

## ANIMAL DRUG USER FEE ACT

Mr. ENZI. Mr. President, on August 1, 2008, the Senate passed H.R. 6432, the Animal Drug User Fee Amendments of 2008. Title I of this bill includes the reauthorization of the FDA's animal drug user fee program, while title II of this bill establishes the FDA's generic animal drug user fee program.

Performance goals, existing outside of the statute, accompany the authorization of animal drug user fees and animal generic drug user fees. These goals represent realistic projections of what the Food and Drug Administration's Center for Veterinary Medicine can accomplish with industry cooperation. The Secretary of Health and Human Services forwarded these goals to the chairmen of the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, in documents entitled "Animal Drug User Fee Act Performance Goals and Procedures" and "Animal Generic Drug User Fee Act Performance Goals and Procedures."

According to section 101(b) of H.R. 6432, "the fees authorized by the amendments made in this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the CONGRESSIONAL RECORD."

According to section 201(b) of H.R. 6432, "the fees authorized by this title will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the CONGRESSIONAL RECORD."

Today I am submitting for the RECORD these documents, on behalf of Senator KENNEDY, who could not be here today, which were forwarded to the Committee on Health, Education, Labor and Pensions on July 30, 2008, as well as the letter from Secretary Leavitt that accompanied the transmittal of this document.

I ask unanimous consent to have material printed in the RECORD.

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

THE SECRETARY OF  
HEALTH AND HUMAN SERVICES,  
Washington, DC, July 30, 2008.

Hon. EDWARD M. KENNEDY,  
Chairman, Committee on Health, Education,  
Labor and Pensions, U.S. Senate, Wash-  
ington, DC.

DEAR MR. CHAIRMAN: I am writing to formally transmit the Agreements on the Goals and Procedures for the reauthorization of the Animal Drug User Fee Act and new authorization for Animal Generic Drug User Fees. These documents incorporate the agreement made between the animal drug industry and FDA and contain the goals for the review of animal drug applications over the FY 2009 through FY 2013 period. These Goals and Procedures are a companion to the authorizing legislation reauthorizing the animal drug user fees and enacting new animal generic drug fees and they represent the commitment of the Administration to apply the user fees authorized by Congress towards the outlined goals and procedures.

We appreciate your leadership and considerable efforts of your Committee to make it possible to reauthorize the important animal drug user fee program and enact a corresponding user fee program for generic animal drugs.

Sincerely,

MICHAEL O. LEAVITT.

Attachments.

ANIMAL DRUG USER FEE ACT PERFORMANCE  
GOALS AND PROCEDURES

The goals and procedures of the FDA Center for Veterinary Medicine (CVM) as agreed to under the "Animal Drug User Fee Act of 2008" are summarized as follows:

1. *Application/Submission Goals*

a. For the application/submission goals below, the term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of an animal drug application, supplemental animal drug application, or investigational animal drug submission which either (1) approves an animal drug application or supplemental application or notifies a sponsor that an investigational animal drug submission is complete or (2) sets forth in detail the specific deficiencies in such animal drug application, supplemental animal drug application, or investigational animal drug submission and, where appropriate, the actions necessary to place such an application, supplemental application, or submission in condition for approval. Within 30 days of submission, FDA shall refuse to file an animal drug application, supplemental animal drug application, or their reactivation, which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110. Thus, the agency will refuse to file an application containing numbers or types of errors, or flaws in the development plan, sufficient to cause the quality of the entire submission to be questioned to the extent that it cannot reasonably be reviewed. Within 60 days of submission, FDA will refuse to review an investigational animal drug submission which is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110. A decision to refuse to file an application or to refuse to review a submission as described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

b. FDA may request minor amendments to animal drug applications, supplemental animal drug applications, and investigational animal drug submissions during its review of the application or submission. At its discretion, the Agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or submission for which a minor amendment is requested. If a pending application is amended with significant changes, the amended application may be considered resubmitted, thereby effectively resetting the clock to the date FDA received the amendment. The same policy applies for investigational animal drug submissions.

c. The term "end-review amendment" is understood to mean an amendment to an animal drug application, supplemental animal drug application, or investigational animal drug submission that is requested by the Agency after it has completed its review of the submitted information and determines that the submission of additional non-substantial data or information would likely complete the application or submission. This term does not include minor amendments requested by the Agency during review of applications or submissions that do not impact upon the user fee goals, as described in paragraph 1.b.

d. The term "submission date" is understood to mean the date CVM's Document Control Unit receives an application or submission.

