
> > From: ORANEWS [<mailto:oranews@fda.hhs.gov>]
> > Sent: Wednesday, December 06, 2006 1:52 PM
> > To: ORA All Employees
> > Subject: ALL HANDS - Progress Report on the State of
ORA and Its
> > Transformation Initiative
> >
> > December 6, 2006
> >
> > Dear Colleagues:
> >
> > A little over a year ago I spoke to you about the many
challenges
> > ORA faced and the hard work that lay before us if we
were to honor
> > our proud tradition and keep ORA an effective force for
promoting
> > the public health. Since then we have launched a
transformation
> > initiative - an unprecedented effort to revitalize
every aspect of
> > ORA. I would like to update you on the progress we
have made and
> > provide you with a clearer overview of where we are
headed.
> >
> > I am happy to say that while we still face many
challenges, our
> > prospects have improved dramatically because of the
proactive steps
> > we made to take charge of our destiny. If you
remember, 2005 was
> > our third consecutive year of shrinking resources and
expanding
> > responsibilities. It was our third year of a hiring
freeze and we
> > were rapidly shrinking by attrition. Our workforce
location and
> > skill sets were increasingly not in sync with our
workload; and we
> > were "mortgaging our future" by cutting travel,
training and IT
> > investments. In short, we were in trouble and there
seemed no clear
> > path for moving forward.
> >

> > Today, thanks to much hard work and the tough decisions we have made
> > this past year we are in better overall shape and our future looks
> > brighter. For example, through careful implementation of a FY 06
> > "early out/buy out" program and an extensive zero based budget
> > analysis, we have gained more capability to wisely invest in our
> > future.
> >
> > We still face budgetary and other challenges, but we are now better
> > able to surmount them and set out on a clear path toward building an
> > even stronger and more effective organization.
> >
> > Over the past eight months, the Transformation Leadership Team's
> > (TLT) comprehensive review and analyses have enabled us to stake a
> > clear direction for advancing toward the future. Among other
> > things, the team has led the development of a proposed
> > organizational structure for the ORA of the future, a structure that
> > will support the ORA Mission and Strategic Plan implementation and
> > will embed Quality Management and
> >
> > Risk Management in everything that we do. The TLT is now "filling
> > in the details" of that structure so that we can present it to the
> > Commissioner for his approval. I know that each of you is anxious
> > to know all of the details of this organizational proposal, and as
> > soon as those details are finalized and approved, we will share them
> > with you. In the meantime, I would like to outline the major themes
> > of the proposal.
> >
> > We are proposing that ORA be structured to:
> >

> > * Fully integrate Quality Management Systems and Risk Management
> > in all of our work
> > 1 Centralize management of laboratory, import, inspection, and compliance functions to promote greater uniformity, flexibility and efficiency throughout ORA
> > 2 Consolidate laboratory and other facilities to allow us to provide state-of-the-art regulatory support to our public health mission, to focus on Center priorities, and to maximize efficiencies
> > 3 Provide policy direction and quality oversight of enforcement cases to ensure that the cases we work on have the maximum public health impact
> > 4 Be right-sized for anticipated resources
> > 5 Meet the needs and priorities of our stakeholders; and
> > 6 Sustain the activities through which ORA accomplishes our public health mission
> >
> > As you can see from these themes, we are looking to significantly strengthen ORA's ability to continue to fulfill our mission in the 21st Century. Our success will depend on the ongoing commitment and contributions of all ORA employees, and I want to assure you that every ORA employee who wants to be a part of this transformation will have an opportunity to do so.
> >
> > Over the next weeks the TLT will consider and make recommendations on such things as which laboratories will remain open and become national centers for regulatory science; how the field and headquarters QMS staff will operate and what their reporting

> > structure will look like; how we should balance our
staffs (i.e.,
> > how many investigators, analysts, etc. we will need);
how to provide
> > them with the support they need to meet stakeholder
needs in the
> > future; and how we can utilize contracts and third
party work and
> > data to support our mission. Again, as final decisions
are made and
> > approved, I will communicate them to you.
> >
> > You know from previous updates and through information
posted on
> > ORA's Transformation Website that the underpinning of
the TLT's work
> > has been the development of an ORA Strategic Plan. To
assure that
> > ORA's Strategic Plan is accomplished, eight TLT
WorkGroups were
> > formed including TLT Members and other employees from
across ORA.
> > The additional insight, knowledge and experience that
the non-TLT
> > members contribute to the WorkGroups has proven to be
extremely valuable.
> >
> > The WorkGroups were responsible for establishing 6, 12,
18 and 24
> > month goals in each of their respective project areas.
Listed below
> > is a sampling of some of the goals established by each
of these
> > WorkGroups -- goals that provide a sense of the types
of activities
> > we will be pursuing over the next two years in
furtherance of our
> > Strategic Plan:
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> > Leveraging Goals - Create and initiate a comprehensive
leveraging
> > plan optimizing the ability of ORA and its partners to
promote our
> > mission
> > -- this includes a full compilation and utilization of
all existing
> > and potential leveraging opportunities.

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> > Workforce Capability Goals - Identify training, certification and
> > skill requirements throughout ORA and institute appropriate programs
> > for maximizing ORA's workforce capabilities.
> >
> > Quality Management Systems Goals - Develop and institute a QMS
> > implementation plan that includes providing primary QMS training to
> > virtually all of ORA employees within a 24 month period.
> >
> > Risk Management Goals - Thoroughly incorporate risk management
> > strategies in ORA programs and operations. This includes activities
> > done in conjunction with FDA's Centers and other stakeholders.
> >
> > Organizational Optimization Goals -- Finalize and implement
> > organizational restructuring plans throughout ORA that will
> > streamline and enhance all key ORA operations within a 24 month period.
> >
> > Laboratory Goals - Complete thorough analysis of ORA's scientific
> > resources and needs and institute measures for harmonizing and
> > upgrading ORA's overall laboratory capability.
> >
> > Import Goals -- Initiate full implementation of a new comprehensive
> > import strategy - including the successful incorporation of Import
> > Strategy Steering Committee-approved recommendations.
> >
> > Information Technology - Refine IT capabilities to support ORA's
> > evolving needs and capabilities. This includes identifying high
> > priority projects and allocating IT resources accordingly.
> >

> > These are ambitious goals, but given the progress we
have made I
> > believe we can achieve all of them. We will keep you
posted as the
> > specific elements of each of these plans becomes
finalized, and
> > senior ORA Management will continue to provide
periodic briefings
> > to NTEU Officials on significant developments in our
transformation efforts.
> >
> > In closing, I am encouraged by the bold, swift and
comprehensive
> > efforts made by the TLT and others throughout ORA, and
I am
> > confident that our endeavor will position us well into
the 21st
> > century as a strong, nimble, mission-oriented
organization dedicated
> > to assuring that all food is safe; all medical products
are safe and
> > effective; and the public health is advanced and
protected.
> >
> > Thank you for your continued support and best wishes
for a happy and
> > healthy holiday season.
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> >
> > Margaret O'K. Glavin
> >
> > Associate Commissioner for
> >
> > Regulatory Affairs
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