



## UCS Food and Drug Administration Survey ESSAY RESPONSES

In 2006, the Union of Concerned Scientists (UCS) and Public Employees for Environmental Responsibility (PEER) surveyed scientists at the Food and Drug Administration (FDA). The 38-question survey featured one essay question that allowed scientists to provide a written narrative. Out of the 997 survey respondents, 502 (approximately 50 percent) responded to the essay question. Response rates from each FDA Center ranged from 45 percent to 59 percent, with an average of 51 percent.

The following are excerpts from the essays provided divided by FDA Center or Office. These text responses have not been edited for grammar or spelling errors. They are displayed exactly how the scientists wrote them, except for some statements that were removed to protect anonymity. Three question marks (“???”) denotes that the handwriting was illegible. Questions labeled in brackets (i.e. [Q29]) means that the statement refers to a specific question in the survey.

**"The integrity of the scientific work produced by FDA could best be improved by..."**

### **Center for Drug Evaluation and Research**

“- Increased “transparency” by decreasing multi-multi layers of review. By the time the most senior review is completed, many (most) of the initial concerns/issues are obfuscated.  
- Increased responsibility/accountability for decision making at every level, with adherence to specific review principles (i.e. “weight of the evidence,” “overall assessment” are meaningless terms yet they often used to justify actions.)  
- Decrease the number of people who have input to (and often delay) significant actions and guidance. Management by committee has neither been effective or clear (since usually it is driven by a pre-selected individual who will push for the “party” view.”

“- There must be clearer guidelines about what is submitted – is often poorly organized, too many volumes, worthless data that we have to make heads or tails of by some arbitrary PDUFA date.  
- Stop implementing initiatives that are not ready (SPL, re-organization, PLR, DAARTS). We are over-run with stuff that doesn’t work already.”

“Hiring more reviewers. Promotions for good people. More money for enforcement.”

“Get rid of Bush and his religious fanatics.”

“Evidence-based documentation with consensus sign off up and down the academic/scientific [team] management ladder-then make a sound decision to market.”

“(1) Retaining good scientists. (2) Getting rid of deadwood or those who scientifically are not sound. (3) Reforming the management by hiring individuals who are having good scientific background and good work ethics.”

“Less pressure from Congress, FDA management, media to ‘approve’ drugs, more credit and attention by same groups of review of drugs-whether outcome is approval or non-approval. Less resistance to asking for additional information to permit better informed decision. [additional questions Q3] Current system of spontaneous reporting can’t adequately capture data to permit informed analysis. Not a function of FDA management structure or personnel. [Q17] Employees chronically overworked. PDUFA provides more deadlines w/o more resources since congress uses PDUFA to replace gov’t dollars not in addition to gov’t funding. [Q19] Adverse event reporting not adequate to fully assess post-market safety only Phase IV requirements for end point trials will provide adequate safety info. Currently, these studies are not required and generally only funded by NIH. [Q20] Congress needs to stop supporting the pharmaceutical industry and support FDA regulatory initiatives.”

“Taking the final decision making away from medical officers and basing the final decision primarily on science.”

“More resources. Less misleading publications by non-FDA people. Facilitating of publication of FDA awareness of confidential data.”

“(1) Appointing a well-respected scientist/clinician as commissioner for a defined term w/o regard to change in presidential administration, & having him/her support healthy scientific culture. (2) Emphasizing need for a culture of open scientific discussion. (3) Rotating senior managers at regular intervals to prevent build-up of organizational empires. (4) Establishing disciplinary procedures for managers who pressure reviewers into changing their conclusions. (5) Providing for performance reviews of managers by subordinates. (6) Establishing a scientific integrity program for education of managers & new reviewers – could be linked with #4 Sr. management. (7) Recognizing that inappropriate pressure on reviewers does occur and is a problem that needs to be addressed.”

“Removal of political pressure from Legislative & Executive branches.”

“I see no problem with the integrity or quality. Resources to perform the work & wider dissemination of funding would vastly improve FDA’s image. The scientific work currently done is outstanding.”

“The work of FDA is already carried out by serious managers and reviewers with a very high level of integrity. I have observed it for decades and the overall quality of work continues to improve. I, like most of us, are embarrassed by the Plan B action, but feel no interference by the political component in day to day activities. People are free to offer opinions and do not suffer if they disagree with supervisors or other reviewers. There is always room for improvement of analytic and technical skills, but FDA’s integrity is not the problem. I note that you “scientists” are anything but neutral here – you presume the problem.”

“Keeping the Congress and the Administration from rising ideological positions on product suitability to determine the safety & efficiency of the product. If they object to a product let them pass a law addressing it.”

“Reduce all outside influences (Congress, Public Interest Groups, Patient Advocates Groups, Drug Companies, Dick Cheney) and let us do our job.”

“FDA Commissioner strength, visibility, integrity, leadership.”

“Depoliticizing the Commissioner’s office. The number of political appointees and related staff has ballooned in the last 5 years.”

“(1) Keep political influences out of here. (2) Provide more resources so that the best and brightest minds can be recruited & retained.”

“The problem at FDA is not the structure of the organization, but the quality and character of persons in managerial positions. Persons who are “yes-men”, who suppress information, minimize risks to patients and place industry’s priorities above those of patients and the public are routinely promoted to positions of authority. There needs to be a better system of a) allowing reviewers the ability to discuss issues IN PUBLIC e.g. in publications without suppression or “clearance” from upper management b) accountability of upper management to their superiors as well as the public c) a change in culture within the Agency to promote scientific discussion, academic achievement, and internal research results ??? regurgitating industry study experts d) or external funding areas for FDA to promote appropriate research.”

“(1) Changes in regulations – more control of product labeling, ↑ authority (2) Modification of PDUFA (Drugs). (3) Separation of safety surveillance/better integration with other Federal/??? Federal Agencies’ data (eg CDL, CMS).”

“Do not permit people coming in from a high level in industry to immediately occupy management level positions. Do a better job of mentoring contact between FDA management & industry. I am aware of a lot of meeting and special treatment of people from Pfizer & Pharsight by CDER/OCPB management.”

“(1) Changes in higher management. (2) Overhaul of government personnel management system to facilitate new hire of qualified candidates and ease of firing incompetent employees.”

“- Split off Foods and Cosmetics & have them regulated by a separate organization, i.e., FDA. With the focus on drugs, biological [therapeutics], medical/vet [devices], animal drugs the agency would have a more focused mission.

- There should be a process whereby non-scientific, non-supportable positions by managers with minimal scientific training or background in pharmaceutical development can be challenged & overturned. There should not be a binding arbitrary “yes” or “no” by managerial leadership that is not supported by the scientific staff. This is not a papacy.”

“(a) Electing (or naming) managers that are not afraid of doing the right thing, even if this is contrary to the upper management/same members of Congress expectations.

(b) Forcing Pharmaceutical companies to [present] the best possible product and not to interfere with the decision-making process by calling upper management or asking members of Congress to partake in the assessment/regulatory action process.”

“Much of the criticism of FDA has been based on media interviews of disgruntled employees who are, quite frankly, mentally ill. We are serious scientists who care about patients. We could use more money to hike reviewers and upgrade resources-the workload is tremendous and constantly increasing. Otherwise, check out your sources before you criticize.”

“I personally think FDA should be a non-governmental place of work and open to public about all aspects of the decision making processes.”

“Removing upper management.”

“-Promoting staff based on scientific expertise and regulatory experience rather than promoting assertive persons with ability merely to articulate the management’s party line (bad for morale of staff and the pharmaceutical industry has no respect to these director/managers who make blatant blunders.)

- Improving measures to retain good workers (who are often lured away from FDA by the industry that offers apparently great incentives to get these workers expertise.)

- Empowering staff to take responsibility for their decisions/reviews/letters, rather than management telling staff to make changes to their reviews/letters, often repeatedly and inconsistently.”

“Reducing the scientists concerns regarding their payroll (often have mistakes and take forever to fix it), hiring (difficult to go through paper work for hiring new scientists), office equipment...scientists in the FDA receive very poor services in these areas, compared to their peers in the industry.”

“Interaction between scientists & management.”

“Stop relying on the ??? degree as an assessment of a persons qualifications. Not everything needs or should be done by an MD.”

“Safety of drugs is an important issue. FDA should not approve certain drugs without adequate long term safety data. Post marketing safety is important, but drugs should not be approved before adequate long term safety data is gathered. The public should not be guinea pigs just to provide industry with revenue.”

“Eliminate PDUFA; Eliminate pharm advertising & the industry accordingly. Increase scientific staff; Increase time available for prof. development. Improve library/educational resources; Provide discipline-specific continuing education. Better control in political appointments.”

“One of the major problems with the FDA is its upper management starting from office directors. Most of these people have personal agenda which only benefits them. These people although claim that their agenda are for the betterment of the public health but in fact, their agenda are driven by personal gains. It seems that the FDA is moving in a circle. Most of these people are appointed to these high level positions due to personal or political contacts. It does not matter if

these people are competent or honest. An incompetent and dishonest person to fill a position and thus a cycle of incompetent managers begins. The best example is Office of Clinical Pharmacology whose office director over the last 10 years is busy promoting himself, seeking honors award from inside and outside of the agency. In the name of science he promotes the ideas which may not be relevant for drug approval process but in order to please people around he will do anything which benefits him personally. This office director is intellectually and scientifically marginal and in order to hide his intellectual and scientific shortcomings he promotes people who are weak and incompetent and are 'yes master type'. He encourages the senior and competent reviewers to leave (by not promoting them or misusing them) so that he can fill the positions with mediocre people who can not challenge his shortcomings. One can clearly see that this is a loss for the FDA but may be a gain for such incompetent and dishonest managers. In the end, the ultimate losers are the American public. The FDA needs serious overhauling with the replacement of the current senior management team (starting from some division directors and higher). An honest and capable center director is an urgent need with the replacement of all office directors. One can argue that if the experienced people are replaced then the agency will run into chaos. Theoretically this is correct but at this time most of these people are neither experienced nor competent therefore, the FDA will have a very little impact on its day to day performance. The reviewers in the FDA are well educated people and capable to evaluate their superiors. At this time there is no accountability for the senior management and their failures are rarely noted. It is of utmost importance that the FDA strictly imposes the rule that every year the reviewers in the FDA evaluate the performance right from the team leaders to the office directors. In the past, at least at the division director level, some evaluations were conducted but no body knows the outcome of these evaluations. It seems that these are mainly done just for the sake of doing something. The evaluation of senior management by the FDA reviewers is very important and will be great help to keep the FDA clean from incompetent and dishonest managerial staff. These evaluations should be used as a part of accountability of the FDA's senior management staff and be conducted every year. The FDA is losing credibility in the eyes of the American public and only way to restore this credibility is to show that the FDA management is accountable for its mistakes and appropriate measures will be taken against the incompetent members of the upper management."

"Mgt not being influenced by who is the sponsor of the application."

"Hiring and promoting medical officers to leadership positions (Division Director, Deputy Division Director) who are conscientious, use science-based methods in their work, read and understand the basic issues involved in meeting questions, NDAS, labeling supplements, etc. My division/deputy director (in the last 3 weeks) stated to me, "If you don't approve this application, I am going to reassign it to another medical officer.""

"Listening to scientific opinion/justification for action(s) to be taken (instead of management of to appease other FDA groups or management."

"It's difficult to improve on the current challenges faced by FDA without a new administration that would replace the current political appointees."

“More attention to science and less to politics (at multiple levels, of multiple types). It is extremely frustrating to receive such a special-agenda-driven questionnaire. The design of your questions is itself too political to elicit a balanced view of the problems.”

“Greater number of staff dedicated to review of applications; more support staff to free up reviewers from performing tasks that would be by others in private industry; Personnel in (CDERS) review divisions are increasingly feeling the pressure of added work without additional staff. Reviewers don’t have enough time to do thorough reviews, but do the best they can to make certain that important issues affecting safety or efficiency are identified.”

“Keeping political agendas out of the scientific decision-making process. 2 examples: (1) Bush trying to put political/religious conservatives on the Scientific Advisory Board for Reproduction Drugs. (2) Congress loves to get in front of the cameras when something goes wrong (i.e. Vioxx) but they don’t want to publicize that they also pressure us not to demand so much of pharmaceutical companies.”

“Fully funding FDA outside of the PDUFA system.”

“More funding opportunities. Scientific work at FDA is definitely needed. FDA mission related research work will improve all the employees’ knowledge and skill, help them to understand better of their regulatory job. Then it will help them perform their task more efficiently and accurately.”

“By promoting participation and interaction with the scientific (appropriate) groups to [keep] expertise in a particular area up to date.”

“↓work load. ↑orientation. Make culture regarding saying ‘no’ or giving negative results more acceptable – very difficult now with meetings, etc. Management is VERY pharma-friendly.”

“- Giving FDA the right to implement a recall.

- Allowing FDA and the Commissioner to not be a political appointee of a political football.

-More funding, especially for the field operations (ORA).”

“FDA’s integrity would best be improved by focusing more on ensuring product safety instead of meeting review deadlines. There should be less emphasis on ‘helping’ industry and more emphasis on overseeing industry and ensuring patients and consumers receive safe and effective medical products at a fair price.”

“Reduce industry influence by removing political appointees & eliminating Title 42 Mgr positions; qualify mgrs for competency & integrity; announce results of investigation into the public/private criticism of Dr. Graham’s work & integrity allegedly by Sr CDER Mgmt; require all industry & FDA Mgmt mtgs/calls/emails to be summarized for internet posting; and END USER-FEES!”

“(1) Preventing abuse of power by some Managers. (2) More respect for the opinion of the primary reviewer. (3) Decreasing the work load of medical officers by added new appointments. (4) More Professional Development. (5) The annual Performance Plan (PEP) should not consider supervisors opinion right & reviewer incorrect – more protection needed.”

“Providing funding and more staff to FDA Center labs conducting REGULATORY research (not basic Research that should be done at NIH or academia). FDA research should help answer reviewer questions & concerns, assist in drafting guidance’s, and bolster regulations/decisions.”

“(1) More reviewers. (2) “Younger” FDA staff should have 2 month details with Senior staff – mentoring plus bringing ideas of younger-newer staff to an entrenched management.”

“In my responses where I have answered ‘disagree’, I have held in my mind specifically issues pertaining to women’s health. The FDA’s decision to stall approval of Plan B and to consider stalling other decisions based on a ‘behavioral outcome’ (ie cervical cancer vaccine) is totally inappropriate and irrelevant to drug safety. Last time I looked, > 50% of the ‘Public Health’ contains women.”

“Getting the Bush administration’s nose out of the process. There has been a distinct shift towards Pharma & extreme conservative positions in the last few years.”

“More independent FDA.”

“Keep the political appointees, the white-house and the congress away from the FDA’s decision making process.”

“Removing political pressure/influence.”

“Eliminating PDUFA.”

“Hiring more reviewers would help. As it is, some review disciplines are stretched thin and work many extra hours routinely. The culture at FDA is to approve drugs. To not approve a drug takes more time for the reviewer to try to gather enough information to mount a strong, defensible argument against approval. As it is with many reviewers working long hours just to keep up with incoming applications, it is easier to ignore what could be a potential problem in an application than to spend even more time & effort to fight against the strong current towards approval.”

“- Reviewer quality is highly variable and managers have little control over personnel actions.  
- The Team Leader role diverts valuable resources away from review work.  
- FDA failures are more often due to reviewer omission or error than management interference.  
- Inconsistency is our greatest injustice; too much is left to individual institutional memory.”

“Keeping office of chief counsel out of decisions made by scientific/regulatory staff. OCC’s role should be returned to providing advice in matters of law; they should not be involved in decision-making regarding scientific merit.”

“- Increased resources across the review functions.  
- Professional development opportunities for review scientists.  
- Recruitment & retention efforts/initiatives.”

“Some section of management be less political and more aware of workers’ needs and morale. Some section of management is very good and concerned about the workers.”

“\* Eliminate PDUFA, increase FDA budget.

\* Formal records of all industry contact (espec. “informal” calls) available to public.

\* Elect progressives →get good appointees.

