEMAN: Yes; while the regulations
18 and the authority was granted under the
19 Bioterrorism Act, it is not specific to
20 bioterrorism or to a terrorist attack. It is based
21 upon the standard of credible evidence of serious
22 adverse-health consequences or death to humans or
23 animals. It goes beyond just terrorist type of
24 activities.
25 That is not to say insects may raise to

at

1 that level or filth or contamination of such
2 nature. We must meet the burden or the hurdles
3 that were placed in front of us before we can use
4 this tool.
5 MR. BARNETT: This one says, "Could
6 extenuating circumstances ever exist to justify the
7 immediate seizure and destruction," and destruction
8 is underlined, "of an article without receipt of an
9 order of detention?"
10 MR. LAKE: Now, that would be outside the
11 procedures. Again, the purpose of detention is to
12 keep the food from getting further into commerce,
13 into consumers' hands, while we, then, go through
14 the next step. The step that the statute has long
15 provided is for us to go into federal court and
16 file what amounts to a law suit against the goods.
17 At that point, the marshal takes over
18 custody of those goods, take possession
19 effectively, and then the matter is litigated in
20 court. Now, arising out of that court decision, I
21 mean, the product could be destroyed. But the idea
22 is to keep it from moving while we go through the
23 rest of this process.
24 MR. BARNETT: Right.
25 MR. NIEDLEMAN: The other thing I want to

at

1 clarify is the administrative-detention authority
2 that we have is the authority is solely for
3 administrative detention. It does not affect our
4 ability to seize product without imposing an
5 administrative detention as we currently do. We
6 will seize product based upon filth, insect
7 infestation, et cetera, as we have done for many,
8 many, many years.
9 This is an ability to just freeze the
10 product in place when we have credible evidence or
11 information about the serious adverse-health
12 consequences. We will still proceed with seizures
13 without providing notice under administrative
14 detention for other type of scenarios.
15 MR. BARNETT: Good. Okay. This one says,
16 "If an importer or customs broker imports food on
17 weekends and that food gets transported to another
18 location not in the original FDA district it was
19 imported through, if FDA wants to see if it can--"
20 this is hard to read. "If the FDA wants to see it,
21 can the shipment," commas would be helpful here,
22 "If FDA wants to see it, can the shipment be
23 inspected by another FDA district or returned to
24 the original district?"
25 MS. FRASER: The question is, in terms of

at

1 the procedures for detention, it is stopping the
2 food where it currently is. So, if the food has
3 moved from wherever it entered the country, or
4 where it was manufactured in the country to another
5 place in a different district, and that is where we
6 determine that there is credible evidence or
7 information of the serious adverse-health
8 consequence, we would stop it here and it is now
9 the FDA district director who is responsible for
10 the new location that has to approve the detention
11 order. It doesn't go back to the old FDA district
12 director because that is where it originated.
13 MR. NIEDLEMAN: There is additional
14 authority under Bioterrorism Law that is associated
15 with administrative detention but not included in
16 the regulations; that is, FDA does have the
17 authority to put a 24-hour hold on incoming
18 products so that we can examine it and determine
19 whether a detention would be appropriate or other
20 action, including an import detention, et cetera.
21 So it would depend upon the specific situation but,
22 as Leslye says, if it is moved to another district,
23 that is where it is detained, that district would
24 have the jurisdiction.
25 MR. BARNETT: This one says, "On what

1 legal authority are you relying to regulate foods
2 that are not in interstate commerce"?
3 MS. FRASER: We did not see a limitation
4 in this provision of the act that said that it was
5 limited to food in interstate commerce. There are
6 other provisions in the Act that specifically
7 specify interstate commerce as a component of that
8 requirement and so our interpretation of both
9 records which applies to all persons who
10 manufacture, process, pack, hold, transport,
11 distribute, receive or import foods, we didn't see
12 a limitation there or with respect to the ability
13 to detain food administratively if it had a threat
14 of serious adverse-health consequences, we see a
15 limitation there.
16 So we did recognize that this is an
17 important question and, as Bob said earlier, in
18 both rules, you will see a specific request for
19 comment on that issue.
20 MR. LAKE: Let me just elaborate on that a
21 little bit, too. As a practical matter, most food
22 is in interstate commerce or is in packaging that
23 has been in interstate commerce. So what is purely
24 intrastate these days is not a big percentage of
25 the U.S. food supply.

