

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2011 are reviewed within 420 days after the submission date.

JINAD study submissions received during FY 2011 are reviewed within 500 days after the submission date. JINAD submissions consisting of protocols without substantial data received during FY 2011 are reviewed within 290 days after the submission date.

Administrative ANADAs received during FY 2011 are reviewed within 110 days after the submission date.

FY12 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2012 are reviewed within 380 days after the submission date.

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2012 are reviewed within 340 days after the submission date.

JINAD study submissions received during FY 2012 are reviewed within 380 days after the submission date.

JINAD submissions consisting of protocols without substantial data received during FY 2012 are reviewed within 190 days after the submission date.

Administrative ANADAs received during FY 2012 are reviewed within 105 days after the submission date.

FY13 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2013 are reviewed within 270 days after the submission date.

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2013 are reviewed within 270 days after the submission date.

JINAD study submissions received during FY 2013 are reviewed within 270 days after the submission date.

JINAD submissions consisting of protocols without substantial data received during FY 2013 are reviewed within 100 days after the submission date.

Administrative ANADAs received during FY 2013 are reviewed within 100 days after the submission date.

Amending Similar Applications and Submissions

The Agency and regulated industry agree that applications and submissions to the Agency will be complete and of sufficient quality to allow the Agency's complete and timely review. The Agency will refuse to file poor quality and incomplete applications and submissions rather than allowing them to serve as "placeholders" in the review queue that are subsequently amended to add the missing or inadequate portions.

The Agency recognizes that there are circumstances in which a controlled amendment process can make the review of similar, pending submissions more efficient, without compromising the sponsor's responsibility for high quality submissions. Thus, starting no later than FY 2012, if the Agency requests an amendment to a non-administrative original ANADA, manufacturing supplemental ANADA, JINAD study submission, or a JINAD protocol submission (a "CVM-initiated amendment"), or issues an incomplete letter for such an application or submission, a sponsor may request to amend other, similar applications or submissions it has pending with the Agency ("sponsor-initiated amendment(s)") in accordance with the following criteria:

1. The amended information for these similar applications or submissions must be the same as in the CVM-requested amendment or incomplete letter; and

2. The amended information must not significantly change the pending application or submission; and

3. The amended information for these similar applications or submissions must be submitted no later than:

a. 120 days after the submission date for a pending non-administrative original ANADA, manufacturing supplemental ANADA, or JINAD study submission; or

b. 50 days after the submission date for a pending JINAD protocol.

If the Agency determines that the above criteria have been met, it will not change the user fee goal for a pending application or submission that has been amended by a sponsor-initiated amendment. If the above criteria have not been met, the Agency may consider the application or submission resubmitted on the date of the sponsor-initiated amendment, thereby resetting the clock to the date FDA received the amendment.

#### REPUBLICAN NATIONAL CONVENTION LAW ENFORCEMENT

Mr. COLEMAN. Mr. President, I rise to express a word of enthusiastic appreciation to the thousands of courageous and principled law enforcement members who did their utmost to allow the Republican National Convention in St. Paul to proceed in an orderly fashion. I saw some of their work with my own eyes and want them to know we respect them and the vital role they play in our Nation.

It has been said that every society is defined by the boundary between each individual's right to do whatever they want and the broader community's right to peace and order. Societies without such a border disintegrate into chaos and eventually repression. That boundary is not an abstract philosophical construct, but the life's work of law enforcement personnel who enforce society's laws.

This past week we saw an extreme test of that principle as self-described anarchists, who represented a very small segment of thousands of peaceful demonstrators, sought to disrupt proceedings of the convention. Law enforcement personnel acted with professionalism, restraint and great skill in the face of serious threats to public safety. The great irony is the actions of law enforcement guarantee the future rights of protestors to protest. I only wish the small minority of violent protestors had not created a climate of fear that may have regrettably kept observers away and reduced the patronage of St. Paul businesses, that were counting on increased sales during the convention week.

The convention, the first in Minnesota since 1892, presented many logistical obstacles. St. Paul is a town of less than 300,000, not the kind of metropolis where these events are usually held. The ability of multiple jurisdictions to work together to scale up their response to the level needed was a great example of the Minnesota can-do spirit.

Many thanks are due, specifically to St. Paul chief of police John Harrington whose team was able to ensure the safety of all of our visitors, displaying Minnesota admirably in the national spotlight. Special thanks are

also very much in order to the law enforcement officers who traveled from all over Minnesota and the rest of the country to assist in the security efforts.

I would also like to take a moment to express my thanks for the excellent work of a few other individuals during the convention: St. Paul assistant chief of police Matt Bostrum, Minneapolis chief of police Tim Dolan, Minneapolis deputy chief of police Rob Allen, Bloomington chief of police John Laux, Ramsey County sheriff Bob Fletcher, Hennepin County sheriff Rich Stanek, and Minnesota Department of Public Safety commissioner Michael Campion all deserve our gratitude. They, and their departments, performed with excellence in the way they did their duty and their integration with other departments.

The week of September 1, 2008, will be remembered by almost all of the thousands of visitors to Minnesota as a great week and proof-positive that our State is capable of putting on a world class event. The ability of our excellent law enforcement personnel to play defense against those who sought to disrupt the festivities allowed the people attending the convention and a worldwide audience to see an orderly process of our democratic society at its finest.

My heartfelt thanks to all the Minnesotans who worked so hard to make our dreams a reality.

#### IDAHOANS SPEAK OUT ON HIGH ENERGY PRICES

Mr. CRAPO. Mr. President, in mid-June, I asked Idahoans to share with me how high energy prices are affecting their lives, and they responded by the hundreds. The stories, numbering over 1,000, are heartbreaking and touching. To respect their efforts, I am submitting every e-mail sent to me through [energy\\_prices@crapo.senate.gov](mailto:energy_prices@crapo.senate.gov) to the CONGRESSIONAL RECORD. This is not an issue that will be easily resolved, but it is one that deserves immediate and serious attention, and Idahoans deserve to be heard. Their stories not only detail their struggles to meet everyday expenses, but also have suggestions and recommendations as to what Congress can do now to tackle this problem and find solutions that last beyond today. I ask unanimous consent to have today's letters printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

Thank you for this opportunity to express my concerns regarding the escalating price of living in Idaho due in large part to the ever increasing cost of energy.

I work for Alaska Airlines in Boise, Idaho. My gas bill to cover my commute has gone from \$100 to \$300 per month. My own industry has been heavily affected by the obscene rise in the cost of aviation fuel. Alaska Air is a profitable business. They have worked hard at putting a lot of cash in the bank. They never just spent their way into bankruptcy then emerged a few years later with