



FOOD AND DRUG ADMINISTRATION (FDA/HHS)

Employees Represented by the National Treasury Employees Union (NTEU)

NTEU is the exclusive representative for most of the bargaining unit employees at FDA. The National Union has issued recommendations to the Presidential Transition Team in a document entitled 'Delivering for Change for America.' NTEU is making this document available to members of the agency review teams as well.

In addition to the recommendations addressed in that document, NTEU also has several recommendations specific to the FDA.

STAFFING -- NTEU strongly agrees with the President Elect that "FDA is badly underfunded for its responsibilities." After years of unwarranted cutbacks in staffing levels, FDA has been given some very modest increases in funding. These modest increases have been just enough to give employees some confidence that future help may be on its way. But substantial improvements in funding are needed. Last year, the independent Science Board concluded that FDA was woefully underfunded.

NTEU is recommending a FY2010 appropriation of \$2.25 billion, an increase of \$386 million. NTEU can provide specific recommendations allocating this increase by function.

FACILITIES AND EQUIPMENT -- The most pressing need for this increased funding is as pertains to the testing of imports. The President Elect has noted that "As our economy brings a rising tide of imported products, the FDA urgently needs expert staff and technology to more rigorously inspect imported food, drugs, and other products like pet food." The chemists, scientists, inspectors and other front line staff the FDA firmly concur with him.

The FDA field laboratories not only need more staff but an upgrade in facilities and equipment. Because of the urgency of this need, it should be addressed in the new administration's stimulus package rather than waiting for the FY10 appropriation. The Denver and Kansas City laboratories are in particular need for upgrades. Kansas City is a leased facility with three years left on the lease. Denver is a GSA owned facility.

None of the labs are prepared with the capacity to deal with national emergencies; e.g. melamine in foods, filth in foods (insects, rodents, hairs, etc.), microbiological contaminations, tampering/terrorist acts, heparin in drugs, etc. They are not ready with the equipment, space, people and methods to test for many contaminants.

NTEU supports the construction of the proposed bio-technology lab at White Oak in Maryland.



OVERSEAS INVESTIGATORS -- There is great concern that not enough resources are being put into on-site foreign inspections. Currently, an investigator is assigned to only one foreign inspection trip per year. FDA has begun to address this problem by stationing foreign investigators overseas, starting in China. Plans are to greatly expand the placement of investigators overseas. US based investigators are represented by NTEU but management has made the determination that when investigators are based overseas, they are not allowed union representation, even though they do the same work as domestic investigators or U.S. based investigators that travel overseas. The result is that many employees, including the most able, do not volunteer for overseas assignments. Overseas work can raise employment issues such as health care, personal safety and other matters. Employees do not want to give up union representation in these situations. NTEU request the new administration include these employees in the bargaining unit.

THE POLITICIZATION OF SCIENCE -- At every level throughout the agency there have been challenges to the rules and laws of science. Scientists have been threatened, directly or indirectly, not to speak out even within their peer groups with regard to science-based decisions. This is especially true at Foods (CFSAN), Drugs (CDER) and Devices (CDRH). The FDA must be freed from the Bush Administration's ideological straightjacket to protect the public health on the basis of sound science.

MORALE -- The lack of staffing, the substandard equipment and facilities, the politicization of science, and the disrespect for employees taking on the difficult and dangerous assignment of working in China and other places has added to an already severe morale issue at FDA. Many in senior management are seen by front line employees as hostile to them and their sense of professional responsibility. Two years ago, management announced an initiative to close half of the FDA field laboratories, in which their employees would either be dismissed or involuntarily re-located. NTEU worked with Congress to successful prevent this ill-advised action. But it has left ill feelings between employees and top management and a lingering suspicion by employees that their jobs are at risk. While many employees are elated with the new administration, affirmative steps are still needed to create a sense of management support for employees.

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