at

1 Aside from that, even the stuff that might
2 qualify as intrastate is generally affecting
3 interstate commerce. So Congress, I believe, and
4 this is not my area, but I believe they do have the
5 authority, using that authority under the
6 Constitution, to regulate the intrastate commerce.
7 It appears that the way they wrote the law, to us,
8 that that is what they did.
9 But, again, as we pointed out, we are
10 inviting comment on that and we would be very
11 interested in what people have to say.
12 MR. BARNETT: Okay. This one says, "When
13 is the effective date for administrative detention
14 ruling?"
15 MS. FRASER: Administrative-detention
16 authority is in effect now. It was in effect when
17 the Bioterrorism Act passed. These regulations
18 would not take effect until after we issued the
19 final rule and specified an effective date in that
20 rule. And, as Bob said earlier, our goal is to
21 publish the final rule by December 12 of this year
22 and, under U.S. law, we would have to give at least
23 thirty days notice before the rule could take
24 effect.
25 So the earliest the proposed rule or the

at

1 final rule could take effect would be thirty days
2 after publication of the final rule.
3 MR. BARNETT: Okay. This one says, "If
4 administrative detention is issued for a single
5 article of food on an import vessel, a truck or
6 plane, et cetera, with multiple articles, are all
7 the articles on that vessel held or only the single
8 article in question?"
9 MR. NIEDLEMAN: That particular article of
10 food would be segregated off. It would be marked.
11 It would be identified and every effort would be
12 made to minimize the chance of it being distributed
13 in commerce. It would be segregated into a
14 quarantine area or somehow, if the quarantine area
15 isn't available, it would be roped off, tied off,
16 et cetera. It would be segregated.
17 MS. FRASER: The one thing I would like to
18 add to that, though; it also would depend on what
19 we thought it was contaminated with or what was the
20 serious health consequence or risk because you
21 could have a situation where one article of food on
22 that shipment was contaminated but it had the
23 ability to cross-contaminate other shipments that
24 were collocated, in which case, our credible
25 evidence or information might be that it is not

at

1 just the one that was contaminated but all of them
2 might pose the serious health consequence, in which
3 case--so it would be a case-by-case basis based on
4 what we thought the credible evidence or
5 information was.
6 MR. NIEDLEMAN: It could cross-contaminate
7 other product.
8 MR. BARNETT: I am going to do the same
9 thing I did with the last panel. We keep getting
10 these faxes in, which is wonderful, but it means
11 that we are going to have to go a little bit
12 quicker because we have got about ten minutes left.
13 I think you covered this before, Leslye,
14 but I will ask you it again, just to be sure. "You
15 refer to days in the appeals time line. Does that
16 mean working days or calendar days?"
17 MS. FRASER: It means calendar days which
18 means hearings could be held on a weekend or
19 holiday.
20 MR. BARNETT: Okay. "Are pet foods exempt
21 as they are in the recordkeeping regulation?"
22 MS. FRASER: No; they are not.
23 MR. BARNETT: "What information would be
24 available to an owner of food product concerning
25 testing of the product during the detention

1 period?"

2 MR. NIEDLEMAN: Can you repeat that, Mark?

3 MR. BARNETT: Yes. "What information

4 would be available to the owner of a food product

5 concerning testing of the product during the

6 detention period?" In other words, I think it

7 means are you going to let them know what you are

8 doing?

9 MR. NIEDLEMAN: We always--it is FDA's

10 policy to share sample results, once they become

11 available, with the owner of the property. When we

12 collect a sample of a food, we also collect an

13 sufficient supply for the owner to run parallel

14 tests to do confirmatory testing of their own as

15 well.

