

## 2. Dosage Characterization

The Agency and the regulated industry agree that dosage characterization is part of the effectiveness technical section of an investigational new animal drug file. In instances where data and/or information about the dosage is integral to the review of a protocol, the Agency and the regulated industry agree that this data and/or information should be submitted as supporting data (INAD H submission) well in advance of the protocol submission. Such information may be needed to ensure selection of optimal study time points and would be particularly important for novel drugs and drugs with modified-release characteristics.

## 3. Animal Drug Availability Act (ADAA) Combination Medicated Feeds Applications

Review and act on 90 percent of qualifying ADAA Combination Medicated Feeds Applications within 60 days after the submission date. An ADAA combination application will qualify for the 60 day review timeframe only if the following criteria are met:

- i. The regulatory requirements for an ADAA combination application have been met as outlined in 21 CFR 514.4(c)(2)(ii)
- ii. A presubmission conference has been conducted and either
  - a. No data are needed (i.e., no tissue residue non-interference study is required) and this is documented in the memorandum of conference for the presubmission conference; or
  - b. A justification for not conducting a tissue residue noninterference study has been submitted, reviewed and found acceptable under an INAD, prior to the submission of the ADAA combination application; or
  - c. A tissue residue non-interference study has been submitted, reviewed and found acceptable under an INAD, prior to the submission of the ADAA combination application.
- iii. No effectiveness or target animal safety data are required.
- iv. No manufacturing data requirements—sponsor can address in meeting assay non-interference, but data submission is not required.
- v. All other information is referenced to previous drug experience reports.
- vi. Sponsor makes submission and it includes: Bluebird labeling, Veterinary Feed Directive (if applicable).
- vii. Includes a request for categorical exclusion from the need to prepare an environmental assessment (EA); i.e., no EA required.
- viii. Reference to presubmission conference.
- ix. Right of reference (if applicable) to NADA(s) not owned by the filing sponsor of the ADAA combination application has been received by the Agency.

Review and act on 90 percent of ADAA combination applications within 100 days for those applications initially accepted for the 60-day timeframe but subsequently determined to need minor amendments.

If any of the above conditions cannot be met, the ADAA combination application will be given a 180-day review timeframe and placed in the original NADA application cohort.

## 4. Categorical Exclusions

Review and act on 90 percent of resubmissions of a previously completed Environmental Impact technical section within 60 days after the resubmission date where:

- i. A Categorical Exclusion was issued; and
- ii. All other technical sections have been submitted; and
- iii. Information contained in the other technical sections reveals a change in the conditions of use of the drug that may affect the previous determination of categorical exclusion.

## 5. Presubmission Conferences

Conduct 90% of qualifying presubmission conferences within a 60-day timeframe when all of the following conditions are met:

- i. All background materials, including presentations, have been submitted, and
- ii. A complete agenda has been agreed upon by the Agency and the sponsor

A sponsor and the Agency can mutually agree to exclude a particular presubmission conference from this performance goal. If a sponsor accepts a date beyond the 60-day timeframe for their scheduling purposes or is unable to meet with the Agency on Agency available dates, the submission will be excluded from the presubmission conference cohort.

## 6. Tissue Residue Method

Commence 90% of tissue residue method demonstrations within 120 days of completion of the “3-hour meeting” process or equivalent process milestone where there is a single laboratory validation tissue residue method demonstration.

### V. WORKLOAD ADJUSTMENT

The workload adjustment will continue to be calculated per CVM Program Policy and Procedures Manual 1243.3022, 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.

### RUSSIA INVESTIGATION

Mr. CASEY. Mr. President, today I wish to discuss the importance of the Justice Department's independent investigation into Russia's interference in the 2016 Presidential election.

The interference with our election process by a hostile government was an attack on our democracy and a threat to our national security, carried out by Russian operatives at the direction of Vladimir Putin himself. As the intelligence community's unclassified report concluded, “We assess Russian President Vladimir Putin ordered an influence campaign in 2016 aimed at the U.S. presidential election. Russia's goals were to undermine public faith in the U.S. democratic process, denigrate Secretary Clinton, and harm her electability and potential presidency. We further assess Putin and the Russian Government developed a clear preference for President-elect Trump.”

Since Deputy Attorney General Rod Rosenstein appointed Robert Mueller as special counsel to investigate Russia's attack, 32 indictments have been returned in connection with the investigation, including indictments against Russian individuals and companies, as well as former Trump campaign manager Paul Manafort and deputy campaign manager Rick Gates, who were charged with “conspiracy against the United States.” Mr. Mueller has also secured guilty pleas from other campaign advisers, including George Papadopoulos and Michael Flynn.