\* Don’t allow industry associated people to be hired into FDA for > 5 years.

\* Hire more reviewers! Reduce workload, better reviews, better morale.

PDUFA should be eliminated and FDA budget increased. But if Admin has position one would not say diff. (no matter the data) to media – does not apply to most FDA review decisions though! Accountability, more regulation, not less! Reviewers do best we can, but can be overwhelmed from above. Despite problems, good people should fight from inside (and get FED pay/pensions!)”

“- Giving their scientists time to educate/refresh their knowledge.

- Letting scientists attend more training/conferences.”

“[Q9] To avoid the appearance of bias I have set aside personally scientifically fulfilling activities so as not to be a liability & to avoid being a distraction. [Q11] Have not have the time to test this, one instance where “censorship” is occurred was when individual (not management) made it difficult to proceed, another instance same individual published and excluded our participation. [Q19] I think communication should be better - postmarketing (FDA) is good but alone is limited - broad health system networks (epidemiology) should be developed. [Q20] The proprietary nature of info in clinical trials limits open disclosure when they do not its because a) science is “young”, b) science needs validation, c) FDA needs to play catch up. [Q30] The best scientists should be encouraged but can [we compete]? Academics has prestige, industry has money, we get the bad press.”

“More resources to better serve the public and allow time for more state-of-the-art training for its employees including good managerial and decision making training. Better managers are needed badly @ FDA!”

“(1) Allowing staff to publish scientific information without censorship by management. (2) Promote those with intelligence rather than those who will keep the “status quo”. (3) Stop forbidding staff from attending congressional inquiries for fear they may be questioned.”

“By instituting better promotion system for scientific personnel, i.e., reviewers, there is no growth. Scientists join as reviewers @ GS13 and retire as GS13. No promotion potential in [spite of] their hard labor.”

“Hiring, promoting, and regulatory action should be based on scientific competence and integrity. Hiring and promotions are currently based on cronyism and being a sycophant. The best scientists in every review area are consistently harassed, intimidated, and not allowed input into scientific policy.

The best managers from medical review divisions to the sciences, are being reassigned to useless tasks and are being replaced with the most dishonest and unethical individuals. Those who get ahead do so by being yes-men, and by copying and pasting what the drug companies say directly into their reviews. The FDA is presently being stacked at every management level

including the lowest levels based on those who will support the big companies' agenda, and the implications for safety and efficacy will be felt long into the future.

Promotion of competent scientists would not only improve safety of drugs, but also would increase productivity and would speed drug development and approval. Management's overruling of competent science results in inappropriate drug development. This is then caught in the review process and results in multiple review cycles and delays in approvals.

There's also favoritism toward the largest companies, senior management wants us to meet with large companies over minor issues that these companies use to tie us up for months, but management doesn't care whether small companies waste their limited resources doing worthless clinical studies that will simply need to be redone. This also drives up the overall drug development and review cycle time which the large companies then use to complain how we're holding up drug availability.

Computer simulations using clearly erroneous models have been used to approve drugs for political reasons.

Submissions are progressively getting worse, even from the largest companies so that we frequently can't even figure out the dose of the drug being used. This appears to be intentional in order to overwhelm us so that we can't find the real problems.

With regard to approval times companies themselves simply refuse to accept appropriate labeling based on marketing decisions. For example a statement such as don't take with food that we want because no drug will be absorbed will be fought over for a year or more because prior approval because it would make the drug uncompetitive with the competition.

When new scientific issues are identified by good reviewers, one tactic used by senior management is to issue a regulatory guidance that effectively prevents the issue from being appropriately addressed in the future.

With the move to the new building, management has physically separated review disciplines so that issues cannot be discussed, and so that new medical officers don't even know their colleagues and what insights other discipline can provide. This is analogous to a medical school actively preventing physicians with different areas of expertise see patients together.

There are numerous safety problems with drugs currently on the market that front line reviewers have tried to have addressed or mentioned in the labeling, but who have been overruled for political reasons. Some of these safety issues may outshine Vioxx when they are eventually recognized. Several drugs that have been withdrawn from the market or that have had black box warnings added were predicted by scientists, but we are prohibited from contacting the post-marketing surveillance group. Steve Galson has recently been meeting with the staff from different offices and been telling them that the new drug safety oversight committee is essentially the same senior managers as before and that the committee and it's reporting structure are simply "to quiet external critics". Senior management repeatedly states: "where are the dead bodies in the street?" And they mean it! In many instances unless it's getting to the point of overwhelming evidence, such that the press would make a stink, nothing happens.

The safety issues that some medical reviewers have made public, gives senior management an excuse to replace their division directors. In several instances these individuals were among the most competent and ethical medical division directors around. These managers were walking a difficult balancing act and cannot address these safety concerns until they sufficient evidence that senior management can't just dismiss out of hand. These reviewers may have won some battles but they don't understand the larger damage they've done and how they've actually have hurt safety.

Congress is also largely responsible for the present situation by not giving us adequate regulatory authority to obtain data. For example it was appropriate not to publicly discuss the issue of suicides in teenagers with antidepressants as we didn't have sufficient data. The companies knew this and dragged their feet for years either not providing the requested information, or providing misleading or wrong information. The companies involved only provided the appropriate data when the issue became public. We also have no penalties for when companies intentionally lie or mislead us, e.g. seizures in animals are reported as severe muscle cramps, and healthy animals with supposedly no signs of adverse drug effects are euthanized. Scientific experts publish certain data, then testify to the exact opposite conclusions when they're brought in by drug companies as experts. When we tally deaths in clinical studies there are twice as many in the drug group, although the sponsor reports in all summaries and tables equal numbers of deaths in the placebo and drug groups. When we do find things, companies have made statements such as 'how were you able to find that?'

The public perception is that post-marketing surveillance is being suppressed, but it's nothing compared to what goes on in the initial drug approval process."

"- Better training of reviewer in methods of analysis of safety & efficacy.  
- Fewer time constraints (deadlines).  
- More reviewers with strong credentials.  
- More support staff (so that reviewers don't have to do their own copying & other admin work).  
- More efficient method of safety review (pre & post approval)."

"Give reviewers enough time to thoroughly review submissions. PDUFA deadlines keep getting shorter and shorter. A reviewer may have to review a 150-200 volume NDA submission in 3 months. Higher management never seeks input from us in the trenches when making major changes at the agency. We hear rumors of political influence at higher management levels but know nothing for sure. There is little overt pressure on reviewers but nevertheless one goes along to get along."

"Limiting direct consumer advertising for 2-5 yrs after drug approval. Reevaluate a new drug in 2 yrs after approval."

"More transparent decision making of policies & procedures & plans. Better documentation of decision making."

"FDA has too many gate keepers & administrative micro managers. Our administrators & even low level paper pushers are on a power trip. They love to push scientists around, just to show-off. They need to be made to understand that their role is to enable the physicians & scientists to do their job, not to bask in power & glory."

"Raising pay of medical officers."

"Less political manipulation."

"Politicians not interfering in scientific matters. Managers should encourage employees to go on with their judgment, if they feel they are right, even after the discussion by the supervisor. I

wish, a government agency could conduct the final testing or clinical trials after the sponsors are convinced about their product benefit.”

- “- Improving salaries to attract and retain better talent; provide relocation packages.
- Change hiring process so that job offers can be made in a timely fashion (i.e. within several wks).
- Removing PDUFA timelines.
- Instilling that mission is to serve public and not industry.
- Appointing a strong, independent commissioner.”

“A narrower definition of proprietary information. FDA should be much freer to share, clinical trial and adverse event information with the public.”

“The public and FDA’s role to serve the public would be best served by improving post marketing safety evaluation, data gathering and review. What does the office of Drug Safety do anyway?”

“Eliminating the User Fee arrangement. It is inherently impossible to regulate industry in an unbiased manner when they are paying our salaries and expenses.”

“Speaking honestly about Agency concerns regarding product safety and efficacy; not allowing discussion agendas to be set by demagogues and people who are trying to further their personal interests – the Agency should be less fearful about answering its critics when science is on its side. Additionally, Agency spokespeople need to learn more effective ways of communicating with the public so that the public better understands the science behind Agency decisions.”

“We spend a lot of time reviewing requests from industry that are bogus and a waste of time. (Look again they ask at an old application for instance). I’d rather be helping to improve clinical trial designs, prospectively designed, and look at an application only [once] unless new data has been provided.”

“(1) Increasing scientific/clinical review manpower & retaining experience reviewers who now leave due to combination of (1) high work load due to inadequate level of staffing and (2) incommensurate compensation (i.e. pay is lower then competing opportunities in industry, academics, practice or other Federal Agencies such as NIH). Difficult to recruit experienced physicians, especially specialists. (2) Getting rid of Republication crony/industry biased political appointees – most visible Gottlebs & Troy Crawford (new gone). FDA is being starved. Only FY 2006 budget has less than FY 2005. Congress doesn’t pay & PDUFA doesn’t pay enough. FDA is acting effectively to protect public health despite antagonistic forces from Republicans/industry. Political appointees have as integrity. Poor morale, overworked, sabotaged by Political appointees. Watch out for letting foxes change rules in henhouse. Current administration committed to revoking “effectiveness” rule for drugs for serious illness. FDA determinations and actions are consistent with the scientific findings contained in FDA documents and reports - always expect for those influence by Republican political pressure Plan B for example. Over the past few years my personal job satisfaction at FDA has decreased due to manpower losses and increased work load.”

“(1) Leaders are scientists (degree in science and research experience) and are familiar (hands-on experience) with the review process. (2) Stronger Leadership, independent of/resistant to pressure from Industry, Lobbying groups/Congress.”

“- A better reporting system for post-marketing adverse events.  
- Less political grand-standing by senators and/or congressman.”

“We need a full time, permanent commissioner, who is not a political appointee. We have not had one in years.”

“(1) Having the Agency have total control over the Label. We currently “negotiate” the label which means we have a give/take relationship for the Label. (2) Stopping all Direct to Consumer Ads. (3) You will notice that I changed some of my answers. Twice in the past month a Division Deputy Director stated during a meeting that they were approving a drug, regardless of the Medical and Statistical review, without ever looking at the data.”

“Stop giving promotions based on ridiculous awards, non-peer reviewed “scientific expertise”, and the buddy system, and start rewarding experience and good judgment in day-to-day work, so that good scientists, who cannot be swayed by politics, will not be constantly out populated by inexperienced reviewers and politicians.”

“Less management control. Merit based promotions. Merit based bonuses. More emphasis on reviewer findings & opinions. More reviewers to handle to workload. Less catering to big pharma. More emphasis on serving the public. More promotion opportunities and professional development opportunities for reviewers.”

“Make all drug approvals provisional for the first 2 years with required follow up on all patients.”

“(a) Removing Drs. Janet Woodcock, and Mac Lumpkin, from FDA. The current sad situation in the review process is because of policies that were fostered by these individuals. Dr. Woodcock for years promoted a pro-industry climate. Her position has always been that the FDA’s customers are the pharmaceutical industry. She never has mentioned that FDA’s primary customer is the US citizen.

(b) FDA employees that leave or retire from FDA must not be allowed to be employed by the regulated industry for at least five years.

(c) Limit the tenure of managers including Center, Office, Division and Branch Directors to two four-year terms. After that their positions should be opened to new candidates.

(d) The role of the Uniformed Corps in FDA must be reevaluated. The concern is that the Corps Officers with their military structure are not actually independent from their Corps superiors. They are less independent than their GS reviewer colleagues. Public Health Corps Officers are more susceptible to pressure by their superiors because if for instance are forced to leave service before completing 20 years then they do not get any retirement benefits. They are not covered by the Union contract. They are susceptible to transfers to other stations of duty in an area their superiors decide to send them. Their promotion can be influenced easily by their Corps supervisors. Thus, it is doubtful that Commissioned Corps Officers working as reviewers or managers could exercise independent judgment in the review process that their GS counterparts

could. At the very least, the number of Corps Officers in the FDA professional workforce, must be reduced at least 50%. Currently 13% of the Corps Officers are employed at FDA. This is a considerable part of the FDA work force.

(e) Reduce the amount of the meetings that industry and sponsors are allowed under PDUFA. Reviewers and administrators are wasting a lot of time in unnecessary meetings with industry.

(f) Transfer the review of all research INDs to the local IRBs of the research institutions where these research INDs are generated. In this way, FDA will save enormous amounts of review time that is required from all review disciplines to process the large number of research INDs that FDA receives. These resources could be devoted in reviewing commercial INDs and NDAs.”

“More/better funding for hiring and training. More review staff, esp. for safety evaluation.”

“- Increasing professional development time, training and professional meetings participation.  
- Ending PDUFA funding for review work and the reduced & restrictive time lines.  
- Increasing resources for all FDA Laboratories in Headquarters and the Field. The cut (reduction) of analytical validation work by field laboratories has been a major handicap to the regulatory review power.”

“(1) Giving Divisions and Review Teams sufficient time to review data and come to conclusions because of the insane workload and arbitrary deadlines (based on managements goals and MAPPS), it has become an unhealthy work environment. It seems that safety (especially in clinical trials) takes a back seat to more trivial deadlines (e.g. meeting minutes). Review teams are burning out and management does not care – but miss a deadline...and you will hear about it. Deadlines are so tight, (because everyone juggles many, many projects at a given time) that a normal perturbation, such as a power outage or a GI virus can have a profound consequences. (2) Hire more scientific reviews; pay them for their hard work. (3) Let us regulate and get rid of the cozy notion of “partnering”. I am not a partner with industry. I do not want to be their consultant (free to them). They should hire experts and let me review. I do not want to do their design work. I want to have sufficient time to review their data. We are forced to do a little too much hand-holding in drug development.”

“Improving the level of expertise through the specific trainings, professional development, site visits.”

“Removing political & industry influence.’

“(1) Avoid or minimized political appointees who can influence FDA – perhaps somewhat inappropriately and for the bidding and policies of the executive branch administration. And (2) stop acting as if industry is highest priority stakeholder and stop planning policies primarily oriented to benefit industry. And (3) make serving the public good as highest priority. And (4) improve top leadership who mainly act as managers instead of inspiring leaders. Comment: No opinion means [literally no opinion] or sometimes yes and sometimes [No] (e.g. neutral overall opinion.) I say thinking that FDA post-marketing organization(s) does not necessarily need more independence and authority – but FDA does need more authoritative legislation to facilitate better post-marketing product safety systems and leverage to be able to force resistant sponsors to do what FDA thinks is needed.”

“(1) Further reduction in bureaucracy – some PhD’s pushing paperwork. (2) Need flat management – (reduce management layers over scientific/medical personnel). (3) Patient education through FDA to consumer then TV ads to consumer. (4) Currently patent expired drug copies are filed as Drug Master Files. There should be approved through generic equivalents under ANDA.”

“Separate safety from OND and have an independent safety review division or agency, which does not depend on PDUFA.”

“Appointing managers (e.g. Division Directors, Deputies and Team Leaders) with clinical and research expertise and a track record for dedication to public health – NOT because of spousal or friendship connections. Hiring medical officers who are loyal to science – NOT “company men”.”

