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 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. 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. 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 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 (human or animal) health concerns unrecognized at the time of protocol assessment under this process are evident.

The term ''submission date'' means the date the FDA Center for Veterinary Medicine (CVM) Electronic Submission System (ESS) receives an application or submission. Upon receipt of an application or submission, the CVM ESS creates an electronic receipt that contains the date of receipt and is sent to the submitter.

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 will be reviewed with the highest possible priority among those pending.

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, 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-initiated amendment or incomplete letter; and

2. The amended information must not significantly change the similar applications or submissions; 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 the similar original ANADA, manufacturing supplemental ANADA; or

b. 100 days after the submission date for the similar JINAD study submissions; or

c. 40 days after the submission date for the similar JINAD protocol submissions.

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

MULTIPLE DATA SUBMISSIONS TO THE CHEMISTRY, MANUFACTURING, AND CONTROLS TECHNICAL SECTION

The Agency will continue to allow two-phased Chemistry, Manufacturing, and Controls technical section submissions under the JINAD process. Timely Foreign Pre-Approval Inspections

1. 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 specified in an abbreviated application, supplemental abbreviated application, or generic investigational file and may be subject to foreign PAIs for the following fiscal year; and 2) a notification 30 days prior to submitting an abbreviated application, a supplemental abbreviated application, or generic investigational file 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.

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

TIMELY MEETINGS WITH INDUSTRY

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

WORKLOAD ADJUSTMENT

The workload adjustment will continue to be calculated per CVM Program Policy and Procedures Manual 1243.3022, page 35, except that, for purposes of calculating the workload adjustment, it has been agreed to reset the base years to FY 2014–FY 2018. There will be no workload adjustment for FY 2019. Workload adjustments are one-time adjustments, and are calculated annually.

REMEMBERING HIGHT PROFFIT

Mr. ENZI. Mr. President, I rise to speak on behalf of Hight Proffit, who is being inducted into the Wyoming Agriculture Hall of Fame. Every year since 1992, Wyoming has recognized individuals who have made substantial contributions to agriculture in our State. During his life, Hight displayed a special talent for agriculture and was a dedicated public servant for his neighbors and friends. Hight is a well-deserved recipient of this great honor.

Hight moved to Wyoming at a young age during the middle of the Great Depression when it wasn't easy to make a living, let alone to be a rancher. Much like he would show throughout his life, he showed what you can accomplish through hard work and resolve and learned to make the best out of everything.

He is remembered as a handyman, as well as an innovator. Hight excelled in improving agriculture and left his mark on the long, proud history of Wyoming agriculture. He worked hard to improve not only his ranch, but also the community around him, from fairly distributing water to expanding electric power.

Among his many accomplishments, perhaps the greatest was the dedication he showed to his family. By his side for over 60 years, was his loving wife, Dorothy. As his son Don puts it, Hight and Dorothy ''established a ranch with the help of the Federal Land Bank on the Bear River, where they raised cattle, sheep and horses, as well as four children.'' Hight and Dorothy were then blessed with numerous grandchildren and great-grandchildren.

Not only did he serve as a role model for his family, but his community as well as a dedicated public servant. Hight served on numerous boards and committees, as a Unita County commissioner, a State representative, and as a State senator. He also served as a mentor to countless young people through 4–H, Boy Scouts of America, Farm Bureau, and his church.

Although it has now been 16 years since Hight has passed, his memory lives on and his example continue to inspire others. I want to extend my congratulations to the family of Hight and Dorothy. Hight truly lived the code of the West, and I am proud to have the opportunity to recognize his achievements and his memory as an inductee into the Wyoming Agriculture Hall of Fame. Wyoming is well served by his lasting and continuing contributions to our State.

TRIBUTE TO DAVE TRUE

Mr. BARRASSO. Mr. President, I rise today to recognize Dave True, who will soon be honored for his contributions to his local community and the agriculture industry across Wyoming. Each year, Senator ENZI and I have the opportunity to introduce outstanding individuals as they are inducted into the Wyoming Agriculture Hall of Fame. As one of the 2018 inductees, Dave is an outstanding addition to their ranks.

Seventy years ago, Dave's father moved to Casper, WY, as part owner of a drilling company and established what would eventually become the True Companies. In the years that followed, Dave worked with his father and brothers to expand the company's focus. Today the True Companies is a