Despite this ample evidence of wrongdoing, the President has attempted to impede the Russia probe every step of the way, falsely branding it a “witch hunt.” So far, the Mueller

investigation has continued to produce results, despite these attacks. We must be clear that any attempt to remove special counsel Robert Mueller or Deputy Attorney General Rod Rosenstein would take our Nation into uncharted territory. I am disturbed that, last week, a group of the President's allies in the House of Representatives filed unwarranted articles of impeachment against Mr. Rosenstein, who has worked to uphold the rule of law and ensure that the independent Russia investigation can continue.

Both Mr. Rosenstein and Mr. Mueller have admirable records of public service. Mr. Mueller, whose qualifications, experience, and character I have previously detailed on the floor, was a decorated hero of the Vietnam war, a U.S. Attorney, and a widely respected director of the FBI. There is no one better equipped to lead the Russia probe.

Mr. Rosenstein, like Mr. Mueller, also has a long and distinguished career in public service. A native of Philadelphia, Mr. Rosenstein graduated from the Wharton School and Harvard Law School, after which he clerked for Judge Douglas Ginsburg of the U.S. Court of Appeals for the District of Columbia Circuit.

He initially joined the Department of Justice nearly 30 years ago through the Attorney General's Honors Program. He started as a trial attorney with the Public Integrity Section of the Criminal Division, prosecuting public corruption cases. Mr. Rosenstein rose through the ranks, serving as counsel to the Deputy Attorney General; special assistant to the Assistant Attorney General in the Criminal Division; associate independent counsel in the Office of the Independent Counsel; and assistant U.S. attorney in Maryland. He was recognized for his work at the Department of Justice with a 1993 “Commendation Award” from the Criminal Division, a 1994 “Outstanding Contribution to Justice” award from the Office of the Deputy Attorney General, and a 1997 “Appreciation Award” from the Criminal Division's Public Integrity Section.

In 2001, he became Principal Deputy Assistant Attorney General for the Tax Division, where he supervised the criminal sections, coordinated tax enforcement activities, and oversaw civil litigation. Then, in 2005, he returned to the Maryland U.S. attorney's office, this time as the top Federal prosecutor. He served as U.S. Attorney for over a decade, until he was nominated to become Deputy Attorney General in 2017. His nomination to this critically important post, at a critically important time for our Nation, was approved overwhelmingly by this body, by a vote of 94 to 6.

Mr. Rosenstein has a wealth of experience at the Department of Justice and has served our country and the American public with honor and distinction since he entered the legal profession. During his many years at the

Department of Justice, he has shown his commitment to the rule of law and the legal process.

At no time could such commitment be more vital. Our rule of law is under siege from multiple fronts, including from members of this administration and the President himself.

Rod Rosenstein and Robert Mueller have so far been able to oversee an independent investigation, but the threat of interference still remains. Both of these respected public servants have been the target of vicious and unfounded partisan attacks with no purpose but to discredit and delegitimize the Russia investigation. These attacks are not only shameful; they are undemocratic.

We cannot successfully counter foreign threats to our democracy without holding up our own institutions from within. A fundamental principle of our democracy—equal justice under law—has been tested by this President and his advisers since he entered the White House. We, too, are being tested. As Members of Congress, will we step up as a coequal branch of government and ensure that there are consequences when our principles are breached? As Americans, will we hold our public officials accountable when they work to undermine the democratic values that define us as a nation?

That is why I call on Leader McCONNELL to bring the bipartisan Special Counsel Independence and Integrity Act to the floor for a vote. It is why I want to emphasize that any interference with this investigation, whether it is with Mr. Mueller, Mr. Rosenstein, FBI Director Wray, or any other official at the Department of Justice, is a line in the sand that must not be crossed. No one—even and especially the President of the United States—is above the law.

#### REMEMBERING SERGEANT FIRST CLASS RESTITUTO OYOLA-ALVAREZ

Mr. BLUMENTHAL. Mr. President, I rise today with a heavy heart to pay tribute to SFC, Retired, Restituto "Tuto" Oyola-Alvarez, a courageous member of our military and devoted family man. Sadly, Sergeant First Class Oyola-Alvarez passed away on July 22, 2018, at the age of 101. He will be remembered for his tireless, dedicated service to our nation.

Sergeant First Class Oyola-Alvarez was born in Arecibo, PR, and he enlisted in the U.S. Army at Fort Buchanan on January 22, 1941. He went on to serve in Puerto Rico's 65th Infantry Regiment during the Korean war. The regiment was referred to as the Borinqueneers, and Sergeant First Class Oyola-Alvarez and the rest of his Latino-segregated unit played a valuable role in helping American war efforts.