“I have worked at the FDA (CDER) for over 10 years and have had a broad array of experiences. I have presented at numerous Public Advisory Committee Meetings as well as Regulatory Briefing Meetings. I’ve also published several papers in the scientific literature and have presented often at national scientific meetings. Because of my interactions and familiarity with other Offices, I am confident that here is not a CDER-wide problem that is systematic. However, there are certain places (in some cases entire Offices) within CDER that exemplify everything that could possibly be wrong with the FDA. The Office that I currently work in is an example. Scientific discourse is strongly discouraged when it may jeopardize an approval, and management is very heavily influenced by Industry. When I go to meetings with my upper management, I honestly prepare myself as though I were going to a meeting with an industry representative. Whenever safety or efficacy concerns are raised on scientific grounds (even if based entirely on clear data or ICH guidelines or CFR), these concerns are not taken seriously. There is a remarkable amount of pressure placed on reviewers to find ‘creative’ ways to approve problematic drugs. Reviewers who approve drugs consistently get special project-related awards, while those who do an excellent job on a product that doesn’t get approved are very clearly ignored. I’ve never once seen a review team receive an award for a product that wasn’t approved. However, this is all done in a very subtle, implied but persistent and clear way which leaves no doubt what is going on, but is very difficult to document. I often speak with numerous colleagues or former colleagues who feel the same way, however, there is no mechanism at the FDA to deal with this in a constructive and healthy way. The problem with the FDA is not that the whole agency operates in an inappropriate way. The problem is that when there are individuals who do behave inappropriately who reach upper management positions, there’s no mechanism at all to address this. As a result, when a “bad apple” moves up the management chain, that portion of FDA festers like a cancer, unchecked and with no recourse for the employees that suffer beneath them. I see no end in sight for what’s going on in our Office. As a result, morale is very low and the most talented people leave regularly. It’s very sad because I really do believe very strongly in the effort to protect the public health. One other issue that should be addressed is that of the Advisory Committee Meetings. I’ve observed that management and companies have found ways to manipulate this process in favor of approval. These methods are very subtle and would not easily be recognized. Such techniques include:

1. As the Division Director, if I think that one particular person on the committee has a strong opinion because of a particular expertise and if I’m worried that such a person may

vote against a drug, I can just choose to schedule the AC meeting at a time when I know that person cannot make it.

2. As a drug company, I can hire, as consultants, just about every single expert on the topic being discussed so that there are no expert consultants available to the FDA. This is exactly what I have just recently experienced, and I found this strategy out via an academic who was hired by the company. I can also hire Advisory Committee members themselves, thus making them conflicted and unable to participate in the meeting.

3. As a Division Director or Office Director, I can change the content of the Advisory Committee Briefing Document so that potentially damaging, but factual information that the reviewers wanted to include is not included. I have witnessed this on 2 separate occasions.

4. Finally, as management, I can pressure reviewers to soften their Advisory Committee presentations.

The other thing that occurs on a regular basis, as witnessed by many reviewers, is the inappropriate communication between companies and management via undocumented “back door” channels. On 2 occasions, I’ve actually seen upper management in their office together with company representatives WITHOUT the presence of project managers or reviewers. Given the pro-approval agenda of certain of those in management, one can only wonder whether or not these NDA’s are sometimes “pre-approved”.

In the end, I realize firmly believe that nothing will likely ever come of this survey. Only a catastrophe or scandal can force a meaningful change in a place like the FDA. But I applaud your efforts, and it is comforting to know that there is someone out there who cares about these issues.”

“- Adequate facilities – NOT White Oak FRC.

- Adequate library space with current materials.

- Enough reviewers on staff to handle the workload.

- Enough time on review clock & allow for thorough review.

- Elimination of the “Rule of 20” so that everyone has the opportunity to attend pivotal scientific meetings.”

“Increasing the number of academics in management.”

“The FDA is under funded and relied heavily on user fees to support its review practice. I think that this represents a conflict of interest. Congress and the American public does not adequately support the FDA in order for it to do the appropriate science that could ultimately speed the review process.”

“(1) I have had an excellent experience with my management, who have based decisions on sound science, medicine, and regulations. Several of my answers are based on what I have heard about well-known cases. (2) Question 18 is too vague, or misleading. It appears to ask whether there is a systematic ignoring of safety issues. In my experience this is not the case. However, I do feel that the trend is toward pushing FDA to respond to industry requests for changes in the approval process. (3) Questions 22 & 24 are skewed. I placed my marks based on my understanding of how the “Plan B” decision was made. See also Qs 5 & 6.”

“(1) Changes in the laws that favor drug companies. (2) Complete separation of science/politics in the Agency. (3) Appointment of a strong, non-political, permanent commissioner. (4) Stronger leadership.”

“Support by Congress, more resources, additional funding.”

“(1) Increased resources (increased library holdings, reviewer F&E’s, increased opportunities to attending meeting). (2) Most important: Get rid of PDUFA and increase Federal base budget. Currently, we are dependant upon user fees and this is a huge conflict of interest. “The fox is guarding the henhouse.””

“Better management interpersonal skills (not higher management, but management at division or lower levels)”

“Separation from upper management wanting to please Pharma. New center leadership needed. Regulating industry which heavily lobbies and funds the executive branch (over ultimate boss) is conflicted. This brings on a pervasive pro-Pharma management style. The “workers” - scientists for the most part - want to “promote and protect” the public health. Doing the “right thing” for patients does not appear to be the #1 goal (implicit/explicit pressures from above).  
Question 20: Laws and regulations are fine, leadership needs to be changed. Pro-Pharma attitude needs to be changed.”

“Preventing political appointees at highest agency levels (O.C., O.C.C. etc.) from applying pressure on those at center and office levels and/or ensuring that this influence is exposed and known to the public and other stakeholders.”

“More resources – more time and people to do scientific work, to develop standards, for internal review.”

“- Less political pressure (e.g. Congress, White House).

- Less urgent responses to media – can’t do my job because trying to explain what was done in the past.

- More opportunity for training and professional development – allows more interaction with non-FDA scientists.

- Less emphasis on adhering to PDUFA timelines and more emphasis on quality of reviews for reviewers.”

“The clinical data reviewed and often accepted by FDA involves too few people, who are not necessarily representative of those who will be treated, and studied over too short a duration! Hiring FDA staff with training and experience in public health (at least an M.P.H.), in addition to clinical experience. The management should cultivate a culture of openness to dissent and allow admission and review of FDA errors. The management should make safety of products a primary concern and should be able to enforce and set time limits for industry compliance with regulatory action! The policy makers should request legislation for the addition of consumer-friendly efficacy information to product information. The management should encourage publication of drug safety information.

Question 1: The Generic Drugs Division has a very large backlog of applications (See Washington Post, page A1, 2/4/05).

Question 2: I don't believe in glut—big budgets allow for too many people doing nothing!

Question 5: Seem to be only interested in getting drugs approved.

Question 6: They go along with what the Office of New Drugs wants.

Question 8: Peer Review program offers grade advancement following application and peer review.

Question 11: Sometimes the clearance process to publish in peer-reviewed journals is onerous.

Question 12: They just stop inviting you to meetings.

Question 14: Many safety issues linger without FDA action or final industry action.

Question 17: I believe the budget and staff numbers are not the answer; we need a staff knowledgeable and committed to public health.

Question 20: The policy makers should be conveying to the Congress the needs for legislation.

Question 23: Sometimes the management asks for silly and trivial changes to put their thumb print on the document and to assert their authority over the staff.”

“Integrity is wrong word. Effectiveness could require more laws go give FDA/CDER more teeth to require: 1) Active controlled trials! 2) Eliminate most DTC advertising.”

“Rewarding scientists for good science and not for arriving at the most convenient results, or for completing drug reviews quickly. Management should never tell scientists what conclusions would be acceptable. Officially, the agency does not put such pressures on its scientists, and yet it has happened to me. A less experienced FDAer would probably feel that they have no choice but to go along with what the boss wants, especially if they need a promotion.”

“Better resources – better information technology as well as personnel with scientific expertise. Need medical officers with strong clinical background. Need more people!”

“Stronger Office of Drug Safety. We are a consulting entity whose decisions can be dismissed. Pharma (esp. big Pharma) can be very manipulative and uncooperative without FDA when it comes to safety.”

“1) Separating scientists from expectation that they will recommend approval.  
2) Separating pre- and post-approval activities with separate centers, each with its own regulatory authority and responsibility. The physician to a pregnant woman is her Obstetrician. Once the baby is delivered, a pediatrician takes over the care and responsibility for the baby – not the Obstetrician.”

“Promotions of employees based on merit, rather than on politics.”

## **Center for Biologics Evaluation and Research**

“The constant talk of removing support for scientific research within the agency has been & continues be a major problem. Scientific research by FDA employees must be supported, and at

a much higher level of funding. Work being done by FDA scientists is work important to public health that would never be done by academia (NIH & universities) or by industry.”

“Increased funding for research & full time review positions a center for biologics to appropriately regulate novel biological products. Workload is unmanageable.”

“Eliminating political interference at the highest levels of the Agency in decisions to approve/disapprove a product. The political views of candidate for advisory committees should not enter into their selection criteria. FDA is being starved for operating expenses and laboratory resources, while deadlines grow ever shorter.”

“Allowing FDA scientists to apply for extramural NIH grants. This will allow FDA scientists to pursue independent research, gain mobility and independence from political pressure, and obtain adequate funding from important research that is currently under funded at the agency.”

“Fostering a stronger scientific culture. Funds for research have dramatically declined in recent years. Many senior researches no longer have post docs. Support is given for very targeted and often low-level research. First class scientists are leaving the FDA, and recruiting new ones will be very difficult. For the record, soon I’ll be leaving for a much better position at NIH.”

“Better focus of upper Management to assure research is relevant to Agency mission and more importantly conduct of research and other mission critical activities within the influence of, and compliance to, a Quality Management System.”

“For CBER: (1) Strengthening the scientific program including the ability of the researcher-regulator to perform in-house research related to regulatory mission with internal FDA funding (this has been decreasing significantly over last decade); (2) Guard and support young scientists it CBER to be independently successful – this is future of CBER (young scientists leaving because no future at CBER – no funds).”

“Injection of politics ceases (e.g. Plan B). Budgetary support & commitment to research. Congress must understand the importance of scientist reviewers who are involved in the creative process & apply it towards review.”

“Funding for FDA research should b provided through a peer-review mechanism similar to NIH funding of research in Academia.”

“More resources, less politics.”

“Removing individuals whose arrogance and personal agenda impede the integrity of those of us who are here to serve the public health. Also, rather than being pressured to bring something to market that was unsafe, I have seen ridiculous requirements [make] of industry, with deliberate attempts to impede progress, again based on personal agendas.”

“- Adequate resources provided by the tax-payers.

- Selection of advisory committee members on scientific grounds without political influence.

- Maintenance of ties to other scientific agencies/communities, especially NIH, to leverage more than FDA alone can support and strengthen FDA.
- Base promotions and resource allocation on peer-reviewed scientific merit, and base regulatory decisions on scientific analysis and the judgment of subject matter experts. Thank you for taking an interest in these issues and doing a survey.”

“Enhancement of intramural (FDA) funding of FDA research labs. In recent years, FDA’s budget for intramural research has decreased to the point where FDA’s research scientists are forced to identify external sources of funding – in some cases via CRADAs w/industry. These are reviewed for conflict of interest. However, increased use of these mechanisms increase opportunities for either potential or perceived conflict-of-interest situations. We should receive sufficient funds from FDA to avoid this potential problem - it’s currently a slippery slope.”

“Provision of sufficient funding for research such that outside funding sources would not be needed, would improve the lot of those doing the scientific work. However, the integrity of that which is accomplished is of the highest order.”

“Actually supporting science-not just lip service!”

- “- Improved management and concern for well-being of employees.
- Less time wasted on superfluous issues & meetings.”

“Integrity of scientists not the question. But support for critical ideas-e.g. post-marketing surveillance, product-related research (esp. correlative/causes adverse events; product characterization – is lacking. Retention difficult – lack of support & training for young scientists.”

“It starts at the top: the higher in the management chain, the poorer the quality of the employee. We select and promote TERRIBLE leadership, who are no qualified as either scientists or manager (and/or we do not attract good candidates). As a direct result, we have no effective advocates, lousy resources, declining respect and morale, and are losing the few good people we do have in droves. Most distressingly, there is no remaining support for, or interest in, SCIENCE.”

“Funding scientific/regulatory research at dollar levels which allow for [sharp], competitive research that will result in cutting edge scientific findings, improved safety of products, and improved products for the consumer. At CBER, the FDA budget funds less than 20% of the lab cost of our research. The scientists have to go out and fund their own research. Other FDA centers are worse off in funding. This level of science is atrocious and will lead to unsafe products.”

- “- Allowing scientists full use of statutory time frames, i.e. not imposing arbitrary, internal time frames that reduce review time by half.
- Hire & assign knowledgeable scientists rather than pliable staff.

- Allow industry to address scientific concerns rather than expecting management to suppress, delete and eliminate sci concerns.
- Reduce dominance of commercial interests.
- Assure that performance evaluations of scientists are based on the quality of their review work product and not to the comfort of managers & supervisors.

Less micromanaging of scientific review by political appointees within the agency and at HHS. Sufficient resources to achieve reasonable workloads, thus ensuring greater staff retention & continuing of review. Sufficient resources to maintain scientific research to support review of novel biologic products. No teeth in post market agreements.”

“Providing adequate resources to do the mission related work both research and regulation.”

“At least minimally adequate resources for scientific work. For example, mission-related FDA research now relies on funding from outside the Agency; intramural funding is sufficient.”

“Not having the top positions filled by political appointment. Politics have no place at the FDA.”

- “- Reviewers should write independent reviews.
- Every file should be presented to management at a mtg open to the whole office/division – frequently management makes decisions without knowing in depth about a products.
- Develop mentoring so better reviews are written.”

“Hiring and retaining ethical scientists, and removing non-productive, unethical scientists who are promoted to levels of management.”

“Getting rid of PDUFA/MDUFMA – direct funding from Congress.”

“(1) Full-funding of justifiable, mission-relevant research. (2) Full-funding of all review activities without reliance on user fees paid by industry.”

“I do not work as a scientist at FDA. My duties involve compliance issues pertaining to blood and blood components. Safety of the blood supply and appropriate oversight of our regulated blood products/components are my focus. Specifically related to blood transfusions and collection fatalities.”

“More support by management with resources (financial).”

“(1) Updating & harmonizing regulations. (2) Training in Evidence Based Medicine. (3) Looking at world-wide collaboration. (4) Continuously looking for best practices world wide. (5) Staff Colleges across FDA with required management attendance. (6) Career counseling & advancement. (7) Cooperation [councils] for NTEU & management across FDA.”

“Having enough reviewers so that reviews can be performed in a timely manner.”

“Resources, resources, resources & less bowing to political pressure!”

“FDA should not need to rely on PDUFA money to run normal operations, such as review and approvals. FDA needs to be allowed to function & do the job (as stated in the FDA mission) without pressure from politicians and military interests. FDA needs the resources (funding, competitive hiring practices, additional reviewers) to maintain and retrieve its reputation as the regulatory “Gold Standard”. Many reviewers are assigned too many products to effectively oversee them-even the best; most intelligent & efficient reviewers have their limitations. I know good scientists who have left the Agency because of their frustration with the status quo.”

“- Eliminating MDUFMA & User Fees. The fees have not increased review staff. MDUFMA mandates are unachievable if public health & science are to be considered.  
- We also need strong post-market surveillance & a strong compliance officer, willing to take appropriate actions when public health is jeopardized.”

“Get rid of MDUFMA & PDUFA. Congressional mandates kill the review process & are not based on science. Only the industry benefits. There is no follow up once a product receives an inappropriately accelerated review. FDA staff wants to do the right thing. Congress & political appointees do not let us.”

“Recruiting more reviewers. Work load has been always heavy; that effects on working condition, efficiency of production (any kind of...), too much being stressed,...”

“Increase funding for the scientific work done at/by the FDA. If the funding decreases are not reversed, the agency will not be effective in recognizing, preventing or mitigating future public health disasters. Increasing public funding of FDA scientific work is a very, very inexpensive insurance that the decisions are made based upon science rather than perception or per-conception.”

“Including the medical, other scientific, and legislators in the process so that there is a greater understanding of how FDA must balance benefits and risks within the constraints implicit in confidentiality and legislative mandates. All safety data should not be considered to be confidential. Articles for publication of clinical trial results should include the original study protocol.”

“Increasing operating funds and consistently considering research as a major priority for FDA employees.”

“Over the past 10 years, CBER management has drastically cut the financial support for the labs, and FDA management seems to question the need for leaving laboratory scientists in-house. We are scheduled to move to White Oak in a few yeas, and now there is a possibility that no labs will be built at White Oak. This will drastically change the researcher-reviewer model of regulatory work that has existed at CBER forever, since it was still a part of NIH. I believe this will negatively impact the review work – it is my experience that the non-research reviewers are less flexible, and more likely to just say no, or to require lots of additional testing, when confronted with a new, cutting edge approach to vaccines. CBER and FDA management should increase the

level of support for basic science, and more importantly, CBER/FDA management should explicitly recognize that basic research is an important part of its core mission.”