2. *Non-administrative Animal Drug Applications*

a. The Agency will review and act on 90 percent of non-administrative animal drug applications and reactivations of such applications within

i. 180 days after the submission date (Day 180) if the Agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or

ii. 220 days after the submission date if the Agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or

iii. 345 days after the submission date if the Agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.

b. The end-review amendment procedure is not intended to prevent the use of minor amendments during Agency review of an animal drug application as described in paragraph 1.b. above.

3. *Administration Animal Drug Applications*

a. Review and act on 90 percent of administrative animal drug applications (NADAs submitted after all scientific decisions have been made in the investigational animal drug process, i.e., prior to the submission of the NADA) within 60 days after the submission date.

4. *Non-manufacturing Supplemental Animal Drug Applications*

a. The Agency will review and act on 90 percent of non-manufacturing supplemental animal drug applications (i.e. supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within

1. 180 days after submission date (Day 180) if the Agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or

ii. 220 days after the submission date if the Agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or

iii. 345 days after the submission date if the Agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.

b. The end-review amendment procedure is not intended to prevent the use of minor amendments during Agency review of a supplemental new animal drug application as described in paragraph 1.b. above.

#### 5. Manufacturing Supplemental Animal Drug Applications

a. Review and act on 90 percent of manufacturing supplemental animal drug applications and reactivations of such supplemental applications within 120 days after the submission date.

#### 6. Investigational Animal Drug Study Submissions

a. The Agency will review and act on 90 percent of investigational animal drug study submissions within

i. 180 days after the submission date (Day 180) if the Agency determines that the submission is complete or incomplete. A submission is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the study submission and reach a decision on the issue(s) presented in the submission; or

ii. 220 days after the submission date if the Agency determines that the submission of additional non-substantial data or information would likely complete the submission and electronically requests an end-review amendment to the submission on or before Day 180, but the sponsor fails to submit such amendment on or before Day 210. If a sponsor submits an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (270 days) will not apply, and a complete action letter will be issued by Day 220 for the original submission; or

iii. 270 days after the submission date if the Agency electronically requests an end-review amendment to the submission on or before Day 180 and the sponsor submits an end-review amendment on or before Day 210.

b. The end-review amendment procedure is not intended to prevent the use of minor amendments during Agency review of a study submission as described in paragraph 1.b. above.

#### 7. Investigational Animal Drug Protocol without Data Submissions

a. Review and act on 90 percent of investigational animal drug submissions consisting of protocols without substantial data, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, within

i. 60 days after the submission date (Day 60) if the Agency does not request an end-review amendment to the protocol.

(1) If the Agency determines that the protocol is acceptable, the Agency will notify the sponsor of this decision electronically on or before Day 50, followed by a complete action letter; or

(2) If the Agency determines that a protocol is not acceptable, the Agency will notify the sponsor of this decision electronically, providing preliminary broad areas of protocol deficiency, on or before Day 50, with the subsequently issued complete action letter providing the detailed protocol assessment. The sponsor may contact the Agency for a brief clarification of these areas of deficiency prior to the issuance of the complete action letter; or

ii. 75 days after the submission date if the Agency electronically requests an end-review amendment to the protocol on or before Day 50, but the sponsor fails to submit such amendment within 10 days of the amendment request date. If a sponsor files an amendment more than 10 days after the amendment request date, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (refer to 7.a.iii below) will not apply, and a complete action letter will be issued by Day 75 for the original submission; or

iii. the greater of 60 days after the original protocol is received by the Agency or 20 days after the amended protocol is received by the Agency if the Agency electronically requests an end-review amendment on or before Day 50 and the sponsor submits such amendment within 10 days of the date the amendment is requested.

b. Sponsors are not required to submit study protocols for review. However, for each voluntarily submitted protocol for a study that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, the Agency will issue a complete action letter providing comments resulting from a complete review of the protocol. The complete action letter will be as detailed as possible considering the quality and level of detail of the protocol submission; will include a succinct assessment of the protocol; and will state whether the Agency agrees, disagrees, or lacks sufficient information to reach a decision that the protocol design, execution plans, and data analyses are adequate to achieve the objectives of the study.

c. If the Agency determines that a protocol is acceptable, this represents an agreement that the data generated by the protocol can be used to support a safety or effectiveness decision regarding the subject animal drug. The fundamental agreement is that having agreed to the design, execution, or analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspectives on the issues of design, execution, or analyses unless the Agency by written order determines that a substantiated scientific requirement essential to the assessment of the study appeared after the Agency's protocol assessment, or public or animal health concerns unrecognized at the time of protocol assessment under this process are evident.

d. The end-review amendment procedure is not intended to prevent the use of minor amendments during Agency review of a protocol without data submission as described in paragraph 1.b. above.