Unfortunately, despite their remarkable dedication, the Borinqueneers' contributions went largely overlooked

once the war ended. After 20 years of Active service and many more decades during which it went unrecognized, Sergeant First Class Oyola-Alvarez was at last granted the awards his unfailing support of our Nation deserved. On Veterans Day in 2012, I was honored to present him a number of hard-earned medals at his home in Hartford, CT. Four years later, I was proud to present him and his fellow Borinqueneers with the Congressional Gold Medal at the Connecticut State Capitol. At the ceremony, Sergeant First Class Oyola-Alvarez also received more medals acknowledging his efforts on behalf of America, including the World War II Victory Medal and Korean Service Medal, among others.

Honorably discharged in 1961, he gained proper recognition for his service when he reached his mid-90s. Citations and certificates from his home State of Connecticut were given by the Connecticut General Assembly, the secretary of the State of Connecticut, and the mayor of Hartford. In 2014, Sergeant First Class Oyola-Alvarez's tenacious defense of our democracy earned him the Lifetime Achievement Award from the Latino Puerto Rican Affairs Commission in Connecticut.

His sincere devotion to his birth island of Puerto Rico, the United States, and the U.S. Armed Forces carried into his family life as well. Sergeant First Class Oyola-Alvarez cherished his wife of 70 years, the late Sarah Rivera, as well as his only daughter, Sara Victoria, his son-in-law, Merrill, and his many grandchildren and great-grandchildren. His years of outstanding leadership, loyalty, and commitment are a model for all of us and have left a lasting positive impact upon the country.

My wife, Cynthia, and I extend our deepest sympathies to Restituto's family during this difficult time. May their many wonderful memories of him provide them solace and comfort in the days ahead.

#### HONORING EUGENE EARLEY

Mr. TESTER. Mr. President, today I wish to honor the life and legacy of a brave American, Eugene Joseph Earley.

Eugene's story begins in 1884 in Waukegan, MN, where he was born to Bernard and Cordelia Earley. He was one of 16 children. He grew up on his parents' farm, learning independence, grit, and an ability to fend for himself.

From his parents' farm, he left to homestead and log the nearby forests in the Black River Country of Northern Koochiching County, MN. There, his determination was tested by the hot summers and long, brutal winters. Through the many challenges he faced, Eugene persevered.

After the United States entered World War I, Eugene enlisted as a private in the U.S. Army 23rd Infantry Regiment, 2nd Division. It wasn't long before he was deployed to France as a part of the American Expeditionary Forces led by General John Pershing.

Under Pershing's command, Eugene prepared for battle. On September 12, 1918, in Saint-Mihiel, France, Eugene and his comrades contributed to a major turning point. The American offensive caught the Germans unaware and in the process of retreating. The courage and determination of the American forces solidified the stature of U.S. military might in the eyes of our European allies and enemies.

During the second day of fighting, Eugene endured a shrapnel wound that would prove fatal. He died on the field of combat in northeast France, less than 2 months before the end of the war. Eugene was just 24 years old. He is buried in the Saint-Mihiel American Cemetery in Thiaucourt, France, alongside 4,153 of his fellow fallen comrades.

Back in Minnesota, Eugene's family honored his memory and mourned his death for the rest of their lives. In the years after his death, Eugene's mother established a local American Legion Post in his name. Watertown American Legion Post 121 still honors the memory and the name of Eugene Earley today.

Earlier this year, Eugene's grandnephew Jim Bruggeman and his daughters Megan and Molly traveled to France to visit his grave. Through their hard work, Eugene was awarded with the Purple Heart Medal in the centennial year of his death. His life and brave service will live on through this honor and the memory that his loved ones hold dear.

To Eugene Joseph Earley, on behalf of myself, Montana, and a grateful nation, I extend our deepest thanks for Eugene's service, sacrifice, and valor.

#### REMEMBERING MARYON PITTMAN ALLEN

Mr. JONES. Mr. President, I would like to take a few moments to remember and honor Maryon Pittman Allen, a former Member of this body, who passed away on July 23, 2018. Maryon Allen was one of only two women ever to represent the State of Alabama in the U.S. Senate.

Born in Meridian, MS, in 1925, Maryon Pittman and her family moved to Alabama in 1926 in order for her father to open a Caterpillar tractor franchise. She grew up in Birmingham, attending Avondale School and Ramsay High School, before matriculating at the University of Alabama, where she planned to major in journalism. While in college, she met and married her first husband, attorney Joshua Mullins, and they had three children. After the marriage ended in divorce in 1959, Maryon entered the workforce, first as a secretary, then in insurance sales, and eventually putting her journalism training to use writing for the "Shades Valley Sun" as society editor.

In the 1960s, Maryon joined the Birmingham News as women's editor. Two weeks into her new job, she drove to Montgomery to interview then-Lieutenant Governor James B. Allen in