“Making it a policy for senior management to prepare accurate and complete telephone memos of their conversations with regulated industry and make these telecons [memoir] routinely available to the staff working on those projects being discussed.”

“Eliminating PDUFA and restoring appropriated funds, with an increased budget. Addressing the concerns of the Korn commission study in the mid-1990’s.”

“Increased funding to conduct post-marketing surveillance inspections; increased independence for the review committees; improved training for scientific excellence; increased inspections for phase-2 & phase-3 clinical trials for the education of sponsors, investigations & IRBs.”

“- Require Congress to adhere to same ethics rules as FDA.  
- The Commissioner should not be a political appointee.  
- Primary reviewers should never be excluded from speaking at advisory comm. meetings.  
- All communications between a sponsor of product under approval review and FDA management at all levels should be documented and distributed to all members of review team so that all involved know what is going on. This includes Center Director.”

“More independence from industry & the administration. Scientists in charge, not political appointees. Having industry pay our way through fees is a mistake. If fees are charged, they should go to the general FDA fund, not directly to the regulators office fund. The Plan B debacle killed morale, scientists were ignored by a guy with a political agenda & then he gets promoted! The individuals in my office are trying to do their best, but our budget gets slashed every year. And the message we get from ‘high above’ is let’s help get treatments to market to help the Industry. I never got an email telling me to look out for patient welfare, just industry. And we see how CD has turned into a political place, ignoring science. The Big Picture is Bad. I’ve been here over 20 years, this is the worst. Science is being ignored or abused. Get politics out of here.”

“The integrity of scientific work would be improved by providing reasonable levels of resources to conduct critical work. Cross agency research interviews would be beneficial.”

“(1) Increasing the number of scientists involved in research and/or review and making sure people understand the priorities of the regulator review process. (2) Allowing the FDA to have more control over post-market commitments.”

“Eliminating interference from politics making all management/supervisory appointments based on ability, rather than favoritism.”

## **Center for Devices and Radiological Health**

“Not having the Office of General Council controlled by the White House.”

- “- Focusing on quality of product engineering as much as underlying science.
- Hiring reviewers with more experience.
- Providing across-the-board training in quality management/risk management/ risk assessment.
- Integrating pre-market and post-market activities.

This question and #19 miss the point. Too many defective products are getting on the market because the pre-market review process is flawed.”

“I may suspect some of this but in no case do I know any of it to be true.”

“Getting rid of all Bush appointed executives.”

- “- Changing parts of the law which force us to make bad decisions.
- Allowing FDA to base their decisions on science instead on the fear of industry appeal, mgmt disapproval, potential law suits.
- Allowing the time & resources for staff to maintain scientific expertise that is current.”

“Not having decisions made politically.”

- “- Additional collaboration with other government agencies.
- Less direct funding from the pharmaceutical industry, which puts shorter review time frames on the review process.
- Management which is more science based rather than administrative.”

“Defining what scientific is/means in a regulatory context.”

“Less interference by career fools.”

“Encouraging management to more strongly consider recommendations by reviewers. In case of upper management turning over a decision, more effort should be made to convince review team of why the decision is more appropriate. Middle management should play larger role in preparing review team for briefing upper mgmt or for appeal meetings, dispute resolution, panels, etc.”

“Adequate funding and laws for medical devices that requires all medical devices to be safe and effective, rather than the “grandfather” (510(k)) mechanism currently in place.”

- “- More lab money – doing good research on \$3-5K per year is unrealistic.
- Don’t change priorities on an almost yearly basis.
- Reviewers ignore researchers and get away with it- reviewers do inadequate reviews and don’t know that answers and help are available in the lab part of FDA.”

“(A) By assuring that decisions are based purely on science and not on politics.

(B) By providing greater funding: (1) to make wages more competitive with industry and private medical practice in order to attract top reviewers; (2) to hire more reviewers to share the workload in order to allow time to perform duties without regulatory deadlines, e.g., public

outreach projects, and to allow time for professional development; (3) for professional development; e.g., to attend professional meetings.”

“Follow the Food & Drug Law.”

“We need new leaders at the top.”

“More funding.”

“- More financial resources-for hiring, for training (conferences, etc.)

- Less emphasis on MDUFMA goals for submissions, be quantity is encouraged – rewarded much more often than quality.”

- If the reviewers were not so overworked (i.e. had money & freedom to hire more people).

- If the FDA could keep the top scientists/engineers/reviewers they hire (by being able to pay them more \$).

“The easy answer is to make more resources available – for training, for laboratory activities, for Compliance & Post Market. The more difficult challenge is for the Center to understand its own processes more completely. This would enable everyone to understand their own role in the big picture as well as what their colleagues roles are – eliminate duplication and enable/maximize effectiveness. Need process mapping & full disclosure.”

“- Less politics at the higher government levels i.e. OMB and up.

- Follow advice of scientists.”

“...removing the CDRH Center Director, Dr. Daniel Schultz. Dr. Schultz has used his position to overturn scientific decisions without sound scientific justifications for those actions. He has abused his position by attempting to force scientific reviewers to change their findings/scientific recommendations. His decisions are politically, not scientifically, based and are not in the best interest of the public health. In addition to Dr. Schultz, there are others within FD mgmt/leadership who misuse their position to overturn scientific decisions in favor of political decisions, for the advancement of their careers. Need more reviewers! CDRH Center Director, Dr. D. Schultz is not capable of leading the center-he lacks the knowledge and integrity to protect the public health. However, the opportunity for advancement is much greater and faster for those on admin/mgmt path. Within CDRH there are many scientific reviewers who fear retaliation. Too often, political pressure restricts FDA from providing information to the public. Too frequently, the FDA acts in the best interest of the regulated industry and not in the best interest of public health. Again, CDRH Center Director is the problem. The laws and regulations are fine. The problem is that the...upper level management (particularly CDRH Center Director) does not enforce and/or abide by the regulations. If CDRH Center Director makes the determination. The FDA is an excellent place to work-the only problem is the current mgmt/leadership within CDRH. Would have increase f not for frustrations with the ineffective leadership of CDRH Center Director.”

“Stronger power of the scientific reviewers.”

“Allowing the scientists to decide what is needed for the public’s health rather than a team of scientists who are not experts on the field (TRC) decide what should be done for only “Pre-

Market” (ODE) missions, e.g. “SPOC”. Neither the TRC nor SPOC care at all about the public’s health, but rather what is needed by one office (ODE) and what Managers “push” for from time to time.”

“No political interference (e.g., White House, Congress,...)”

“Placing in key administrative/management positions the right individual(s) who has (have) the knowledge and commitment to protect humanity and not compromise life because industry may not be happy.”

“- Prevent managers from giving poor ratings for not meeting deadlines (non-statutory) for purposes of assuring safety & effectiveness.

- Getting rid of political appointees.

- Removing awards for employees who agree to overlook safety & effectiveness concerns in order to meet unreasonably short deadlines.

- Stop promoting incompetent reviewers/managers.

- Reward those who find safety & effectiveness concerns & work to resolve issues.

- Reward those who are not afraid to demand information/data needed to adequately review products.

- Stop “secret” meetings between Managers and industry & subsequent decisions without reviewer participation.

- Stop allowing quack products on market without clarification that FDA chooses not to review these or does not agree with claims.”

“More rigorous expectation by industry to design and implement blinded, randomized, statistically sound clinical trials of medical devices. I don’t know why industry’s first and continuing position is to design the weakest study possible. Some promising therapies have failed due only to ineffective study design. FDA doesn’t have authority to expect and enforce a better level of study design.”

“The integrity is not a question; resources and other limitations prevent faster progress. I wish there were more technicians.”

“Increased resources (staff, technology) & opportunity to pursue professional development (continued education, training, etc).”

“Getting us a permanent (not acting) committed (to the mission) Commissioner would make a difference. It’s been years since we’ve had someone with leadership skills that actually cared like Kessler-Lester Crawford is an idiot and the Agency languished under him. Without a strong leader – special interests & greedy managers start to advance their own interests.”

“The Center for Devices and Radiological health has very low standards for device effectiveness when making approval decision. This is not an integrity issue. However, it results in many ineffective devices being approved or cleared for marking. The 510(K) pre-market notification process is a farce CDRH clears device through 510(K) that often lack any demonstrated effectiveness. I see no way to improve this, as it has been ingrained within the culture of the CDRH since the Agency began. Public interest groups ignore this problem. They direct their attention to safety and integrity. They are blind to the real problem at CDRH.”

“Rather than have a separate research office within each Center, combine all into one center of research. This would serve at least two purposes: 1) increase cooperation between Researches associated with different Centers working on similar research; 2) reduce Center conflicts regarding research and review priorities and budgets. It would also allow the research to be more independent, especially on products that have been approved. Research that may detect problems with products which have already been approved by FDA is not encouraged currently in the Centers.”

“More recognition and funding for science and engineering. There is an over abundance of funding for NIH and military projects and very little going to FDA to maintain expertise or in areas for future concern. A former center deputy director used to say “FDA science budgets amount to rounding errors compared to NIH”. This is nonsense since the products and devices coming from NIH and the military eventually come to FDA.”

“Managers should be scientists & well qualified in the field they manage.”

“Having more “Hawaiian shirt” days at work.”

“More resources & staff at headquarters & field offices. Stronger enforcement throughout.”

“Requiring industry to submit their devices for FDA inspection and operation. If a picture is worth 100 words then having the device is priceless. Inspection of the device prior to market is worth much more than trying to recall a device after it has caused problems or killed people. Such inspections could fund laboratory evaluation and make FDA more effective.”

“Providing more time to become very familiar with the relevant medical literature. This requires more reviewers reviewing instead of doing “research.””

“Maintaining a well-supported staff of scientists! An incredible no. of scientists have retired & no hiring has resulted. As well, contract-based support is frustrating – people come & go, have no real commitment to our mission. We’ve had 3 secretaries in one year. I now do all my own admin tasks. Finally, the new Procurement system is a shame. We have one vendor who now won’t do business with us because it took 8 months to get paid.”

“In my experience, it is never the “low level” reviewers in the FDA who breach the integrity of our work. It is usually at much higher levels, such as center directors and above. Those higher levels are so far removed from the scientific work we do that politics has even more sway over their decisions. At the reviewer level, little if nothing is gained by playing politics. The people I work with are truly dedicated to serving the American public and doing whatever is in their power to ensure their safety. We despise seeing anything swaying decisions based on solid scientific facts.”

“More people.”

“Sunshine! We have many restrictions on what we can say and publish that are politically, not legally, based. In the past several years final approval to publish or speak is moving to higher and higher levels; lower management is more and more afraid to make decisions. We are not

allowed to say that resources are too inadequate because that would be “lobbying Congress”, which is illegal. We are not allowed to say anything critical of FDA performance. We have trouble getting permission to say that medical products have safety problems. Staff outrage is pervasive.”

“Provide manufacturers of all information required in an IND or PMA device submissions. I understand that guidance was in draft, but that a decision was made not to pursue it to completion. FDA reviewers of device submissions need certain basic information for adequate review, inspections, & approval. A “refuse to file” is truly a waste of reviewer time & inspection assignments are incomplete & time consuming if appropriate information is not provided by the firm at the onset.”

“(1) Abolishing “user fees” paid by manufacturers for product marketing application review. (2) An effective Commissioner”

“Not allowing influence by Congress and Executive branch on scientific decisions. They are extremely political in nature, and do not serve individuals or public health. Allow FDA to be a scientific agency that is politically and religiously neutral. Allow individuals & clinicians the opportunity to make their own decisions.”

“- Better science-sometimes review staff ask for too much, including irrelevant or uninformative tests. It’s not just doing too little. (Because they do things the old way. They can’t be held responsible for problems if they ask for a lot of tests.)

- A serious policy of science – based decision-making.

- More political independence of the agency from various interest groups/politicians.

- Serious and adequate support of the laboratories – now vastly under-funded.

- Labs should be supported to do independent analyses that no one else does, e.g. studying drug/drug and drug/device interactions-this will be a larger & larger problem, effects of drugs in old & young populations –esp. metabolism, e.g. developing new procedures for safety assessment – the safety assessment for concern hasn’t been updated for decades.

- Serious and adequate professional development for scientific staff. We wither into scientific nonentities. Can’t go to meetings or read journals. Even if permission is given, the workload doesn’t allow it.

- Better advocacy for the public interest/let FDA staff assume more of this role. Sid Wolfe is the “lone wolf” here-not adequate, not comprehensive, not always right.

We don’t know. They just take you off the product review entirely if they don’t like your opinion.”

“(1) Increase the budget of FDA, esp. for lab research. (2) Remove ability of management to reverse reviewers’ decisions. (3) Reviewers are promoted based on # approvals, not on quality of work, or # decisions made. This should be changed. (4) Due dates for reviewing applications should be increased from 30 days to 90 days. (5) Get rid of user fees, and pay for FDA budget out of the treasury. (6) Increase the budget!”

“(1) Divorcing politics from public safety & product effectiveness. (2) Assuring best technical/clinical expertise for all FDA issues. (3) Encouraging scientific & technical excellence

rather than just timeliness. (4) Encouraging the selection & promotion of management that is more concerned with the FDA mission and supporting the scientific, technical, & clinical staff under his/her supervision rather than self-aggrandizement and “covering his/her own butt”. (5) Promoting individuals who prefer to remain scientists and/or clinicians rather than become managers. (6) Allowing scientists & engineers the time to keep pace regarding “state of the art” of their professions.”

“I have seen managers leak corporate secrets to help outside people get jobs. I also see routine instances of sexual harassment. Nothing is ever done. OIG never does its job. Our own OIA works to intimidate employees when they point out blatant criminal acts in management. This is a horrible situation; the taxpayers are better served by closing the agency if this culture of abuse continues.”

“(1) Keeping Congress’ hands off the process. More independence! (2) Increasing # of scientists and clinicians. (3) Increasing salary and benefits to attract the best. (4) Increasing funding and opportunities for continued education of FDA scientists & clinicians.”

“More reliance on the scientific, clinical, and statistical reviews.”

“(1) FDA considers their customer to be the manufacturers. The customer should be the public. (2) Speedy time frames dictated by Congress make more mistakes, likely. (3) Manufacturers feel they have “a seat” at FDA’s decision maker’s table. They do, but should not. (4) Bullying-I was pressured to recommend to approve a device I thought unsafe. Management negotiated for labeling that tells of the problem & how to avoid it. I agreed with this. (5) FDA outgunned-manufacturers come to meetings with many lawyers & famous doctors, while FDA has only one doctor & 1 scientist. We don’t have the ‘firepower’ to negate their position. \*(6) FDA’s performance should not be judged by the number of devices cleared/approved, but rather the # of devices cleared/approved that do not show up as problems within X years of approval. (7) FDA’s main tool when safety issues arise, should not be just labeling changes, e.g. adding warnings, contraindications.”

“Encouraging FDA scientists to freely conduct research not just related to current submissions and products, but also to forward-looking technologies and methods that have the potential to improve public health. Please note that I am a CDRH scientist, and therefore not familiar with many of the issues confronting other centers.”

“\* I’ve been a manager as well as a reviewer. I prefer review at this point but do have management experience. (1) Changing the 30 day time line for original CDE applications to 45 or 60 days. Thirty days is far too small a period for making decisions regarding significant risk devices. Patients are at risk. (2) Encouraging reviewers to do better reviews. Many MS and BS level reviewers do NOT adequately consider safety and effectiveness issues. (3) Management allows a sacrifice of review quality for timelines. Far more interested in the clock than making sure an adequate review is done. User fees have greatly influenced this position.”

“Removing the job, Commissioner, from the list of politically appointable positions. Requiring Congress to appropriate \$\$ for annual operating expenses as a more realistic figure proportionate

to the actual Fraction of Gross Domestic Product that FDA is charged with regulating. Thus, as healthcare's proportion of GDP increases, so should FDA's appropriation. Take FDA's appropriation out of Agriculture's appropriation package! [To prevent USDA from raking \$\$ from FDA's share to continue to fund their budgetary shortfalls.]”

