FDA EMAILS

The correspondence below is actual correspondence between Ryan Sanchez and the FDA between August 12 and August 23, 2007. The representative would not disclose their identity and avoided a lot of the questions that were asked. See for yourself and you decide.

Ryan:
Sent: Sunday, August 12, 2007 11:36 PM
My partner suffers from a Latex Hypersensitivity. That means she is EXTREMELY allergic to latex. The only way we have found it possible to live with her disability and to allow her to carry on a good quality of life is by avoidance. However, avoiding latex has proven to be a daunting challenge, especially in the food service industry. The members of the food service industry make living a normal life impossible.

We live in Tampa, Florida and currently have only eight restaurants we can eat at in our entire city that we know of. All other restaurants use Latex gloves when preparing their food. If she eats at any restaurant using Latex gloves in their food preparation, hours of vomiting, diarrhea, and joint pains follow the meal. There are many other people with this same handicap so I know this is not the first you have heard of this. I notice on your web site that there are several mentions of states and task forces that have either banned latex from food service or are looking into the effects. Where has all that gone? Why are there only a couple of states banning latex from food service rather than the entire United States? If there are codes discouraging the use of latex gloves, why are they not enforced? If it is a known fact that people are getting sick from something that is put in their food, why hasn't the FDA taken more proactive steps to do something about the problem? What can I do to help advocate the banning of Latex gloves from food service everywhere? Thanks for your help!

FDA Representative:
Sent: Tuesday, August 14, 2007 11:27 AM
Dear Mr. Sanchez: Your state sets the regulations for food service facilities. Please contact the state health dept.

Ryan:
Sent: Tuesday, August 14, 2007 1:35 PM
Shouldn't something like this be corrected nation wide rather than on a per state basis? Does the FDA not have that power?

FDA Representative:
Sent: Tuesday, August 14, 2007 1:45 PM
The FDA does not have the authority to override state rights in this case. We have authority over preprocessed foods shipped in interstate commerce. This is the way the constitution was written.

Ryan:
Sent: Tuesday, August 14, 2007 1:48 PM
Thanks for much for your quick response and information. I know for a fact that a lot of preprocessed food is prepared using latex gloves. Is there any regulation for that? For example, mushrooms are picked from the ground using latex gloves and preprocessed salads that are sold in bags are often prepared with latex. That is just a couple. This is stuff people eat and a lot of people get sick from it. Thanks

FDA Representative:
Sent: Tuesday, August 14, 2007 2:29 PM
Sorry but no there are no regulations on this. Under Good Manufacturing Practices they are required to use gloves but we do not tell them what type of gloves. It is up to the manufacturer to determine what to use. You might want to contact the manufacturing trade associations for some help with this. Your issue is not that unusual.

Ryan:
Sent: Tuesday, August 14, 2007 3:01 PM
What would it take for the FDA to start regulating something like this? If it is something that is not unusual and people everywhere are getting sick from this, why have they not done anything about it? When there is something else in the food making people sick like ecoli or something of that sort, it makes big news and there is a big recall. When something like that happens, only a couple of people die from it. With latex people die all the time. Not all cases are reported because many medical professionals don't know much about it and they can't figure out where the contamination came from. The CDC says on their web site that latex should not be used in food preparation. However, there is nobody enforcing it. It is my opinion that since this is such a problem, latex gloves should be banned nationally from the food preparation industry and that anyone caught using them should get fined. Are there any steps I can take within the FDA to get them to enforce something like this? Would I have to petition this? What is the process of getting an act like this passed? Is there anyone I can speak to that would have the power or want to put something like this through? Thanks again for all the help! Ryan

FDA Representative:
Sent: Wednesday, August 15, 2007 8:46 AM
Contact your elected officials as they have the authority to change legislation.

Ryan:
Sent: Thursday, August 16, 2007 11:09 PM
So when a recall is issued on a contaminated product, my congressman orders it? That doesn't make any sense. I'm sure there is someone there who controls which foods are allowed on the market for consumption. Who is in charge of that? If a food is contaminated enough to cause people to get sick, it should not be allowed on the market; whether the contamination is bacterial or not.

FDA Representative:
Sent: Tuesday, August 21, 2007 11:34 AM
Dear Ryan: FDA does not have the authority to require a recall on products. If the manufacturer is not willing to voluntarily recall a product then the Agency will go to court, get an injunction and seize product. This could take a significant amount of time so it is to everyone's benefit to work within the voluntary recall process. Here is information on how recalls work.