#### 8. Electronic Review of Applications/Submissions

a. The Agency will develop an electronic submission tool for industry submissions and online review capability within 24 months of

appropriated ADUFA funds for FY 2009. The Agency will consult with the sponsors in the development of this tool.

#### 9. Pre-Approval Foreign Inspections

a. The Agency and regulated industry are committed to improving the review and business processes that will facilitate the timely scheduling and conducting of pre-approval inspections (PAIs). To improve the timeliness and predictability of foreign PAIs, sponsors may voluntarily submit 1) at the beginning of the calendar year, a list of foreign manufacturing facilities that are subjects of animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and may be subject to foreign PAIs for the following fiscal year; and 2) a notification 30 days prior to submitting an animal drug application, a supplemental animal drug application, or investigational animal drug submission that informs the Agency that the application includes a foreign manufacturing facility. Should any changes to the annual list occur after its submission to the Agency, the sponsor may provide the updated information to the Agency.

b. The Agency will keep a record of the number of foreign PAIs conducted for new animal drug applications, along with the average time for completing the PAIs, and include this information in its annual performance report. The time for completing the PAIs is understood to mean the time from the date of scheduling the inspection through notification to the Center of inspectional findings.

#### 10. Public Workshops

a. The Agency and regulated industry agree to participate in 10 public workshops by the end of FY 2013 on mutually agreed upon topics.

#### 11. Additional Efforts Related to Performance Goals

a. The Agency will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable Application/Submission Goal time frame (noted above) will be reviewed with the highest possible priority among those pending.

b. The Agency and the regulated industry agree that the use of both formal meetings (e.g., presubmission conferences, workshops, etc.) and informal communication by both parties is critical to ensure high submission quality such that the above performance goals can be achieved.

c. The Agency and the regulated industry agree to explore and discuss the applicable use of pharmacokinetic/pharmacodynamic data in the development and evaluation of new animal drugs submitted for approval.

d. The Agency and the regulated industry agree to explore opportunities for exchange of information regarding the characteristics of a new animal drug, and to identify safety and effectiveness issues as early as possible in the drug development process.

e. The Agency and regulated industry commit to work together to explore shorter timeframes commensurate with the magnitude of the submitted data/information referenced under 11.c and 11.d.

#### 12. Workload Adjustment

The Animal Drug User Fee Act requires FDA to annually adjust fee revenues after FY 2008 to reflect changes in review workload utilizing a weighted average of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions. The Agency will use the method detailed below to calculate the workload adjustment, and the percent increase in fees will be the amount of the

workload adjuster that is greater than one (1.0).

The term “workload adjuster” applicable to a fiscal year consists of the sum of the following 5 components:

a. The percent of change in the total number of original and reactivated animal drug applications submitted (comparing the five-year average number of such submissions for fiscal years 1998–2002 to the five-year average for the most recent five-year period ending June 30 before the start of the next fiscal year) times a weighting factor that is the percent of direct review time spent on the review of original and reactivated new animal drug applications over the most recent five-year period.

b. The percent of change in the total number of original and reactivated supplemental animal drug applications submitted for which data with respect to safety or effectiveness are required (comparing the five-year average number of such submissions for fiscal years 1998–2002 to the five-year average for the most recent five-year period ending June 30 before the start of the next fiscal year) times a weighting factor that is the percent of direct review time spent on the review of original and reactivated supplemental animal drug applications for which data with respect to safety and effectiveness are required over the most recent five-year period.

c. The percent of change in the total number of original and reactivated manufacturing supplemental animal drug applications submitted (comparing the five-year average number of such submissions for fiscal years 1998–2002 to the five-year average for the most recent five-year period ending June 30 before the start of the next fiscal year) times a weighting factor that is the percent of direct review time spent on the review of original and reactivated manufacturing supplemental animal drug applications over the most recent five-year period.

d. The percent of change in the total number of investigational animal drug study submissions submitted (comparing the five-year average number of such submissions for fiscal years 1998–2002 to the five-year average for the most recent five-year period ending June 30 before the start of the next fiscal year) times a weighting factor that is the percent of direct review time spent on the review of investigational animal drug study submissions over the most recent five-year period.

e. The percent of change in the total number of submitted investigational animal drug protocol submissions (comparing the five-year average number of such submissions for fiscal years 1998–2002 to the five-year average for the most recent five-year period ending June 30 before the start of the next fiscal year) times a weighting factor that is the percent of direct review time spent on the review of investigational animal drug protocol submissions over the most recent five-year period.