“By providing more resources consistently to hire & keep qualified scientists-FDA can remain a quality regulatory agency & increase human subject protection in clinical trials & the products approved for use & followed effectively to determine issues arising when in use with other drugs/devices in the “real world.””

“(1) Scrap PDUFA, MDUFMA, and 3<sup>rd</sup> party review programs, increase congressional funding to support adequate in-house review staff. (2) Provide support for expanded post-market oversight & product evaluation. (3) Expand support for compliance activities to allow uniform enforcement of existing regulations on adulterated and misbranded products. (4) Criteria for FDA appointed positions should explicitly exclude all political considerations.”

“Using science more often as the basis of decisions.”

“- Providing laboratory space for each WORKING scientist. [Not all scientists work in lab or work at ll. A true scientist considers his/her laboratory as his/her home. The working environment should match his/her comfort level (trust issues) to a certain degree.]

- Preventing intellectual property theft. [Prohibit authorship of those (administrators and their pets) who really do not work constructively in a project but run their mouth only.]
- Stopping retaliation if a scientist does not want to work with a manager's pet. It is FDA, not military. Team work (or donation of data) must not be mandatory in the name of quality control of technical work.
- Promoting scientist for their merit and not for their golf skill or their spouse's connection to area golf fields or wherever.
- Terminating senior administrative positions (GM-15 and up) of any manager after 4 years (6 max) of service. Universities rotate their department chairs periodically. [The US President has to quit his chair officially after 4 years unless he wins the voters by proving himself. The Secretary of Health and the Commissioner of FDA change more than we want them to. In FDA, some scientists work hard and bullies take the credit; then they become managers (GM-14 or 15) forever and bully even more than ever before.] We are told that one needs to be an internationally known expert to obtain a GS-15 position. Hence, the trend is to become GM-15 and hang onto it forever. Rotate managers from office to office within the agency or outside of the agency or else they become too comfortable in their chair. OR, make the managers go back into the lab and run an instrument instead of running their mouth. Managers at FDA are generally given a lump sum to spend; they do not go out to earn a grant. As result, they are busy doing bean-counting not quality work. Reading and writing competency is required but should not be a surrogate to technical competency. A few managers are running this laboratory because they have a pseudo Ph.D. in English and not because they have any technical competency at all. What more do you expect?”

“Revamping notion of “substantial equivalence” from 510(K). This is a scientifically ill-defined concept. Especially for diagnostics – 2 devices can be “substantially equivalent” but both be

ineffective. Equivalence tells us little about accuracy and therefore little about effectiveness. Also diagnostic labels should be made readily available to public – analogous to Physician’s Desk Reference.”

“(1) Allowing the science to be more important than politics. (2) Not having FDA management yield to pressures from higher level managers and from industry. (3) Having FDA determinations and actions follow the science. (4) Having managers give equal scrutiny to approval decisions as they do to disapprovals. Stop rubber-stamping all approvals and questioning all disapprovals!”

“Less emphasis on review deadlines more on accurate, competent science. Less bureaucratic review procedures. Managers with scientific competence.”

### **Center for Food Safety and Applied Nutrition**

“Management stepping in and making a decision involving disputes/disagreements between internal divisions/offices and informing all parties of their decisions.”

“- Over the last several years I have noticed a significant increase in the number of decisions that have become politicized (e.g., increasing requests to review even simple regulations and changes, both by Congress and the Commissioner’s office and to make apparently politically-motivated changes in language and sometimes to alter bottom line results), and I think the integrity of scientific work could be improved by minimizing the ‘politics’ of the process. - Selection of individuals, appointees with strong experience, attitude, and track record of protecting the “public” health rather than special interests.”

“Increasing resources to permit FDA to maintain itself as a premier regulator of foods, drugs and cosmetics.”

“Ensuring that the workers have the resources to do their jobs.”

“CFSAN: Since laboratory scientists have been reduced in number, the scientists need to be combined into one office. Currently the laboratory scientists are dispersed in various program offices. Laboratories need to be combined in CFSAN.”

“Increase resources – funding and personnel. Subsidized long-term planning. Recruitment of expertise. Subsidized collaborations.”

“Diminishing the excessive influence that certain, key stakeholders have on the Federal gov’t in general.”

“Have Management with strong scientific (biology, toxicology) background, with practical (hands-on) experience so they understand the issues and are familiar with misleading information that is submitted to FDA for review. Many managers are driven by ego and personal gain, have significant psychological issues, and therefore are willing to bend to political whims rather than protecting public health. These managers promote others that have similar drive and ego issues,

little integrity, and personal agendas. Many reviewers are very dedicated, intelligent, responsible scientists who truly care about protecting public health. These reviewers are usually put down by management. This is very sad.”

“(1) Funding for in house projects. (2) Career enhancement programs, e.g. ability for scientist to attend professional meetings both locally, nationally and internationally. (3) Management should place science as the basis of decision-making, not politics.”

“Placing scientific integrity above political ideology. Never in my 28+ years as a Ph.D. laboratory scientist at FDA have I seen the agency so politicized as is has been under George W. Bush. Some science and science-based decision making have been bastardized.”

“All of the Centers have been chronically under-staffed for years, and also under-funded. When professionals leave a position, they are often not replaced, because this vacant position is used as a way of meeting budget shortfalls. The latest budget cuts to the CFSAN drastically threatens the scientific expertise of the Center by cutting programs and research projects. Maintaining a strong science base is dependent on a solid budget that can support research programs and attract and encourage scientific experts to stay employed with the Center. Removing political influence over policy decisions is also important.”

“More active pursuit of review memos, Record of Decision by public interest groups and industry. Even industry rarely requests copies of reviews and ROD documents – they do not know what deficiencies reviewers find unless more information is requested or Application is rejected. Congressional actions block FDA efforts.”

“Protection from Congress & OMB. Increased budget for core functions. Increased FTEs.”

“(1) Fostering an environment where scientific disagreements are acknowledged as being a necessary part of the scientific process. (2) Providing resources, including time, access to scientific library databases, funding for training and meetings, so that scientists and medical officers can keep current in their field; in areas of cutting edge science, employees should probably be required (given appropriate funding) to complete continuing education.”

“Not decreasing our funding every year.”

“Legislative actions.”

“Increased funding. Long-term budgets (planning). Too many political appointments periodically appeal who are either not qualified (Levitt) or of questionable focus (Crawford) – the focus should be the consumer!!!”

“I regret that the questions in this survey were frequently slanted. My comments have been influenced by my own particular bias; in that I have a very difficult management where I have encountered discrimination and favoritism. This situation is not unique to the Food & Drug Administration, and has a lot to do with anti-female biases. I would expect that independence at FDA would have been adversely affected by this Administration. But I can't prove anything, I

have only hearsay. It should be of great concern to you and the public that large budget cuts are expected in FY 07. Then cuts are expected to be especially drastic for the research positions of the agency. The worst legacy of this terrible Administration (in my opinion) may be the systematic dismantling of the agency by budget cuts.”

“Increased research funding.”

“The problem that I often face is the current literal interpretation of the law – rather than intent. I am also disturbed that lack of information on an ingredient in foods eases its [passage] into food – FDA has the burden of showing harm. This is particularly disturbing in the GRAS/food additive program. The agency will not proceed with finding a substance to be an [unregulated] food additive when there is strong evidence of safety problems. CFSAN (bottom line) needs to engage more outside expertise safety problems in its scientific review process. The staff cannot have expertise in all areas with increasing complexity of food ingredients. This would at least help with some of the problems noted above. The other solution involves changes in laws. Note we are also hampered by lack of training, resources, and staff.”

“Peer review of upper management. Why must only the scientific/research staff face peer review scrutiny? How can Management lead if they have no vision – simply the ability to maintain the status quo. There is a challenging question proving my point. How many leaders in CFSAN’S office of the Director have training in NUTRITION? These are the leaders who protect the nutritional quality of the US Food supply.”

“Need better AND more collaboration with academia in research. FDA scientist need more leeway in their projects. With current budget cuts, CFSAN is going to be almost useless. Public beware!!”

“More funding and more scientists to do the job.”

“Changing laws, regulations, and guidelines that are outdated. Many of the laws and policies we follow date back over twenty years and no longer make sense or are no longer applicable. Congress and the FDA should modify the Food and Drug Act, the CFR, and other legal codes to eliminate confusion and improve efficiency.”

“(1) Hire more qualified scientists. (2) Provide more resources for maintenance of scientific skills. (3) Encourage more interaction with peers outside of FDA. (4) Decision making must be more collaborative, less top-down, and more transparent both internally and externally.”

“More: adequate funding, allowing more latitude in research, having a clearer view of our mission.”

“Funding to do appropriate research and corresponding management approval & prioritization.”

“Getting FDA back onto Food and Drug safety and out of defense and terrorism.”

“We need to investigate new areas, for example. Instead of looking at Patulin in apple cider; much of which is sold retail at farms – why not look at bottled water. Lets look at soft drinks and beer and not look at the same fish dealer year after year.”

“We need more money. We need new equipment. We should be using the latest analysis techniques & modern technology instead of relying on conventional methods. We should be collecting & analyzing a much larger percentage of import & domestic food samples/products. We need an easier way to deal with the non-performers. We need better leadership at the first & second line level.”

“Having decisions be made by scientists, not GC.”

“I have a narrow specialty and any significant suggestions I could offer would likely reveal my center, my division, & my own identity. I do not wish to jeopardize my status or my division’s status. Our proposed 2007 budget is seriously deficient. However, management has never allocated a reasonable portion of money/resources to support an important aspect of the projects that I work on, regardless of the size of the budget. Nevertheless, I feel this is a better place to work than multiple other federal agencies I’ve worked at. Perhaps I can volunteer with UCS when I retire. You should advertise for volunteers in your newsletter.”

“There is good, sound, conscientious scientific work and assessments being done at the lower, non-management levels at the Center. However, it is frequently not employed or utilized by management in their activities and decisions. First, some of it is that there are now growing number of management levels/positions that it gets lost or discarded in the power plays and turf wars of all this management (and “advisory” staff). The Office of the Center Director has grown massively with very highly paid management/advisory positions in the last several years at CFSAN while the lower ‘actual worker’ level science positions are shrinking with staff not being replaced (after retirements and job moves/changes etc.) A reduction in all this management & so-called expert/advisory positions in the Office of the Center Director may assist in the hindrances of getting the science information/assessments done by scientist to top decision makers. Second, although much is frequently made by upper management about FDA & CFSAN being science based Agency/Center that makes science-based decisions, the science staff feels decisions are sometimes made more on the basis of ‘political science’ than ‘science’ alone. Also strong – contrary science opinions and their open decision are often discouraged (on sometimes implicitly) or not rewarded at the Office of Center Director level. (they don’t like “conflict”). In addition the Office of the Center Director has employed more and more lawyers which have gotten more & more power and influence on the science-related decisions and regulations put out versus the scientific experts. Third, the Center should treat the science staff with more respect and integrity and reward these doing good science. The staff, for the most part, have the greatest (and increasing) workloads (especially review scientists) and are doing work of greater difficulty and required expertise than others and this effort is appreciated and recognized the least. As the number of science laboratory staff and science review/assessment are gradually (and recently fairly quickly) diminishing the Office/Center consistently hires more and more Consumer Safety Officers (CSOs). The job of the CSO is to take the basic scientific information produced by science staff and put it into regulations and communications to the field, the outside and upper management. Although they do less work of lesser difficulty, they consistently get rewarded,

awarded and promoted more often and much more quickly\* than the scientists doing the original core work that they take from. This vast and pervasive inequality in treatment is bad for the morale of the scientists at FDA and CFSAN and ultimately for their scientific efforts as time goes on. More equal and appropriately fair treatment(x) between CSOs vs scientists at FDA would improve the integrity of scientific work at the Agency/Ctr.

\* Some feel that it occurs because of CSO's frequent interaction and consistent contact with management. In addition, some feel this is because CSOs are more prone (willing?) to "massage"/manipulate the core science more often to be in line with what they see/sense management's desires are and are less willing to voice contrary opinions or fight for science positions (than maybe a scientist doing the work would).?

(x) More respect and regard for scientists efforts."

"No industry fee based work. Keeping the budget steady."

"We don't have the money to educate the public. We don't have enough regulatory authority. Not enough employees to enforce."

"Although I am unaware of any CFSAN scientist asked to change or suppress results of CFSAN research, I feel that the quality of CFSAN research has been degraded by what CFSAN scientists have *not* been allowed to accomplish. Research and other mission-relevant programs have been suppressed not only by cutting CFSAN funding but also by controlling how CFSAN utilizes its scant resources. Control of funding is largely and inappropriately influenced by special interest groups outside FDA and, to a lesser extent, by FDA and CFSAN managers who have chosen to lead in the direction desired by these special interests. A few examples of how CFSAN programs are degraded and could be improved follow.

Stop directing scant resources towards development of programs and policies that support narrowly focused political agendas (such as Food Defense) and industry interests (such as Qualified Health Claims). Re-direct resources to develop and maintain scientific knowledge and expertise in the broad topic areas of food safety (chemical, microbial, and nutritional qualities of safe, honest, and nutritious food) that CFSAN has statutory requirements to address. In the past decade, CFSAN resources increasingly have been used on programs motivated by politics or industry while mission-related activities have been severely curtailed. Example 1: Stop mandating that FDA spend resources on ways to protect food from terrorists that potentially may use toxic substances to contaminate food (Food Defense). Instead, use resources to develop and maintain a strong base of knowledge and expertise that may be used not only to protect food from potential terrorists but also to improve food by gaining a better understanding of deleterious effects of environmental contamination, poor agricultural practices, and inappropriate food processing and packaging. Example 2: Stop using resources to devise labeling statements that succinctly summarize how little scientific information is firmly established (Qualified Health Claims). Instead, use resources to actually determine effects of nutritional components of food on health. (Do the research). The Qualified Health Claims initiative has consumed substantial resources and has provided little or no benefit to the consumer.

Mandating spending on political and industry motivated programs not only has severely curtailed mission-relevant programs required by statute; it also has degraded integrity of programs that eventually do get funded. In order to justify funding for CFSAN activities, CFSAN employees have had to work on projects only tenuously related to the CFSAN mission

or have had to make dubious claims of the purpose and value of some CFSAN work products. This problem has increased severely in the past 5 years and many CFSAN employees now feel that honesty and scientific objectivity have been compromised and that demonstrating scientific objectivity could cost them their jobs.

Stop funneling money out of CFSCAN and into organizations that lack *regulatory* knowledge and expertise. Instead, use appropriated funds in-house. CFSAN has a wealth of expertise and institutional knowledge that is under utilized because its scientists and programs are under funded. At the same time, CFSAN is spending substantial time and money trying to obtain work products from institutions that are unfamiliar with the needs of a regulatory agency. At a minimum, work products obtained via extra-mural contracts with the University of Mississippi (dietary supplements), the University of Maryland (Joint Institute for Food Safety and Nutrition), and the Navel Research Laboratory (NRL, Maryland) should be audited by an agency such as the US Government Accounting Office (GAO) to determine (1) how well the product meets the regulatory needs of CFSAN, (2) if benefits of the product are worth the cost, (3) if the product could be produced as efficiently and inexpensively in-house, (4) if the product delivered is the product described in the original contract, and (5) if the product is a high enough CFSAN priority to be done at all.

Increase resources for compliance with current regulations, including resources for legal staff to prosecute violations. I have seen violations that were not prosecuted because legal staff and/or management knew that the time required to prosecute some violations (such as mercury in fish) would take legal resources away from other violations that would have more immediate and severe health consequences (such as microbial contamination in food). FDA does not have sufficient resources to enforce regulations and policies under the purview of CFSAN. FDA does not have the resources to do the job that the American people expect it to do.

Repeal the Health Claims provisions in the NLEA and Qualified Health Claims provisions in the DSHEA.”

“Repeal DSHEA.”