16 MR. BARNETT: Okay. It says, "Are

17 administrative detentions going to be part of the

18 public record and will they be available? Will

19 detention records be in a searchable system like

20 recalls and import alerts?"

21 MR. NIEDLEMAN: Yes; they will. They have

22 historically for medical devices and they will

23 continue to be so for foods. That is public

24 information.

25 MR. BARNETT: Okay. "Can you explain the

at

1 difference between an import detention and an
2 administrative detention?"
3 MR. NIEDLEMAN: Certainly. The burden for
4 an import detention is a much lower threshold for
5 the agency. We just need to have an appearance of
6 an adulterated or a misbranded product to be able
7 to place a product under import detention and
8 refuse its entry into the United States or provide
9 an opportunity for someone to present evidence as
10 to why that product should enter into this country.
11 For an administrative detention, as I
12 mentioned before, you have a much higher threshold
13 that you have credible evidence or information that
14 the product poses a threat of serious adverse-
15 health consequences or death, which is a much
16 higher standard than just the appearance of
17 adulteration or misbranding, which is why it is
18 less likely we will use this authority for imported
19 products.
20 MR. LAKE: I would just like to emphasize
21 that. Because the word "detention" is here, and I
22 can tell from the questions that a lot of the
23 audience is thinking import detention, this really
24 is about detained product that is moving in
25 commerce within the United States.

at

1 Because of the authority that we already
2 have and have been exercising for many, many year
3 for keeping product out of the U.S., we will
4 continue to use that when we know there is a
5 problem when it is being offered for entry.
6 This authority that we are talking about
7 here today is brand-new authority and it is not
8 fundamentally about imports. It is about food
9 moving in domestic commerce which means it is
10 mainly going to be about U.S.-produced food. Now,
11 it could be that a product that was imported and
12 originally allowed in is later found to be
13 contaminated or it could be that that product,
14 whether it was originally import or manufactured in
15 the U.S., was okay when it left the manufacturer
16 and that somewhere in transit a terrorist got a
17 hold of it and contaminated it.
18 It is in these situations where we find it
19 somewhere in the United States and it triggers the
20 standard that we would be detaining using this
21 authority.
22 MS. FRASER: I would sort of like to go
23 back to the pet-food question about why this
24 applies to pet food. Again, it goes back to the
25 standard of we can detain food that we see presents

at

1 a threat of serious adverse-health consequences to
2 death to humans or animals. So there could be
3 instances where pet food or other food for animals
4 that are used as food for humans would be at risk.
5 So that is why there is a distinction.
6 With records, we looked at those records that we
7 thought would be needed in areas that could most
8 impact a trace-back investigation and the trace-
9 forward investigation.
10 MR. BARNETT: Okay. We have about seven
11 minutes before the program is over. We still have
12 a few faxes. This one says, "It is not clear in
13 the Act who will assume the cost of storage and
14 protection of the food. This is especially
15 important because foods can be detained for up to
16 twenty or thirty days. Similarly, it is not clear
17 who will pay the costs of labeling or marking the
18 article of food. Who bears these costs?"
19 MR. LAKE: Basically, the cost is on the
20 owner. If we find that the food presents a serious
21 threat to humans, of serious adverse consequences
22 or death to humans or animals, then, to execute our
23 public-health responsibility, we have to act. The
24 cost will be born by the owner of the product.
25 However, the other aspect of that question with

at

1 regard to marking, frankly, at least in my mind is
2 less clear and we would invite comment on that.
3 MR. NIEDLEMAN: Just to add to that.
4 Traditionally, in the area of medical devices, the
5 agency has marked the product, has identified it
6 and segregated it.
7 MR. BARNETT: Okay. "Does the Act address
8 procedures for reparation if the basis for the
9 detention is proved to be groundless? We are
10 concerned about both monetary losses and the
11 reputation of the company."
12 MR. LAKE: The Act does not address that.
13 MR. BARNETT: Okay. These I think you
14 have covered already. So I am finished with my
15 pile of faxes. I am told that there is one more
16 coming in, at the last minute. So we will wait for
17 that one to come in.
18 This was a very good discussion, by the
19 way. I think--ah; here we go. Last one. It says,
20 "Does the detention proposal apply to food--"I
21 think you covered this, but, "Does the detention
22 proposal apply to food-contact material such as
23 substances that migrate from packaging to food?"
24 MS. FRASER: Yes; it does. Under our
25 definition of food, food-contact substances are