FDA Recall Policies
The recall of a defective or possibly harmful consumer product often is highly publicized in newspapers and on news broadcasts. This is especially true when a recall involves foods, drugs, cosmetics, medical devices, and other products regulated by FDA. Despite this publicity, FDA's role in recall activities is often misunderstood not only by consumers, but also by the news media, and occasionally even by the regulated industry. The following headlines, which appeared in two major daily newspapers, are good examples of that misunderstanding: "FDA Orders Peanut Butter Recall," and "FDA Orders 6,500 Cases of Red-Dyed Mints Recalled."

The headlines are wrong in indicating that the Agency can "order" these recalls. The Federal Food, Drug, and Cosmetic Act, (the law) does not generally authorize FDA to "order" a manufacturer to recall a food, cosmetic or supplement. The agency may request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request. Only when a medical device, human tissue products, and infant formula pose a risk to human health; that the law specifically authorizes FDA to prescribe a recall and to rule on the scope and extent of the same*.

The manufacturers or distributors of the product carry out most recalls of products regulated by FDA voluntarily. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall. Usually, the company will comply.

If the firm does not recall the product, then FDA can seek legal action under the FD&C Act. These include seizure of available product, and/or injunction of the firm, including a court request for recall of the product.

This cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of FDA, as well as industry, to get unsafe and defective products out of consumer hands as soon as possible.

FDA guidelines for companies to follow when recalling defective products under the Agency's jurisdiction are published in Title 21 of the Code of Federal Regulations, Part 7. These guidelines make clear that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, companies are expected to notify FDA when recalls are started, to make

progress reports to FDA on recalls, and to undertake recalls when asked to do so by the Agency.

The guidelines also call on manufacturers and distributors to develop contingency plans for product recalls that can be put into effect if, and when needed. FDA's role under the guidelines is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned and investigates why the product was defective.

Generally, FDA accepts reports and other necessary recall information submitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. However, FDA maintains the prerogative for investigational visits and other in-person communications where the agency considers it appropriate.

The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinal toxin, food with undeclared allergens, a label mix-up on a life saving drug, or a defective artificial heart valve.

Class II recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.

Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling in a retail food.

FDA develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that each defective product has been recalled or reconditioned. In contrast, for a Class III recall, the Agency may decide that it only needs to spot check to make sure the product is off the market.

Even though the firm recalling the product may issue a press release, FDA seeks publicity about a recall only when it believes the public needs to be alerted about a serious hazard. For example, if a canned food product, purchased by a consumer at a retail store, were found by FDA to contain botulinal toxin, an effort would be made to retrieve all the cans in circulation, including those in the hands of consumers. As part of this effort, the Agency also could issue a public warning via the news media to alert as many consumers as possible to the potential hazard.

FDA also issues general information about new recalls it is monitoring through FDA Enforcement Reports, a weekly publication available in FDA's Internet page at: http://www.fda.gov/

For additional information on recalls, contact the FDA District Office nearest you.

*Sec. 412, and Sec. 518, Food Drug and Cosmetic Act; Sec. 351 Public Health Service Act.

Ryan:
Sent: Tuesday, August 21, 2007 2:53 PM
Thanks so much for all the information. Can the FDA request that a company or firm change the way they produce their products to remove the contamination from future products without doing a recall? For example, in our case, can they request that a company stop using latex products in their food production?

FDA Representative:
Sent: Wednesday, August 22, 2007 6:43 AM
Dear Mr. Sanchez: No, we can't ask them to stop using latex gloves. We do not see this as a contaminant at this point.

Ryan:
Sent: Wednesday, August 22, 2007 12:51 PM
Why do they not feel this is a contamination? Is it because they don't have enough people coming forward with the problem. It was mentioned in a previous email that the FDA has heard a lot about this. I work with a lot of people who have this problem and can have everyone who has this problem come forward. If I start a petition, rest assured there will be thousands of people with the same request. Unfortunately, a lot of people have no choice but to live in fear of their future because of this contamination. That fear should not be alive in a country built on freedom; especially when a government subsidized administration can do something about it.

Have I been speaking to the same person in all these emails? If so, what is your name and what is your position?

FDA Representative:
Sent: Thursday, August 23, 2007 6:52 AM
Dear Ryan: Yes, I have answered all your questions and you can reach me through this email. The term "contamination" is defined under the Food, Drug and Cosmetic Act as amended. I can understand your concerns and how you define contamination. We are required to apply the law as it is written. Your concerns have been noted and forwarded on to the appropriate office.

Ryan:
Sent: Thursday, August 23, 2007 1:23 PM
Yes, you've been great. What was your name and position there? What were the names of the people who can make decisions on this matter? Thanks.