“- Asking Professional Societies to recommend experts to serve on review panels. Currently, political appointees or senior FDA managers pick the external panelists, hence raising questions about panel’s impartiality.

- Having “whistle-blower” system to confidentially review cases when senior scientists feel that they are being pressured to reach a pre-determined conclusion.

Congress prohibits FDA from proactive action.”

“-More money for the agency

-Stop using affirmative action as basis for assigning responsibility

-Allow more scientific meetings

-Disseminate information better”

### **Center for Veterinary Medicine**

“FDA does not do a lot of scientific work (conduct studies etc.). FDA does a lot of scientific review of work submitted to them. In our center is would be important to develop new

regulations in the pre-approval process so we can give the field and industry a better sense on how to conduct studies in order that their applications would be a better quality.”

“Providing funding for post-approval surveillance and compliance activity. Post-approval funding at my Center has been cut in order to ensure that the pre-approval work has funding enough to continue the User’s Fees program. This is discriminating post-approval capability and morale.”

“- Discontinuing user fees.  
- Removal of political appointees.”

“Removing the lawyers from the scientific determinations.”

“A thorough re-evaluation of how FDA leadership and/or management implements FDA’s mission of protecting the public health. The focus should truly be on protecting public health instead of catering to the interest of industry while pretending to protect public health. FDA leadership/management should let FDA scientists do the jobs they were hired to do instead of penalizing those who refuse to go along with FDA management/leadership’s eagerness to cave into political/industry pressures at the expense of public health.”

“Removing the political considerations from the process. If decisions are to be science based, there should not be a place for political input. Reaching defensible, scientific conclusions can be difficult enough without managements constant reminders of the politicians, industry members, consumer groups, etc, who may be unhappy with the conclusion. I was hired as a scientist.”

“Making sure each Center has enough funds available to obtain “state of the art” equipment and supplies required to conduct good quality research. We also need funds to ensure personnel can be replaced or added in order to adequately manage the workload.”

“Adverse event reporting should be mandatory, not optional. NARMS should be properly designed to track developing patterns of antimicrobial resistance in human and animal populations and in retail meats, and adequately funded. It has the potential to be very useful. Existing drugs should be reviewed every 10 years, and applicable new science applied. This would require that sponsors do more testing in many cases. Sponsors of new antimicrobials should be required to provide benchmark resistance rates during the pre-approval process. There should be no political appointees in the FDA, anywhere. They sidetrack and derail the science for political ends and goals.”

“Removing political appointees, political interest and industry influences from the Agency. We should be totally free and committed to public health safety without political or industry influences.”

“Getting George Bush out of office. Banning lobbyists \$ from Washington.”

“Removing politics from the review process and making decisions based solely on science.”

“Eliminate fees from industry-remembers lobby activity. FDA should be independent of \$ pressures.”

“Independence. FDA Commissioner should not be a political appointee.”

“Firing the Managers, other people who have agendas we need teeth – put some of the firm’s leaders in jail close down their plants – get rid of all appointees. Thin down management, add more reviewers etc. We are top heavy with managers, assistant managers, assistant-assistant, etc. Appoint someone from the center to be center director not some political hack. We need to regulate industry not be their partners – like all managers say now.”

“Keeping an eye on the push by politicians and industry on FDA to release drugs & biologics quickly. The critical path may not be all that the upper leadership is leading us to believe and thus approved products many be getting to market that are not fully safe or effective. More \$ and scientists need to be allocated to post-marketing surveillance to figure out if the critical path is a useful tool or not.”

“Removing White House policy influence/concerns from the scientific decision. This is an impressively fair survey form.”

“More training opportunities as technology and theory changes.”

“Hiring more scientists and fewer administrators. I work in a small center, and the number of working scientists is small. Every time there is a hiring freeze we can’t fill scientific slots for sometimes years, but we are always hiring people for any new function in our office of management. Twenty years ago there were 2-3 personnel administrators-now there are 50 in that office plus additional administrators attached to each of the scientific offices. Many of them are high school graduates, but are paid as much or more than working scientists.”

“Keeping politics out.”

“Ending the partnership of FDA with those we are charged with regulating. The FDA mission needs to be re-evaluated in the light of service to the public, not profit to the pharmaceutical industries. Science should be brought to the fore-front of the decision making process. Currently science takes a back-seat to profit and industry.”

“Removing political appointees. Providing more funding.”

### **National Center for Toxicological Research**

“Increasing the independence of agency decisions & regulations in the interest of public health.”

“More funding for research.”

“There is nothing wrong with the integrity of our scientific work now – however, it is being threatened by excessive budget cuts.”

“The major problem at FDA is insufficient resources (money) to conduct the needed high quality research. Under the current budget, research at FDA will almost cease to exist. Without research scientists the Agency will not have the scientific expertise to make science-based regulatory decisions.”

“Removing the excessive political and pharmaceutical industry influence on the agency’s decisions, which has increased over the past 6 years would be the most important step. As a note, since the Iraq war started our center, which is research oriented, has steadily lost its funding. Next year (2007) the funding will be at such a level that we may no longer be able to conduct research.”

“Adequate funding.”

“Getting the pharmaceutical companies out of the FDA, especially the FDA Advisory Panel!”

“An Inspector General system that had the power to investigate, recommend changes, and reveal corruption and incompetence. This IG system would report to a Congressional oversight board. Creating by example and fiat a culture of integrity in all of its management. What starts at the top filters to the bench. Thanks for asking!”

“More of a commitment by FDA management and the political establishment towards reversing the decline in the FDA science base. The recent trend for FDA research is to attract outside funding through IAGs, CRADAs, etc. While this has been useful in preserving our scientific careers, it does little to support the FDA regulatory mission. Morale is at the lowest point I’ve seen in 2+ years at FDA; I am glad I will be eligible for retirement soon.”

“Funding – more things are expected to get completed with less funds.”

“(1) Reverse the trend to view the pharmaceutical giant as FDA customers and return this role to the American citizen. It is clear that neither Congress nor the FDA are a match for the powerful pharmaceutical industry and therefore needs the funding to be independent. (2) The FDA administrators/managers are of a political and business mentality. To justify promotions they simply layer on bureaucratic requirements on to the struggling scientific researchers. (3) Prevent political appointees from making questionable regulatory decisions contrary to the recommendations of the FDA researchers and reviewers.”

“Increasing research fundings.”

“More funding. Our research budget has been reduced by > 80% over the last two years. These funding cuts have stifled laboratory research.”

“Increase funding within research facilities and continue IAG, [CRADA] and other leveraging funding sources. Reduce administrative weight for basic or applied research projects i.e., let scientists review and approve scope and specifics of work, reduce influence from non-scientists.

“Not starving the agency of funding.”

### **Office of Commissioner**

“Dollars. Personnel.”

“Right to publish research without management review.”

### **Office of Regulatory Affairs**

“Funding (especially ORA).”

“Increasing the Enforcement for Regulatory Actions Against Industry and Importers.”

“Complying to the rules and regulations and not being subject to some politicians whims would improve FDA’s integrity. At least people would know what to expect from us. Black ‘n white – not gray!”

“Taking decision based on science. Encouraging and supporting scientists to take higher management positions. Keeping public health as the mission not supporting business.”

“Reducing gov’t waste – most, if not all, of my negative responses are a direct result of Government Waste! We are self destructing: by sticking with policies that don’t work; keeping employees who don’t produce; and spending huge amounts of dollars wastefully, unwisely and uncaringly.”

“In my opinion, it is already too late to worry about the integrity of FDA’s scientific work. There are many other problems that will destroy the agency’s credibility first. It is fact that FDA cannot even cover all the employees’ salaries with their budget. This is leading to further lab consolidation/lab closures which will further dilute the FDA’s scientific knowledge base. This has already been doomed by the management setup. FDA management has passed the “good ol’ boy” system, and proceeded directly to pre-selection. Many desired jobs are filled by either pre-selected employees that have no idea how to do the job but have a friend pulling them up, or are set aside for employees of similar ethnicity. The managers are chosen to blindly follow upper management’s way of thinking. I have witnessed a constant decrease in management’s abilities during my [10+] years with FDA. Management is afraid to take responsibility for their actions evidenced by my director’s complete lack of knowledge and inability to make a decision, upward to regional director’s (RFDDs) who answer questions with double talk that leaves situations in utter chaos. This continues also with directors from the centers that push for industry rights, yet publicly blame others when problems are exposed. This continues all the way up through

Congress who look for “risk-based” actions thinking they are getting “more bang for the buck” and setting on numbers alone (# samples run, # inspections done) without realizing that the number of violations is low because of the effort of many FDA employees, over time, to get it that way. This enforcement by the FDA, over time is what Congress is oblivious to. The problems of lack of understanding by Congress, preferential treatment of industry by senior management, and lack of ability and knowledge by lower management, inserted not to make waves becomes a never ending circle that of which no amount of scientific integrity can fix. Laboratory consolidation, which took place approximately 10 years ago, illustrates the inability of FDA management. When a manager thinks he can consolidate labs, thus losing experienced analysts with 20+ years FDA experience, and then think they can replace that person, one for one, with a new hire and not have any drop in production or quality is ridiculous. Examples illustrating the lack of backing FDA scientists receive include: a F.E.R.N. (Food Emergency Response Network) project that will ultimately put FDA labs out of business which is failing much worse than FDA managers would ever admit to, or the recent push by upper management to have our labs accredited, despite being a regulatory body and not a manufacturer of a product producing a profit, yet getting no additional resources to bring this all about. FDA management will make sure science will take a back seat to politics, more labs will close, and the ability of FDA to remain science based will disappear. President Bush has already damaged our economy and society to such a point that things will not be reconciled in my lifetime. Now he is invading privacy. And taking away (starting to) basic American rights that made this country what it is today. I apologize for the negative views, but these are the facts.”

“I work with enforcement not science.”

“Better accountability for decision-making via planned documentation & audible under a quality system.”

“(1) Removing politics from the evaluation process; (2) Ending all user fees; (3) Making FDA an independent entity; (4) Reorganizing FDA by function, not product class. (5) Improving collaboration among units; (6) Replacing current senior management at the highest four levels; and (7) A comprehensive, honest GAO audit.”

“More money to increase manpower to review and do investigations and inspections of the underlying data and manufacturer of product. Increase manpower to support legal action [unless] justified.”

“Independence from the executive branch.”

“Not accepting money from industry (applicants). You are aware of Medical device and drug user fees, for applicants. This has deteriorated the agency approval process and has reduced the integrity of scientific work. Part of the science integrity issue is management being influenced by industry (applicants) and the other is Commission Corps people being placed in mgt. positions w/out qualifications.”

“Appointing competent managers. Managers in my office appoint because they are friends of upper managers. Incompetent managers are unwilling to make decisions.

Two things: strict adherence to science based decisions, and adequate funding to accomplish public expectations.”

“Basing decisions on scientific merit without political and special interest input.”

“Increasing resources particularly financial and personnel resources. We are unable to effectively fulfill our mission with such limited resources; this is our weakness. Protecting the public on limited resources is like re-using an old condom to make sure pregnancy is prevented.”

“Allowing scientific knowledge & conclusions validated by industry & academia to be used in lieu of required methodology from the centers that is far behind industry standards. With the ~50% reduction\* in operational funding over the past 3 years, the need/requirement for rapid testing to conserve funds is essential! \*At the field level.”

“Adequately supporting the infrastructure required to produce it, and (2) prohibit interference with regulatory activities associated with results by political cronies and special interest groups, and (3) insist on more transparent operations.”

“- Less politics in selection of Commissioner.

- Provide long term funding for entire FDA mission-not related to product approvals.  
- Change laws to (1) give FDA automatic jurisdiction-not have to document interstate commerce, (2) give FDA recall & seizure authority, (3) give FDA authority to seize & discard illegal imports upon arrival @ port.”

“Integrity is pretty good: (1) Methodology improvement needs greater investment-center investment in analytical science. (2) Infrastructure needs more support. (3) Incorporation of IT based systems needs better management, proper beta testing, vastly improved central competency/training? (4) Scheduling/balance of workplans between centers is unbalance-in [homogenous] in structure.”

“FDA in my area is very slow and reluctant to embrace new technology and accept the scientific base that is provided with new methods. FDA would be better served to be able to respond quicker to these new developments.”

“Adequate money to buy supplies and materials to perform the best science possible. Support to explore new technologies to perform analyses faster and simpler, accept screening methods w/o full scale analyses for surveying food samples. Hire/promote managers for technical merit-not their ability to say “yes, sir”. Allow more free communication between working scientists and policy makers-insist on a dialogue. ORA managers are terrified into inaction and to follow chain-of-command (thus little gets done waiting for the big boss to communicate decision down on small matters). They also only communicate from the top down, employees concerns/needs be damned. Total INTERTIA due to Good Ol’ Boys atmosphere allows little effective or fresh change. We do it this way because we’ve always done it this way. Now scared Bush cronies have made their way to ORA. And one more suggestion for better science w/in ORA- (1) They need to employ the scientists in work groups that fall closest to one’s interests and background-this allows for better passion and drive and hence work product. There is pushing around going on

and those people working in product areas not suited to them are quite unhappy. (2) Management needs to actually have RESPECT for the scientists talents and abilities, as well as ideas and suggestions. Thanks for asking the “right” questions!”

“Keeping politics out of the decision making process.”

“The FDA would serve the public better if the Agency would focus on “legitimate” assignments rather than “creating” assignments in order to justify their jobs. I feel that “user fees” are a joke, and should be eliminated. Decisions should be made based on “science,” rather than politics. The FDA has the “human resources” to accomplish the mission, but the work is not distributed fairly, or rewarded fairly. In other words, those who do the least are rewarded the most.”

“Efforts to improve demonstration of competence of the managers and to a lesser extent the analysts and technicians need to be done. Quite frankly, many of the managers lack good scientific background & training. They are promoted by some other criteria, unfortunately.”

“I don’t really have anything to say. I work in Investigations Branch/ORA. We don’t do scientific studies or methodology development. However, my immediate managers seem to be motivated to bore me to death as opposed to giving me assignments that are both interesting and challenging. A spirit of “glory grabbing” exists here among my peers.”

“Providing adequate funding.”

“FDA is a pathetic and fickle collection of spineless hypocrites, corrupt boot-lick policy makers and unqualified misandrists. We’re supposed to block affordable, safe and effective drugs from Canada YET we are powerless to act against the fraudulent dietary supplement industry that bilks diseased Americans out of billions of dollars a year. Our policy shifts like the tides to favor whichever special interest group happens to have the biggest pile of cash on hand at the moment. There is no internal accountability. This Agency sucks – and the second I have the opportunity to leave I’ll take it. I am ashamed of my involvement with FDA.”

“By limiting the influence of political appointee’s personal opinions when making decisions which involve public health & safety.”

“Conducting more detailed inspections of the Medical device industries or other regulated industries by FDA. Our Districts do not have enough personnel to cover all areas of the regulated industries.”

“Not having a political appointee serve as Commissioner. We need a full time Commissioner. Centralization has hampered productivity and efficiency, decentralize our work. Restating our mission-Protect the Public Health.”

“Eliminate the 1609 process.”

“(1) Putting science (research) in the hands of peer-scientists who are actively engaged in Research. (2) FDA currently operates with a budget of  $1 \times 10^9$  \$ to manage all the Food, Drugs

& Devices we come in contact with. Compare this to a budget of  $50 \times 10^9$  \$ for the CIA. The rank & file in FDA are very committed to Public Safety. (3) Individuals with little appreciation & understanding for science are promoted to management positions to get them out of the laboratory. FDA managers need to have education & experience (including management experience) commensurate to their counter parts in academia & industry. [Q4] However, FDA could manage its resources much better.”

“Better communication between all concerned.”

“Funding to support full & valid research and the freedom to publish findings regardless of political sensitivity.”

“By allowing us field tools for our exams and letting us use our knowledge for samples. More room for mistakes-there is a 0 tolerance for even small mistakes. Scientific [courses] (workshops) for new info that relates to our work.”

“A greater commitment to science, a removal of political influence. An increase in financial resources.”

“Standardizing the procedures of investigations & compliance operations.”