#### ANIMAL GENERIC DRUG USER FEE ACT PERFORMANCE GOALS AND PROCEDURES

The goals and procedures of the Food and Drug Administration (FDA or the Agency) as agreed to under the “Animal Generic Drug User Fee Act of 2008” are summarized as follows:

Five-Year Goals (to be implemented by September 30, 2013)

1. Review and act on 90 percent of non-administrative original abbreviated new animal drug applications (ANADAs) and reactivations of such applications within 270 days after the submission date.

2. Review and act on 90 percent of manufacturing supplemental ANADAs and reac-

tivations of such supplemental applications within 270 days after the submission date.

3. Review and act on 90 percent of generic investigational new animal drug (JINAD) study submissions within 270 days after submission date.

4. Review and act on 90 percent of JINAD submissions consisting of protocols without substantial data, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA, within 100 days after the submission date.

5. Review and act on 90 percent of administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 100 days after the submission date.

For the application/submission goals above, the term “review and act on” is understood to mean the issuance of a complete action letter after the complete review of an original ANADA, supplemental ANADA, or JINAD submission which either (1) approves an original or supplemental ANADA or notifies a sponsor that a JINAD submission is complete or (2) sets forth in detail the specific deficiencies in such original or supplemental ANADA or JINAD submission and, where appropriate, the actions necessary to place such an original or supplemental ANADA or JINAD submission in condition for approval (“incomplete letter”). Within 30 days of submission, FDA shall refuse to file an original or supplemental ANADA, or their reactivation, which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110. Thus, the agency will refuse to file an application containing numbers or types of errors, or flaws in the development plan, sufficient to cause the quality of the entire submission to be questioned to the extent that it cannot reasonably be reviewed. Within 60 days of submission, FDA will refuse to review a JINAD submission which is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110. A decision to refuse to file an application or to refuse to review a submission as described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

FDA may request minor amendments to original or supplemental ANADAs and JINAD submissions during its review of the application or submission. At its discretion, the Agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or submission for which a minor amendment is requested. If a pending application is amended with significant changes, the amended application may be considered resubmitted, thereby effectively resetting the clock to the date FDA received the amendment. The same policy applies for JINAD submissions.

Sponsors are not required to submit study protocols for review. However, for each voluntarily submitted protocol for a study that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an original or supplemental ANADA, the Agency will issue a complete action letter providing comments resulting from a complete review of the protocol. The complete action letter will be as detailed as possible considering the quality and level of detail of the protocol submission; will include a succinct assess-

ment of the protocol; and will state whether the Agency agrees, disagrees, or lacks sufficient information to reach a decision that the protocol design, execution plans, and data analyses are adequate to achieve the objectives of the study. If the Agency determines that a protocol is acceptable, this represents an agreement that the data generated by the protocol can be used to support a safety or effectiveness decision regarding the subject new animal drug. The fundamental agreement is that having agreed to the design, execution, or analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspectives on the issues of design, execution, or analyses unless the Agency issues a written order that a substantiated scientific requirement essential to the assessment of the study appeared after the Agency's protocol assessment, or public or animal health concerns unrecognized at the time of protocol assessment under this process are evident.

The Agency and the regulated industry agree that the use of both formal meetings (e.g., presubmission conferences) and informal communication by both parties is critical to ensure high submission quality such that performance goals can be achieved.

The term “submission date” is understood to mean the date the FDA Center for Veterinary Medicine (CVM) Document Control Unit (DCU) receives an application or submission. DCU date stamps an application or submission on the day of receipt.

#### Work Queue Review Procedures

The Agency will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable. Application/Submission Goal time frame (noted below) will be reviewed with the highest possible priority among those pending.

#### Interim Goals

##### Interim Application/Submission Goals

FY09 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2009 are reviewed within 700 days after the submission date.

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2009 are reviewed within 600 days after the submission date.

JINAD study submissions received during FY 2009 are reviewed within 700 days after the submission date.

JINAD submissions consisting of protocols without substantial data received during FY 2009 are reviewed within 400 days after the submission date.

Administrative ANADAs received during FY 2009 are reviewed within 120 days after the submission date.

FY10 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2010 are reviewed within 680 days after the submission date.

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2010 are reviewed within 570 days after the submission date.

JINAD study submissions received during FY 2010 are reviewed within 680 days after the submission date.

JINAD submissions consisting of protocols without substantial data received during FY 2010 are reviewed within 390 days after the submission date.

Administrative ANADAs received during FY 2010 are reviewed within 115 days after the submission date.

FY11 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2011 are reviewed within 500 days after the submission date.

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