1 considered food and this would give us the
2 authority. Again, if it rises to that level of
3 creating a serious health consequence, we would
4 detain the food.
5 MR. LAKE: Let me just add to that. I
6 think normally a migrant from a food-packaging
7 material would not be. But it is certainly
8 conceivable that a terrorist could decide to line
9 food packaging with something that would pose a
10 serious threat to humans. Certainly, in that
11 context where it migrated into the food, it would
12 be a food. So, if we found it, we would act
13 against it.
14 MR. BARNETT: That is the last word. I
15 thank you all. This was a very good discussion.
16 We hope you found this broadcast interesting and
17 that the information is going to be useful to you.
18 Again, we really want your comments on these two
19 regulations, so please send them to our Dockets
20 Management Branch.
21 In just a moment, we are going to show
22 that address on your screen as well as the FDA
23 Bioterrorism website address where you can get
24 information on future broadcasts. Until then, this
25 is Mark Barnett.

at

1 [Whereupon, at 2:55 p.m., the broadcast

2 was concluded.]

3 - - -

CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

Alice Toigo

ALICE TOIGO

Errata Sheet
For the Official Transcript of
May 7, 2003 Satellite Broadcast

Please note that the page and line number reference in this errata sheet correspond to the official printed version of the transcript. The page and line number of text in the electronic version does not match the page and line number of the same text in the official printed transcript.

The following changes in the transcript are submitted.

Page 4, line 17:

Current: Throughout, the broadcast today, we will giving you
Correct: Throughout the broadcast today, we will be giving you

Page 7 and throughout transcript:

Current: Niedlelman
Correct: Niedelman

Page 7, line 11

Current: the Public Health security and Bioterrorism
Correct: the Public Health Security and Bioterrorism

Page 7, line 12

Current: Prepared
Correct: Preparedness

Page 7, line 23

Current: Let me just give you an example of what
Correct: Let me just give you an example of why

Page 8, line 12

Current: better enable FDA to do its job or protecting the
Correct: better enable FDA to do its job of protecting

Page 9, line 14

Current: companies going to be required to still fulfil
Correct: companies going to be required to fulfill

Page 13, line 3
Current: food direction to consumers
Correct: food directly to consumers

Page 13, line 19
Current: syrup, of all of the ingredients
Correct: syrup, if all of the ingredients

Page 18, line 15

Current: is available to assure the identify of all
Correct: is available to assure the identity of all

Page 18, line 18

Current: distinguish between Firm A, B, or C.
Correct: distinguish between the flour from Firm A, B or C.

Page 23, line 25

Current: federal, state, local or even local
Correct: federal, state, or even local

Page 28, line 14

Current: define a recipe as
Correct: to define a recipe as

Page 42, line 10

Current: extent the
Correct: extent that

Page 51, line 4

Current: detention is not new to the FDA. The are
Correct: detention is not new to the FDA. There are

Page 54, line 6

Current: consequences, before and administrative
Correct: consequences, before an administrative

Page 55, line 23

Current: for example, if FDA determines it appropriate
Correct: for example, if FDA determines it is appropriate

Page 66, line 12

Current: would also either authorize or ourselves
Correct: would also either authorize or we would ourselves

Page 71, line 12

Current: other information, would not raise
Correct: other information, would not rise

Page 75, line 25

Current: That is not to say insects may raise to
Correct: That is not to say insects may rise

Page 83, line 12

Current: we also collect an
Correct: we also collect a