“FDA should not be led by political appointees. Our leaders should have strong science-based degrees & have conducted peer-reviewed research.”

“Getting the budget out on time.”

“(1) Keeping the political views & policies of the White House out of the decision making process. (2) Making the Commissioner of the FDA a career appointment, rather than a political appointment. (3) Provide FDA with sufficient funding to effectively complete mission, including funding for Presidential mandates.”

“Better management!!!”

“Changing law & policy on dietary supplements. Many are harmful yet FDA ignores these products. Provide more training. To CSOs: labeling & dietary suppl. Improve data reporting systems (ex: FACTS-antiquated, cumbersome, etc.) HQ personnel should be more helpful to RP & public.”

“Changing the laws by Congress to give FDA more authority to seize instead of relying our authority on CBP.”

“It is obvious that looking at 1-4% of imported products regulated by FDA is dangerously low and there are not enough field personnel to consistently be thorough in examinations due to the high volume individuals are required to complete daily. There should be many more people in the field putting their eyes & hands on the products.”

“Increasing FDA’s authority in dietary supplement claims regulation-put the burden of truth on industry rather than the agency to ensure that health claims have a real scientific basis, rather than obscure “clinical studies”. Take the political influence of the supplement industry out of the regulations.”

“Providing the funding to get the job done. For too long has the FDA not had the money to effectively do the work it has been asked to do.”

“Focus more on having good lawyers who can defend good science in court rather than wasting valuable resources implementing quality control programs which reach stupid extremes! Measure productivity by the number of real samples analyzed or real inspections conducted, rather than desk-bound activities like writing SOP’s!”

“- Better and more consistent funding.

- Formation of new separate food agency to cover all human edible foods.”

“Enforcing existing regulations. Basing decisions of safety and efficacy on science and not political climate or industry contributors (\$\$) to top decision makers (policy makers) within FDA and HHS.”

“Actually including local scientists in decision-making, rather than having a top-heavy administration in Washington, DC which ignores the field offices, and regional directors who never consider how their decisions affect the bench level scientist.”

“More funding and a chance to do research to improve scientific methods. Current methods and the ability to update regularly. We use or are mandated to use ancient scientific methods and it’s almost impossible to update. We are in 2006 not the 70’s!!! More computer technology would be nice.”

“Curbing the number of nepotism practice. Analysts not performing to their expectation should not be promoted or rewarded with easier duties. Managements or supervisors need to be more non-biased and evaluate employees’ performance based on their actual accomplishments and do it in an objective manner. New hires (those hired past 9/11), many of the new hires at least cannot work independently, must be lead through the analyses almost through every steps; yet, they are given special projects and assignments over more qualified analysts. In the mean time, more experienced analysts are being treated as second-class citizens.”

“Increased funding for better maintenance of equipment and ability to purchase needed supplies and consumables. More accountability for productivity all the way up the chain of command-when one unit’s productivity is linked to a non-related organization, accountability needs to be placed at source of problem as well as at first line.”

“- Increase the budget. We have too many people with no money to keep everyone busy.

- Reduce management layers. Too many managers. Not enough ‘workers.’”

“With the management in Rockville, MD, our ability in this field to enforce laws & regulations have been hampered. I feel ineffective in carrying out my duties to protect the consumers. Our operating budget is constantly being cut each year by Bush & Congress, which makes the FDA unable to achieve its objective to protect the public. We are no longer proactive, we’re becoming reactive to problems.”

“Keeping politics out of science.”

“The FDA no longer relies on “science.” It is, unfortunately, pressured by politicians and influenced by the military to truly be “scientific.” Those with the most power and influence within the FDA acquired their positions due to their political savvy rather than their actual skills and knowledge of their job requirements.”

“People resource and equipment maintained by service contracts.”

“Giving us the resources & number of skilled professionals we need to meet the demand. We are the oldest Public Health Agency in the nation and yet our resources are far less than CDC & USDA. FDA can’t lead when we don’t have adequate resources.”

“By having strong scientific professionals, that have real concerns with the quality of the foods and drugs being introduced to US Commerce. Not dumb axxx’s with personal interests in private industry, where the corporations are directing every FDA decision.”

“Using state-of-the-art equipment with proper training of personnel. Establish a better accountability system for managers & non-manager personnel.”

“Recognizing employees with respect, and understanding their legit opinions on how the mission is being carried out versus how could be improved. HQ needs to involve more employees from the field in most of their policies and decision that ultimately will affect those employees. And definitely, better budget implies better consumer protection, which will protect ourselves.”

“(1) Taking the (scientific) recommendations from employees who actually perform the work! (ie: who have the knowledge & experience in the field). (2) Making big changes to the “merit promotion” process, so that “favoritism” in promotions occurs much less frequently then it does; (this stifles morale and productivity more than anything else and ultimately decreases the level of service to the public at large. (ie: when much poorly qualified & unmotivated persons are routinely and consistently selected over much more qualified candidates based upon a manager’s whim.)”

“(1) Reducing the number of non-scientific personnel and Management, including Regional & District Directors, and reducing the # of Administrative, non-mission oriented staff at Headquarters. (2) Giving FDA the authority it needs to carry out Regulatory Action against violative firms!”

“Not letting politics into the scientific findings & decision making.”

“More action against RDTC act violations rather than a voluntary compliance approach for business.”

“Cleaning house.”

“Removing politics!!!”

“Budget constraints-the district level employees are scattered about at various resident post and never get the opportunity to come together. Our district has not had a conference in over 4 years. There are many new hires whom we haven’t met. It is crucial for us to come together.”

“Making FDA independent whereby decisions are actually based on science/data with integrity rather than per White House policy/directive. The agency’s mission, independence, integrity, and morale have drastically plummeted under this administration. Consumers no longer trust FDA decisions or personnel as they know we no longer enforce the regulations but rather protect regulated industry/big business to the detriment of the consumers. Pre-approval applications of investigational articles should be better scrutinized not just post approval products.”

“- Providing additional resources.

- Return FDA to its roots. FDA is a regulatory agency charged...
- Strengthening the FD&C act to permit FDA to effectively regulate.
- Return FDA to its traditional role of protecting the public and not satisfying industry and performance goals.”

“Being able to levy fines against all regulated industry with repeat offenses/violations; More control by first line supervisors; fewer management levels; better computer resources; praise & rewards for good work and enforced consequences for poor job performance; and better pay for good employees.”

“Let the scientists do their jobs by allocating more funds and tools to do their jobs, and the Government out their way. Too much red tapers.”

“(1) Hiring top scientists from good universities. (2) All lab managers should have MS or PhD’s in science related to their position. The higher the position the more academic background like at CDC. (3) FDA should be able to fire/get rid of those scientists who demonstrate poor skills (science) and especially those who lie in results.”

“Lessening the bargaining power of the National Treasury Employees Union and allowing managers and supervisors to perform their jobs; local stewards frequently pressure employees to file grievances, threaten management when trying to accomplish goals, openly bad mouth managers and supervisors, regularly conduct business in a self-serving manner, and interact with favoritism in regards to fellow employees. Thus giving the appearance of the NTEU of being counter to the mission of the FDA.”

“Promoting people within the FDA that are strong in science.”

“Strong encouragement from supervisors, along with providing relevant references to keep the employees updated in technical information. I would also like to be sent to Annual Meeting(s) and workshops pertaining to the specific field(s) of industry that I’m performing inspections in. It is important to speak “the language” and adds to the agency’s credibility.”

“Better communication channels.”

“The lab’s work integrity is very good, just like the field inspections/investigations. The problem is funding, no funds for surveillance samples. Plus no equal pay for CSI and CSO. CSI’s doing same job in Seattle with same knowledge and education. Couple CSI’s in [SEA-DO] have more college than counterpart CSO’s and/or more import knowledge and skills. Problem is discrimination from 1<sup>st</sup> line supervisors and directors on hiring and/or assignments. [Q18] Funding problem concerning sampling.”

“Note: I am Consumer Safety Officer and not a scientist. Since I am not scientist, many of the questions could be answered as no opinion only.”

“If FDA did not have to rely on other agencies to enforce the law. FDA depends on US customs (CBP) for immediate action on violative products. In the eyes of other agencies it makes FDA look weak.”

“Bigger budget. \$162,000 to run a lab is entirely laughable.”

“Making sound science a priority, and by changing to a merit based system. We have several GS-12 Chemists and one GS-13 Chemists in my section who do as little work as they can get away with. There is no reward for working hard, and no punishment for slacking off. Our samples are assigned to the people who will get them done, while those who don’t want to work are ignored, but still paid their GS-12 or GS-13 salary. Getting samples analyzed should be my number one priority, but managers above me do not feel the same way.”

“New management – more attentive.”

“New management.”

“- Being supported by upper management.  
- Have allocated funds and resources.  
- Having the educational background and work experience related/required for the area of expertise.”

“FDA budget was increased in or to do the required work and buy things we need. Budget majority is going to DHS.”

“Providing the money and resources needed to replace old instrumentation, and purchase items needed/identified for an analysis. Also more training is needed to keep up the latest technologies. Very few opportunities are offered to lab personnel. FDA is doing the best job they can with the limited resources provided.”

“Invest in more resources to CSO’s to have at disposal to enhance quality of inspections (i.e. more digital cameras, better internet/intranet connections, better sampling equipment).”

“Providing supplies and equipment needed to perform the necessary work.”

“Promoting persons with background, experience, competence i.e. utilize individual skill-sets (as opposed to personal friendship, loyalty, etc.) to best advantage, instead of placing marginally qualified personnel in positions requiring high level of specialized expertise. Do not allow management to “solve” problems by placing blame on subordinates instead of objectively investigating out of spec. data. In short, more objectivity is needed.”

“Hiring managers who have the ability, knowledge and integrity to do their jobs.”

“Clear and concise guidelines between the centers and ORA. The program guides need to be monitored and updated more frequently. The quality system needs to be consistent from ORA lab to ORA lab. Finally, the budget cuts are beginning to affect our productivity. Any more cuts and we’ll be ground to a stop.”

“Allow employees who mostly do import work to do some domestic inspections. We could use the experience to help further our careers and help from being bored.”

“Stronger and independent post-market review of approved drugs and services. Independent in that it is FDA, but a separate group not involved in approval process.”

“Improving morale in the work place. People that have been with the agency for some time, feel strongly that new hires with little or no experience are being promoted through the ranks like rockets.”

“To minimize the human elements in science might be all we can hope for, and then, only in those labs that need it most. Overall, the best way to preserve scientific integrity, I think, is through competent, confident leadership that can shoulder the discipline and responsibility needed for scientific integrity. Labs need leaders who are not afraid of scientific principles, and who are willing to support those principles any way they can. Some of the specifics for doing so could include the following:

1. Reduce bunker mind-sets. Right now, many labs are completely enclosed and withdrawn. Outside contact is minimal, while the employees are subjected to the whimsical rule of a few. Not all of this mind-set is caused by tight budgets.
2. Allow open contact and scientific networking through email and telephoning, and by attending scientific meetings, even the small ones. Also, allow open communications within a laboratory, so most everyone has an idea of what’s basically going on in the other sections of it.
3. Assure typical lab analysts and workers that their future and job security does not depend on compromising scientific accuracy. This issue is a big one, and difficult. Many lab workers are fearful in this respect, feel intimidated by it.
4. Provide incentives for those who are scientifically capable, rather than punishing or suppressing them for control reasons.

5. Encourage honorable collaborations where participants can contribute to projects, rather than forcing them into situations meant to demean them or their scientific work. That is, for example, don't force capable scientists into collaborations based on falsification of any kind, particularly involving the data, but also, the credits.
6. Reduce the influence of chronic game-players. Peers often sandbag or throw monkey wrenches into the scientific programs and projects of others, or cause them to fail, somehow.
7. Reduce the influence of power-gaming leadership. Often, the agenda of leaders is their own control above all other issues, even above scientific accuracy and principle. The attitude causes demeaning control practices over scientists.
8. Encourage all workers to avoid 1) playing both ends against the middle or vice versa, 2) having or playing single issues both or multiple ways, 3) being all things to all situations, 4) leaping into tangled webs of deceit, false pretense, and unethical or criminal behavior, and 5) fabricating highly sophisticated devices for blaming others.
9. Control those who fabricate problematic situations that seemingly on the surface can only be fixed through deceit and falsification of some kind. This ploy is too common.
10. Hire and install confident leaders who allow sufficient wiggle room for scientific innovations and successes, and who aren't threatened by scientific accuracy and integrity."

"Change the management structure. I do not think that there is any sort of FDA-wide conspiracy as portrayed in the media. The real problem is bureaucracy. Bad news is strongly discouraged from flowing up. The lower level people know the problems but each level is scared to send bad news to the person over them. You just say what your supervisor wants to hear and life is easier that way."

"Not allowing budget cuts to DHHS/FDA."

"Better communication between field offices and HQ."

"Eliminate the excessive, and many times unnecessary, paperwork for sample analysis. It can take me a day or two for me to complete my analytical assignment, but it takes weeks for all the paperwork to be finally completed."

"Providing the agency with the appropriate funding to do the job right. FDA is barely starting to man the border ports of entry, but as of today we don't have nearly the appropriate amount of staff. Furthermore, we don't have the funding to do our job. How can we protect the US consumers (taxpayers) if we are not given the appropriate budget to do the job. Our morale is good, just give us the resources to do our job well. Please help."

"Integrity is fine the way it is."

"Better leaders at the supervisor level and their supervisors."

"Management Section/Job Satisfaction. Basic negativity is related to our leadership personnel having our office "compete" with other POE's within our district to have us overcome them in everything (i.e. stats, collections, reporting, seizures, etc.). All while our port (POE) is actually doing successfully good already . . . yet not being recognized . . . hence, low morale – our

supervisor never places his CSO's for awards; we receive awards usually when district has funds left over . . . never a nice feeling, especially after T4 does well over the year and completing the work plan.

As for #10 question: Budget cut after budget cut, less and less every year – our POE has less and less to work with as far as office and collection supplies are concerned. Yes, we meet our work plan in collections however, instead of it being a smooth transactions we go through tremendous obstacles in order to complete the collection (i.e. no bubble wrap, no toner, old fax machining, etc.).”

“Cutting down the proverbial monkey climbing tree. It goes something like this: Everyone is climbing a tree. Those at the top look down and see only smiling faces. Those climbing see only ass . . . Management needs to stop being at odds with non-management. We should be equal. P.S. Might get rid of unions too.”

“- Continue to strengthen and enrich the professional development of the scientists employed by FDA.

- More positive feedback.

- Be proactive to change and new scientific developments and move those developments to the mainstream so that regulatory procedures can be updated, the turnaround time increased which could generate more and better surveillance for FDA regulated products.”

“Too much cronyism and favoritism exists.”

“Getting rid of scientifically incompetent mean spirited sons of bitches in management. Removing the establishment that is choking the hell out of the office of Regulatory Affairs. Question 8: I was told last week that Scientists and Engineers do not make good managers.”

“Return to the basics of science. Accept the experience of qualified analysts. The 150 project forced upon laboratories is contrary to many basics of good science. Too much attention is devoted to accounting procedures not analytical procedures. There is little or no respect for analyst common sense. Non scientific personnel are dictating analytical policy.”

“Stronger avenues for peer review both in and out of the Agency; interaction with independent (as is possible) academic scientific sources; free exchange of ideas with industry and other constituents; more focus on education within the Agency in scientific areas.

Question 7: Local management chain is better than national.”

“I have over 20 years Government service and FDA has been one of the harder places to do the job as expected . . . and when looking to move up the “ladder” to a professional series I did not get much encouragement from management, partly because of cuts in the budget (programs for lower ranking employees to first). The budget cuts have affected quality of work and quality of life. The hiring freeze to replace employees puts more stress on those still remaining since you have to do the work of two people now.”

“Risk analysis, cost analysis, common sense, working with the front line employees and asking for their advice before making decisions.”

“Buying new equipment by having a larger budget to protect the public health.”

“Implementation of repercussions for scientifically unsound work. I have seen analysts falsify data, day lab, and continue with their work. There is no accountability for bad science, and management turns a blind eye. Woe to the American people!”

“By hiring those or encouraging more scientists to apply for FDA, having less commission corps that have to leave or be deployed so frequently. This leaves civilians to do all the work. They seem more concerned about other issues rather than FDA work.”

“Focus on science not politics. Better management of money. More money to field operations. Replace out-dated lab equipment.”

“Having experienced and knowledgeable people in management that have the skills that are specific to the work they are managing. People in management/ supervision should know the work that is done in the field so they can manage it effectively. Supervisors should actually do field work (to some extent to keep up with skills) not just sit back and “manage.””

“Focusing on science and not ethical implications”

“By putting the time and money as well as effort in making sure that we look out for public “not” the companies regulate. Also by getting the politics of doing our jobs out of it!”

“Eliminating political appointees.”

“Having supervisors and managers that are technically competent and experienced in the areas that they supervise. Many supervisory and management positions are interdisciplinary. Biologists can be managing Chemists, etc. or Chemists managing a chemistry unit without any experience in that unit.”

“Not a Scientist or lab person. Lack of enough training of investigators is a concern. Hard to conduct proper investigations by reading CP guidelines and OJT all the time.”

“The agency needs supervisors and managers who are more knowledgeable in their subject areas. More funding is needed for better equipment, supplies and the hiring of laboratory aides.”

“If the labs were more in keeping with industry with up to date instrumentation and procedure.”

“Allowing scientific reviewers and investigators to do the science-based jobs they are trained and paid to do and respecting their knowledge, expertise and recommendations and supporting their work by making appropriate decisions commensurate with the recommendations when a firm is obviously violative to FDA investigator and violations have been appropriately documented. Compliance and the centers are afraid to pursue regulatory action, even by sending a warning letter, for fear of upsetting regulated industry. FDA scientists and investigators are knowledgeable and conscientious and are the first-line contact with regulated industry. We

know the facts of the situation, yet managers, centers and compliance constantly second guess and overrule or negate our regulatory recommendations. This leads to ineffective agency, and low morale within ranks of agency.”

“By shifting the focus within the agency from one that centers on making certain that we appear to be doing everything (and correct) to one that encourages input, new ideas, and better approaches into how we do our jobs. Sorry that wasn’t very clear – to me it seems that the management of the FDA is only concerned with covering their own butts, and not at all concerned with whether or not anything is being done in a good way, so long as nothing was done against the rules.”

“Lengthening of deadlines for sample analysis from seven to fourteen days within the unit.”

“Allowing field investigators to have more input into the annual work plan to inspect forms that are more of a public health risk/concern than those who are consistently found to be in regulatory compliance year after year. Also, by allowing productive employees to work at home or in resident posts more often to help increase work productivity.”

“Cooperation and peer review of ones articles and/or findings. Both monetary and “verbal” support by management to provide the best resources and equipment/instruments needed to carry out ones research/testing mission.”

“1) Building new building (laboratories) with a good quality equipment to conduct testing and research. 2) Afford appropriate resources to keep up with the advancement of professions. 3) Encourage employees to expand their knowledge by providing easy access to academic courses.”

“1) Hiring more personnel to collect and analyze samples. 2) Giving more powers (e.g. embargo the product) to FDA.”

“Expecting publications and at least 20% research and development from each Scientist. Giving real time off for academic study (graduate degrees). Not advancing employees on the basis of race, creed or ethnic background with weak backgrounds. Raise the levels and standards of training courses. Not hire individuals with weak academic credentials.”

“Scientists are becoming ineffective because of the imposition of an overwhelming amount of inappropriate QA and other tasks not directly related to the primary mission of screening for violative and dangerous products. Scientists need to focus on the science and not rush to produce attractive sample statistics.”

“Allocation of funds for purchasing instruments. Managers that are technical experts in the area they supervise. Allocation for appropriate training.”

“Management listening to FDA scientists and hearing with open minds, even if the message shows the agency in a poor light – as long as it protects the consumers. Not ostracize scientists or black ball them because their foresight sees a problem with a drug, device, food, biologics, etc. that possess a potential hazard to health now or in the future.”

“- Keeping politics out of science, that is, evaluating scientific data without pressure and influence of management to achieve a ‘desired’ conclusion, and  
- Promoting senior management from within to fill critical decision-making roles as opposed to placing more and more political appointees who are given ‘marching orders.’”

“Hard work and funding – no opinion at this time.”

“Increased funding and manpower.”

“Giving every employee “equal” opportunity to increase their experience in different (fields) areas – not just having a good rapport with management.”

“The corruption is so systematic that those participating in it no longer perceive it as wrong. Any attempt to bring them face to face with the realities of the law will be destroyed.”

“No promotions, they tell you go to school to better yourself once you get a degree, they forget about you and say all the time “over our FTE’s” (meaning they are overstaffed in one area of the country).”

“Maintaining a high level of integrity, without reprisals when enforcing the laws. The agency must be able to function with scientific evidence, and uphold laws and regulations without interference with due process of law etc. The interest of the “consumer” must take precedent!”

“Management that fairly and intelligently rewarded and recognized individual contributions.”

“Providing more money for the research and labs needs.”

“1) Allowing more freedom for scientific inquiry and collaboration with academia, 2) affording time and resources to keep up with academics in the profession, 3) making it easier to publish in peer-reviewed scientific journals, even within agency policies and positions, 4) offering opportunities for advancement based on scientific expertise, not just on administrative and supervisory expertise. Presently, it is extremely difficult to advance professionally based on scientific expertise. Consequently, administrators and supervisors, who are often less qualified academically and scientifically, determine whether the Scientist is allowed to pursue research, and/or to publish fundings in peer-reviewed journals.”

“Support from First Level Supervisors. After 9/11 I take emergency situations into my own hands and do not wait for management to act!”

“Increase the use of field laboratories to analyze port market domestic and international imported products. Start allowing the field laboratories to perform microbiological testing of vaccine products imported into the US for sterility integrity. Do not allow contract private laboratories to perform the product testing of consumer goods. Use only FDA laboratories.”

“Less politics!”

“Very good.”

“1) Repeal P.D.U.F.A. Who do we work for? Answer: American Consumer – not big Pharma.  
2) Hire more CSO’s: especially in imports.”

“Allowing the centers to do a thorough investigation of new drug applications. In my opinion, FDA scientists are pressured to approve new drugs in a short period of time, which in turn leads to adverse reactions. The FDA is doing a disservice to the general public by catering to industry and Congress.”

“Increased performance incentives. The reward to go above and beyond your job description is too often a lousy \$250.00. If the performance incentives were higher, I wouldn’t be considering an industry career. Currently, if I work my tail off and get a number of regulatory actions, more times than not I don’t even get a “good job,” so you can forget about a monetary reward.”

“Reduce the hiring of Comm. Corp. Officers and discontinue contracting third parties to do FDA work. Also, produce more funds (Operating).”

“Having people more focused on a particular field rather than having them be able to handle many different fields.”

“Promoting quality and not quantity when it comes to work plans for field staff. The level of competency of our current supervisors (leaders) needs to be improved as far as their knowledge of our field work to promote quality of their staff. We have very few supervisors (leaders) that did quality field work themselves and how can they expect quality when they don’t know what it is? Our leaders (supervisors) receive management/ leadership skills, but not quality of field work skills. 10+ years ago – yes . . . now – no.”

“Returning US education methods to the German Humboldt system. Scientific method restricted to mechanistic type thinking, as opposed to dynamic thought precludes solving problems of disease and human health. Bernard Reiman, Kepler, Leibniz exemplify dynamic method of problem solving. Results were realized in early 20<sup>th</sup> Century of Western Civilization. Thank you!”

“Field management incompetent”

“Continuing with current infrastructures and legal guide posts with periodic adjustments as necessary in keeping with the times.”

“We are so short staffed there is no way FDA can protect the public. It’s just a disaster waiting to happen. One would think that because we’re so understaffed that management would treat employees better – but it’s not the case. We continue to lose people.”

“Allow the FDA (a science-based agency) to use science to improve the lives of consumers and to protect the public. Get the politics and special interest groups and FDA-regulated

industry(ies) out of the way of attaining/maintaining the FDA's mission statement. We work for the consumer, the US citizen and no one else. Thank you for asking me for my opinion!"

"Better resources, separation from political/religious considerations."

"Being more proactive instead of reactive. There are a lot of health and safety concerns that FDA needs to evaluate and address but instead we are always trying to react to the next hot topic or the next crisis instead of dealing with future safety concerns. It feels like politics often have much more of an effect on what's happening in this agency when the only concern should be protecting public health. There are a lot of highly qualified, well educated, intelligent people in this agency and instead of using them as best they could, everyone gets bogged down in paperwork and politics."

"The budget decreases over the years has made it hard to continue to perform the work required. After the laboratories were required to become ISSO certified, performing normal duties become more tedious and more expensive. I am not against the certification but I do believe it came at a bad time."

"Better funding. Funding can increase by decreasing "management" or special projects positions at higher HQ. HQ is top heavy and the field offices are bearing the brunt of it."

"The integrity of scientific work produced by FDA could be best improved by putting scientists (Bio/Chem/Micro) into upper management positions, not political appointees. Or, if not scientists, then seasoned FDAers who have come up through the ranks with a solid understanding of what goes on at all levels of the "work." Also, final decisions need to be made based on science not politics, opinions, or fear of responsibility."

"My opinion: The drug industry has too much influence on decisions made by FDA."

"Granting FDA its autonomy from HHS and make it a stand alone organization or completely dismantled FDA-break up the different centers and put them under other agencies ex. CFSANQDCUM and food inspection combining with UDSA, Drug-CDOR and Drug inspection go to DEA, imports should go to Homeland Security/CBP. But FDA needs more authority to enforce the laws and regulations it does have without influence from industry and political appointees as well as Congress."

"Better laws that don't protect/shelter industry. More funding for Field Offices/ Laboratories. Paying for further education of scientists."

"There is plenty of money available to run FDA satisfactorily. However, the people hired and promoted are to fulfill protected class quotas. People that are productive, knowledgeable, able and clean are not welcome. Our mission is to promote health, cleanliness and consumer protection. However, our managers do not reflect these qualities/missions. It's the opinion of many that only non-productive women, minorities and effeminate sycophants work for FDA. Our district director doesn't even know the products we regulate."

“Having competent, well-versed management who supports and works together with employees. I have noticed that the Managers (upper management, especially) obtain the position without really having sufficient knowledge of multiple facets of FDA workings.”

“More personnel, funding and decision making placed in the field.”

“Post-approval long term monitoring of clinical trials.”

“More funding. Our operating budget in the field lab has been dramatically cut over the past 5 years leading to the elimination of necessary consumer protection programs. We do not have the resources to fully evaluate the safety and efficiency of products on the market or in development.”

“Providing adequate funding for training of its scientists, both in refresher courses and new analytical techniques. Work harder on completing the certification program for its analysts and provide more opportunities for cross-training of scientific personnel.”

“I think FDA could be vastly improved if Congress allocated more money to FDA. Resources are being spent on the war in Iraq and not on public health in our own country. Every year, I hear we have less and less money to work with but are supposed to be producing the same quality of work. In our district we do not even have the equipment to do our jobs properly and we are short-handed, both in support staff and investigators. This is the biggest reason I hear for not being allowed to do the inspections that are needed, not enough money (either for extra investigations, for increased time to develop a case or travel that requires an overnight stay). In the investigative field, improvement could be gained by using the human resources they have to the best possible level. FDA (driven by Congress) is too focused on “numbers” and not quality. I think Congress needs to focus less on number of inspections and more on quality and issues. I joined this agency after 9/11 (leaving a professional occupation) in order to make a difference. I am very passionate about my work but I feel suppressed by management in my job. Ignoring the safety of investigators is another problem area at FDA. It is going to take a death of an investigator unfortunately to get this agency to take safety of employees seriously (as the case of the USDA and State of CA employees that were killed at the sausage plant in San Leandro in 2000). Due to lack of employee in this district, many violative cases is in the office and never make it to headquarters for action. I believe it takes serious illness of the public and/or deaths in order to get FDA to do anything (Vioxx as an example). The attorneys for FDA seem to find reasons to turn down cases. It seems as if they are protecting industry not the consumer. I also believe this agency should be allowed to impart financial fines on many times of firms and businesses with repeat violations. One area I think this would be very useful is farms involved in continuous tissue residues. A small fine will make these farmers take notice and shape up more than a letter of warning which some of them cannot even read. I do not think the public realizes how much antibiotics and other drugs are given to animals every day. Only a fraction of these animals are tested for residues by USDA at slaughter and in some cases, there are not tests available to check for certain drugs that are being used in these food animals. This is the case with milk testing also. The majority of the drugs used on these farms are not even being tested for in milk. Sometimes I think the government does not care. I work with some very wonderful, hard working colleagues who are all frustrated by the poor leadership in our own office (as well

as the agency as a whole) and the lack of action taken against firms who continually violate the FD&C Act. Morale has declined so much in the last three years in our office that experienced people that would have continued working after reaching retirement age are now counting the days until they can leave. The incompetence I see in management is unbelievable. I know of people in my office who are very upset and disgusted with problems in our office and the agency. But they were afraid to fill this out.”

“More resources, less management layers, better way to utilize resource.”

“Putting scientists in charge of the agency –not lawyers, accountants, economists, etc. Enforcing the ethics, financial regulations as they pertain to outside interests while employed with the agency. Embrace change, innovation, new technology etc. with enthusiasm. Increase the budget to hire more scientific staff to get the job done.”

“Using technically competent managers and aligning organization functionally rather than geographically.”

“Empowering scientists and cultivating permanent scientific expertise and staff. Maintaining institutional memory.”

“Post market surveillance needs to be improved through more funding for post market supv. insp. (including user facilities) and technology for tracking and trending post market data. Also, enforcement to mandate reporting from user facilities and firms. FDA should be trending all data (same devices with mult. Manuf., same manuf. And mult. Devices, etc.) and issue inspectional assignments based on trending to prevent adverse events. Just tracking adverse events, and not including misuse by user (laboring or instruction problems), malfunctions and complaints, etc. is not enough! We must be trending all postmarket data, issue assignments based on trending, inspect user facilities to verify compliance with MDR regs. And ensure malfunctions are reported, in order to prevent adverse events. Of course surveillance inspections or manufacturers should continue, only improve post market to prevent adverse events.”

“1) Removing the undue influence of the media and the politics behind the decision-making. 2) Increased scientific resources and review by technically competent management. 3) More technically competent management.”

“Removing political influence as much as possible. The Bush Administration’s political lackeys have made the FDA a laughing stock, between the Plan B debacle (courtesy Commissioner McClellan) and the sudden “departure” of Commissioner Crawford. Bush’s right wing agenda has taken a huge toll on this Agency, and U.S. Consumers pay the price.”

“At the local level, there is blatant favoritism for certain individuals to get high profile assignments which lead to promotions. At the national level, agency decisions are influenced by industry lobbying and political pressure by the current administration.”

“Senator Grassley’s (R-Iowa) opinions of FDA’s management are right on target. Total lack of integrity, total lack of technical backgrounds, total lack of management skills, total disgrace!

The last sentence describes FDA's management across the board, from the smallest Resident Posts to the Commissioner (or acting Commissioner)!"

"Better equipment and work-related materials, along with better management!"

"More resources."

"Increasing funding so we could operate without seeking outside funding."

"New management!"

### **Unknown Center/Office**

"1) Not allowing investigators to conduct inspections in FDA regular areas that they have no experience or training in.

2) Allowing sufficient inspection time at firms so data collected would be more accurate and representative. One and two would facilitate improved FDA direction, decision making and spending."

"More emphasis placed on science and less emphasis placed on political "good ol' boy" mentality which is rampant throughout the agency. If methodology is poor, it should be addressed but rather than this it is not. I believe this is attributable also to "good 'ol boy" mentality as well. I also believe the agency is ineffective due to budgetary constraints."

"Better management. Management that will follow "rules" when it comes to hiring practices, permanent government employees being supervised by temporary post docs. Management encouraging employees to obtain promotions, not preventing them from advancing."